FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: CLOROL 200 SC

Product name(s): Catanga 200 SC, Boland 200 SC

Chemical active substance:

Chlorantraniliprole, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o

Submission date: September 2024

June 2025: GAP correction by the Applicant

zRMS Assessment:12 September 2025

Following commenting period/Verification List of References: 18 November 2025

GAP correction by zRMS: 01 June 2026

Version history

When	What
June 2025	GAP correction by the Applicant
September 2025	zRMS assessment
November 2025	Following commenting period/Verification List of References
June 2026	GAP correction by zRMS
August 2026	Correction/zRMS comment

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7 Metabolism and residue data (KCA section 6)

Studies for chlorantraniliprole and Coragen 200 SC have been evaluated during inclusion of it on Annex 1 and approved in 02.08.2007. Also First registration on Coragen 200 SC in Poland was in 2011 (Authorization number: R-65/2011). According to reg. 1107/2009 data protection is expiring after 10 years since first registration, so data for chlorantraniliprole and Coragen 200 SC is already not longer protect. Additionaly Clorol 200 SC and Coragen 200 SC have the same compostion of formulation.
Therefore, to support the authorization of Clorol 200 SC (Catanga 200 SC, Boland 200 SC) INNVIGO is allowed to refer to EU and Coragen 200 SC approved reports.
The applicant provided additional information regarding the identification of the studies used in the assessment. Appendix 1 and 2 has been updated.

7.1 Summary and zRMS Conclusion

Chlorantraniliprole

Storage stability

The storage stability of chlorantraniliprole was investigated in the framework of the peer review in different groups, including high water, high oil, high starch and high acid content commodities, animal tissues and in some processed commodities. Chlorantraniliprole is stable for 24 months in all matrices and 12 months in processed fractions and animal products. Stability of chlorantraniliprole in honey is not required as residues in honey were determined within 30 days after sampling. No further data is required.

Metabolism in plants and animals

Metabolism studies indicated that the metabolism of chlorantraniliprole is similar in different crop categories crops. A residue definition for monitoring and risk assessment is proposed as chlorantraniliprole. Animal residue definition for monitoring is chlorantraniliprole and for risk assessment - sum chlorantraniliprole and metabolites IN-HXH44 and IN-K9T00 expressed as chlorantraniliprole.

Processing

Chlorantraniliprole is stable under pasteurisation and sterilisation conditions, but it is slightly degraded to IN-F6L99, IN-ECD73 and IN-EQW78 under baking/brewing/boiling conditions (11-14% TRR).

Magnitude of residues in plants (NEU)

In most cases, the applicant referred to residue studies already assessed and extrapolated the results to other crops. The applicant has submitted new residue trials in sugar beet, oilseed rape and honey.

Based on the available data the use of chlorantraniliprole in the following crops is considered accepted:
whole group of pome fruits before and after forming of the edible part,
whole group of tree nuts before forming of the edible parts,
whole group of stone fruits before forming of the edible parts,
potato, carrot and whole subgroup (c) other root and tuber vegetables, sugar beet,
grapes,
tomato, pepper, cucumber, courgettes, melon, aubergines/eggplants, okra/lady's fingers, whole subgroup (b) cucurbits with edible peel and whole subgroup (c) cucurbits with inedible peel,
lettuce, lamb lettuce, whole subgroup (a) lettuces and salad plants, whole subgroup (d) water cresses, whole subgroup (b) spinaches and similar leaves,
maize, sweet corn, millet,
cauliflower, broccoli and cabbage,
oilseed rape, winter turnip rape, linseeds, poppy seeds, mustard seeds and gold of pleasure,

The following uses are not accepted:
sweet potatoes and yams,
sorghum, sweet cane, brussels sprout, kale and Chinese cabbage,
sunflower, soybean, pumpkin and hemp,
loquat, cresses and other sprouts and shoots, baby leaf crops, okra, watercresses.

Residues in honey

Clorol 200 SC is predicted to use in melliferous crops. A new honey studies were submitted and the results indicated no exceedance of MRL (0.05 mg/kg) in honey.

Livestock feeding

There is no risk for animal MRL to be exceeded.

Succeeding crops

According to EFSA (2020) conclusion Significant residue levels of chlorantraniliprole are not expected in succeeding crops, provided that chlorantraniliprole is applied in compliance with the EU GAPs.

Consumer risk assessment

The proposed uses of chlorantraniliprole in the formulated product do not represent unacceptable chronic risks for the consumer.
As ARfD is not established, the acute risk assessment is not relevant.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation product code are presented in Table 7.1-1. They have been selected from the individual GAPs in the CEU for all crops.
A list of all intended uses within the CEU is given in Part B, Section 0.
Justification for the selection of the critical GAP

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for chlorantraniliprole as laid down in Reg. (EU) 396/2005 is ~~not~~ expected for sweet potato, yams and brussels sprout.
The chronic and the short-term intakes of chlorantraniliprole residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS agrees with the authorization of the ~~intended~~ uses as indicated in Table 7.1-1.

According to available data, ~~specific mitigation measures~~ the growth stage (BBCH) for chestnuts, stone fruits, cabbage red and white ~~should apply~~ needs to be changed.

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

none

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

PPP (product name/code):	CLOROL	Formulation type:	GAP rev. , date: 29.05.2024 SC (a, b)
Active substance 1:	Chlorantraniliprole	Conc. of as 1:	200 (c)
Safener:	-	Conc. of safener:	- (c)
Synergist:	-	Conc. of synergist:	- (c)
Applicant:	Innvigo	Professional use:	☐
Zone(s):	Central zone (d)	Non professional use:	☐
Verified by MS:	yes		
Field of use:	insecticide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safen-er/synergist per ha (f)	**Conclucsion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Potato *Solanum tuberosum* SOL-TU 211000	F	*Leptinotarsa decemlineata* LPTNDE	Spray, medi-um sprayer	after the pest occurrence, BBCH 31-60	a) 1 b) 2	10	a) 0.050-0.0625 L/ha b) 0.125 L/ha	a) 10.0-12.5 g as/ha b) 25 g as/ha	150-400	14	-	
2	PL	Maize *Zea mays* ZEAMX 500030	F	*Ostrinia nubilalis* PY-RUNU	Spray, medi-um sprayer	BBCH 53-69	a) 1 b) 1	n/a	a) 0.125 L/ha b) 0.125 L/ha	a) 25 g as/ha b) 25 g as/ha	300-400	7	-	
3	PL	Winter oilseed rape *Brassica napus var. napus* BRSNW	F	*Ceutorhynchus assimilis* CEUTPL, *Dasyneura brassicae* DASYBR	Spray, medi-um sprayer	BBCH 61-71	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7		

		401060												
4	PL	Winter oilseed rape *Brassica napus var. napus* BRSNW 401060	F	*Ceutorhynchus assimilis* CEUTPL, *Dasyneura brassicae* DASYBR, *Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE	Spray, medi-um sprayer	A: BBCH 30-50 B: BBCH 61-71	a) 2 b) 2	14	a) 0.10-0.175 L/ha b) 0.350 L/ha	a) 20-35 g as/ha b) 70 g as/ha	200-300	7		
5	PL	Apple *Malus domestica* MABSD 130010	F	*Cydia pomonella* CARP-PO	Spray, medi-um sprayer	BBCH 70-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		
6	PL	Apple *Malus domestica* MABSD 130010	F	*Tortricidae* 1TORTF	Spray, medi-um sprayer	BBCH 56 or BBCH 70-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		

Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
Minor uses according to Article 51 (zonal uses)														
7	PL	Sugar beet *Beta vulgaris* subsp. *vulgaris* var. *altissima* BEAVA 900010	F	*Asproparthenis punctiventris* CLEOPU, *Scrobipalpa ocellatella* PHTOOC	Spray, medium sprayer	BBCH 31-49	a) 1 b) 1	n/a	a) 0.10 L/ha + 0.1 L/ha adjuvant Asystent+ b) 0.10 L/ha+ 0.1 L/ha adjuvant Asystent+	a) 20 g as/ha + 0.1 L/ha adjuvant Asystent+ b) 20 g as/ha + 0.1 L/ha adjuvant Asystent+	150-200	28		
~~8~~	~~PL~~	~~Sweet Potato *Ipomoea batatas* IPOBA~~ ~~212020~~	~~F~~	~~*Autographa gamma* PYTOGA, *Delia florilega* HYLEFG~~	~~Spray, medium sprayer~~	~~after the pest occurrence, BBCH 31-60~~	~~a) 1~~ ~~b) 2~~	~~10~~	~~a) 0.050-0.0625 L/ha~~ ~~b) 0.125 L/ha~~	~~a) 10.0-12.5 g as/ha~~ ~~b) 25 g as/ha~~	~~150-400~~	~~14~~		MRL exceedance
~~9~~	~~PL~~	~~Yams *Dioscorea* L. 1DIUG~~ ~~212030~~	~~F~~	~~*Trialeurodes vaporariorum* TRIAVA, *Thysanoptera* 1THYSO, *Tetranychus* 1TETRG~~	~~Spray, medium sprayer~~	~~after the pest occurrence, BBCH 31-60~~	~~a) 1~~ ~~b) 2~~	~~10~~	~~a) 0.050-0.0625 L/ha~~ ~~b) 0.125 L/ha~~	~~a) 10.0-12.5 g as/ha~~ ~~b) 25 g as/ha~~	~~150-400~~	~~14~~		MRL exceedance Not minor crop in PL
10	PL	Carrot *Daucus carota* subsp. *sativus* DAUCS 213020	F	*Chamaepsila rosae* PSILRO, *Autographa gamma* PYTOGA	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21		
11	PL	Beetroot *Beta vulgaris* subsp. *vulgaris* var. *conditiva* BEAVD 213010	F	*Athalia rosae* ATALCO, *Barathra brassicae* BARABR, *Pieris brassicae* PIERBR, *Plutella maculipennis* PLUTMA, *Delia radicum* HYLERA, *Artogeia rapae* PIERRA,	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21		
12	PL	Horseradish *Armoracia rusticana* ARWLA 213040	F	*Athalia rosae* ATALCO, *Barathra brassicae* BARABR, *Pieris brassicae* PIERBR, *Plutella maculipennis* PLUTMA, *Delia radicum* HYLERA, *Artogeia rapae* PIERRA,	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21		
13	PL	Radish *Raphanus sativus* RAPSR 213080	F	*Athalia rosae* ATALCO, *Barathra brassicae* BARABR, *Pieris brassicae* PIERBR, *Plutella maculipennis* PLUTMA, *Delia radicum* HYLERA, *Artogeia rapae* PIERRA,	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21		

14	PL	Celery *Apium graveolens* APUGV 213030	F	*Chamaepsila rosae* PSILRO, *Autographa gamma* PYTOGA	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21		
15	PL	Jerusalem artichoke *Helianthus tuberosus* HELTU 213050	F	*Autographa gamma* PYTOGA, *Homoeosoma nebulellum* HMOENE	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21		
16	PL	Parsley *Petroselinum crispum* PARCR 213070	F	*Chamaepsila rosae* PSILRO, *Autographa gamma* PYTOGA	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21		
17	PL	Parsnip *Pastinaca sativa* PAVSA 213060	F	*Chamaepsila rosae* PSILRO, *Autographa gamma* PYTOGA	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21		
18	PL	Salsify *Tragopogon porrifolius* TROPS 213090	F	*Chamaepsila rosae* PSILRO, *Autographa gamma* PYTOGA	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21		
19	PL	Rutabaga *Brassica napus* subsp. *rapifera* BRSNA 213100	F	*Athalia rosae* ATALCO, Brevicoryne brassicae BRVCBR, *Barathra brassicae* BARABR, *Pieris brassicae* PIERBR, *Plutella maculipennis* PLUTMA, *Delia radicum* HYLERA, *Artogeia rapae* PIERRA,	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21		
20	PL	Turnip *Brassica rapa* BRSRR 213110	F	*Athalia rosae* ATALCO, *Barathra brassicae* BARABR, *Pieris brassicae* PIERBR, *Plutella maculipennis* PLUTMA, *Delia radicum* HYLERA, *Artogeia rapae* PIERRA,	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21		
21	PL	Scorzonera *Scorzonera hispanica* SCVHI 213090-003	F	*Chamaepsila rosae* PSILRO, *Autographa gamma* PYTOGA	Spray, medium sprayer	BBCH 12-49	a) 1 b) 1	n/a	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	300-800	21		
22	PL	Sweet Corn	F	*Ostrinia nubilalis* PY-	Spray, medi-	BBCH 53-69	a) 1	n/a	a) 0.125 L/ha	a) 25 g as/ha	300-400	7		

		Zea mays subsp. *saccharata* ZEAMS 234000		RUNU	um sprayer		b) 1		b) 0.125 L/ha	b) 25 g as/ha				
23	~~PL~~	~~Sweet cane *Saccharum officinarum* SACOF~~ ~~900020~~	~~F~~	~~*Ostrinia nubilalis* PY-RUNU~~	~~Spray, medium sprayer~~	~~BBCH 53-69~~	~~a) 1~~ ~~b) 1~~	~~n/a~~	~~a) 0.125 L/ha~~ ~~b) 0.125 L/ha~~	~~a) 25 g as/ha~~ ~~b) 25 g as/ha~~	~~300-400~~	~~7~~		Extrapolation from maize (whole plant fresh) to sugar canes (0900020) before forming of the edible parts allowed only for herbicides Not minor crop in PL
24	~~PL~~	~~Sorghum *Sorghum bicolor* SORVU~~ ~~500080~~	~~F~~	~~*Ostrinia nubilalis* PY-RUNU~~	~~Spray, medium sprayer~~	~~BBCH 53-69~~	~~a) 1~~ ~~b) 1~~	~~n/a~~	~~a) 0.125 L/ha~~ ~~b) 0.125 L/ha~~	~~a) 25 g as/ha~~ ~~b) 25 g as/ha~~	~~300-400~~	~~7~~		According to EFSA (2020): No NEU uses are authorised for sorghum grains.
25	PL	Millet *Panicum miliaceum* PANMI 500040	F	*Ostrinia nubilalis* PY-RUNU	Spray, medium sprayer	BBCH 53-69	a) 1 b) 1	n/a	a) 0.125 L/ha b) 0.125 L/ha	a) 25 g as/ha b) 25 g as/ha	300-400	7		
26	PL	Spring oilseed rape *Brassica napus var. napus* BRSNS 401060	F	*Ceutorhynchus assimilis* CEUTPL, *Dasyneura brassicae* DASYBR, *Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE, *Plutella xylostella* PLUTMA, *Athalia rosae* ATALCO	Spray, medium sprayer	BBCH 61-71	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7		
27	PL	Flax *Linum usitatissimum* LIUUT 401010	F	*Cochylis epilinana* PHA-OEP, *Aphthona euphorbi-ae* APHTEU	Spray, medium sprayer	BBCH 61-71	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7		
28	PL	Opium poppy *Papaver somniferum* PAPSO 401030	F	*Neoglocianus maculaalba* CEUTMA	Spray, medium sprayer	BBCH 61-65	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7		
29	PL	White mustard *Sinapis alba* SINAL	F	*Ceutorhynchus assimilis* CEUTPL, *Dasyneura brassicae* DASYBR,	Spray, medium sprayer	BBCH 61-65	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7		

		401080		*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE, *Plutella xylostella* PLUTMA, *Athalia rosae* ATALCO										
30	PL	Winter Turnip rape *Brassica rapa* subsp. *oleifera* BRSRO 401060-002	F	*Ceutorhynchus assimilis* CEUTPL, *Dasyneura brassicae* DASYBR, *Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE, *Plutella xylostella* PLUTMA, *Athalia rosae* ATALCO,	Spray, medium sprayer	BBCH 61-65	a) 1 b) 1	n/a	a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha	a) 20-35 g as/ha b) 20-35 g as/ha	200-300	7		
~~31~~	~~PL~~	~~Sunflower *Helianthus annuus* HELAN~~ ~~401050~~	~~F~~	~~*Autographa gamma* PYTOGA, *Homoeosoma nebulellum* HMOENE~~	~~Spray, medium sprayer~~	~~BBCH 61-65~~	~~a) 1 b) 1~~	~~n/a~~	~~a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha~~	~~a) 20-35 g as/ha b) 20-35 g as/ha~~	~~200-300~~	~~7~~		No extrapolation from rapeseed possible
~~32~~	~~PL~~	~~Soybean *Glycine max* GLXMA~~ ~~401070~~	~~F~~	~~*Delia florilega* HYLEFG, *Ostrinia nubilalis* PYRUNU~~	~~Spray, medium sprayer~~	~~BBCH 61-65~~	~~a) 1 b) 1~~	~~n/a~~	~~a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha~~	~~a) 20-35 g as/ha b) 20-35 g as/ha~~	~~200-300~~	~~7~~		No extrapolation from rapeseed possible
~~33~~	~~PL~~	~~Pumpkin *Cucurbita pepo* CUUPE~~ ~~401100~~	~~F~~	~~*Delia florilega* HYLEFG~~	~~Spray, medium sprayer~~	~~BBCH 61-65~~	~~a) 1 b) 1~~	~~n/a~~	~~a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha~~	~~a) 20-35 g as/ha b) 20-35 g as/ha~~	~~200-300~~	~~7~~		No extrapolation from rapeseed possible
~~34~~	~~PL~~	~~Hemp *Cannabis sativa* CNISA~~	~~F~~	~~*Ostrinia nubilalis* PYRUNU~~	~~Spray, medium sprayer~~	~~BBCH 61-65~~	~~a) 1 b) 1~~	~~n/a~~	~~a) 0.10-0.175 L/ha b) 0.10-0.175 L/ha~~	~~a) 20-35 g as/ha b) 20-35 g as/ha~~	~~200-300~~	~~7~~		No extrapolation from rapeseed possible
35	PL	White cabbage *Brassica oleracea* var. *capitata* f. *alba* BRSOH 242020-004	F	*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE, *Delia radicum* HYLERA, *Athalia rosae* ATALCO, *Plutella xylostella*	Spray, medium sprayer	BBCH 20-49	a) 1 b) 2	14	a) 0.125 L/ha b) 0.250 L/ha	a) 25 g as/ha b) 50 g as/ha	200-600	1		Before BBCH 19

				PLUTMA, *Phyllotreta* sp. PHYESP, *Pieris rapae* PIERRA, *Mamestra brassicae* BARABR										
36	PL	Red cabbage *Brassica oleracea* var. *capitata* f. *rubra* BRSOR 0242020-002	F	*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE, *Delia radicum* HYLERA, *Athalia rosae* ATALCO, *Plutella xylostella* PLUTMA, *Phyllotreta* sp. PHYESP, *Pieris rapae* PIERRA, *Mamestra brassicae* BARABR	Spray, medi-um sprayer	BBCH 20-49	a) 1 b) 2	14	a) 0.125 L/ha b) 0.250 L/ha	a) 25 g as/ha b) 50 g as/ha	200-600	1		Before BBCH 19
37	PL	Kale *Brassica oleracea* var. *viridis* BRSOA 243020	F	*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE, *Delia radicum* HYLERA, *Athalia rosae* ATALCO, *Plutella xylostella* PLUTMA, *Phyllotreta* sp. PHYESP	Spray, medi-um sprayer	BBCH 20-49	a) 1 b) 2	14	a) 0.125 L/ha b) 0.250 L/ha	a) 25 g as/ha b) 50 g as/ha	200-600	1		No extrapolation from cabbage/cauliflower/broccoli possible
~~38~~	~~PL~~	~~Chinese cab-bage/pe-tsai *Brassica rapa* subsp. *pekinensis* BRSPK~~ ~~243010~~	~~F~~	~~*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE, *Delia radicum* HYLERA, *Athalia rosae* ATALCO, *Plutella xylostella* PLUTMA, *Phyllotreta* sp. PHYESP~~	~~Spray, medi-um sprayer~~	~~BBCH 20-49~~	~~a) 1 b) 2~~	~~14~~	~~a) 0.125 L/ha b) 0.250 L/ha~~	~~a) 25 g as/ha b) 50 g as/ha~~	~~200-600~~	~~1~~		No extrapolation from cabbage/cauliflower/broccoli possible
~~39~~	~~PL~~	~~Brussels sprout *Brassica oleracea* var. *gemmifera* BRSOF~~ ~~242010~~	~~F~~	~~*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE, *Delia radicum* HYLERA,~~	~~Spray, medi-um sprayer~~	~~BBCH 20-49~~	~~a) 1 b) 2~~	~~14~~	~~a) 0.125 L/ha b) 0.250 L/ha~~	~~a) 25 g as/ha b) 50 g as/ha~~	~~200-600~~	~~1~~		MRL exceedance

				~~*Athalia rosae* ATALCO, *Plutella xylostella* PLUTMA, *Phyllotreta* sp. PHYESP~~										
40	PL	Cauliflower *Brassica oleracea* var. *botrytis* BRSOB 241020	F	*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE, *Delia radicum* HYLERA, *Athalia rosae* ATALCO, *Plutella xylostella* PLUTMA, *Phyllotreta* sp. PHYESP	Spray, medium sprayer	BBCH 20-49	a) 1 b) 2	14	a) 0.125 L/ha b) 0.250 L/ha	a) 25 g as/ha b) 50 g as/ha	200-600	1		
41	PL	Broccoli *Brassica oleracea var. italica* BRSOK 241010	F	*Ceutorhynchus quadridens, syn. C. pallidactylus* CEUTQU, *Ceu-torhynchus napi* CEUTNA, *Brassicogethes aeneus syn. Meligethes aeneus* MELIAE, *Delia radicum* HYLERA, *Athalia rosae* ATALCO, *Plutella xylostella* PLUTMA, *Phyllotreta* sp. PHYESP	Spray, medium sprayer	BBCH 20-49	a) 1 b) 2	14	a) 0.125 L/ha b) 0.250 L/ha	a) 25 g as/ha b) 50 g as/ha	200-600	1		
42	PL	Pear *Pyrus communis* PYUCO 130020	F	*Cydia pomonella* CARPPO, *Dasineura pyri* DASYPY, *Contarinia pyrivora* CONTPY, *Tortricidae* 1TORTF	Spray, medium sprayer	BBCH 56-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		
43	PL	Plum *Prunus domestic*a PRNDO 140040	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		Before BBCH 65
44	PL	Common quince *Cydonia oblonga* CYDOB 130030	F	*Cydia pomonella* CARPPO, *Dasineura pyri* DASYPY, *Contarinia pyrivora* CONTPY, *Tortricidae* 1TORTF	Spray, medium sprayer	BBCH 56-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		
45	PL	Wild Apple *Malus sylvestris* MABSY 130010-001	F	*Cydia pomonella* CARPPO *Tortricidae* 1TORTF	Spray, medium sprayer	BBCH 56-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		

46	PL	Chinese Pear *Pyrus pyrifolia* PYUPY 130020-001	F	*Cydia pomonella* CARPPO, *Dasineura pyri* DASYPY, *Contarinia pyrivora* CONTPY, *Tortricidae* 1TORTF	Spray, medium sprayer	BBCH 56-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		
47	PL	Common medlar *Mespilus germanica* MSPGE 130040	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		
~~48~~	~~PL~~	~~Loquats/Japanese medlars *Eriobotrya japonica* EIOJA~~ ~~130050~~	~~F~~	~~*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU~~	~~Spray, medium sprayer~~	~~BBCH 56-87~~	~~a) 2~~ ~~b) 2~~	~~14~~	~~a) 0.125-0.175 L/ha~~ ~~b) 0.350 L/ha~~	~~a) 25-35 g as/ha~~ ~~b) 70 g as/ha~~	~~500-750~~	~~14~~		Not minor crop in PL
49	PL	Peach *Prunus persica* PRNPS 140030	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		Before BBCH 65
50	PL	Apricot *Prunus armeniaca* PRNAR 140010	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		Before BBCH 65
51	PL	Sour Cherry *Prunus cerasus* PRNCE 140020-006	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		Before BBCH 65
52	PL	Sweet cherry *Prunus avium* PRNAV 140020	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		Before BBCH 65
53	PL	Hazelnuts/cobnuts *Corylus avellana* CYLAV 120060	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		Before BBCH 65
54	PL	Walnuts *Juglans regia* IUGRE 120110	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		Before BBCH 65

55	PL	Chestnuts *Castanea sativa* CSNSA 120040	F	*Rhagoletis cerasi* RHAGCE, *Furcipus rectirostris* ANTHRE, *Grapholita funebrana* LASPFU	Spray, medium sprayer	BBCH 56-87	a) 2 b) 2	14	a) 0.125-0.175 L/ha b) 0.350 L/ha	a) 25-35 g as/ha b) 70 g as/ha	500-750	14		Before BBCH 65
56	PL	Table grape *Vitis vinifera* VITVI 151010	F	*Tetranychus urticae* TETRUR, *Lobesia botrana* POLYBO, *Eupoecilia ambiguella* CLYSAM	Spray, medium sprayer	BBCH 57-BBCH 83	a)1 b)1	-	a) 0.270 L/ha b) 0.270 L/ha	a) 54 g as/ha b) 54 g as/ha	700-1500	30		
57	PL	Grapevine *Vitis vinifera* VITVI 151020	F	*Lobesia botrana* POLYBO, *Eupoecilia ambiguella* CLYSAM	Spray, medium sprayer	BBCH 57-BBCH 83	a)1 b)1	-	a) 0.270 L/ha b) 0.270 L/ha	a) 54 g as/ha b) 54 g as/ha	700-1500	30		
58	PL	Tobacco *Nicotiana tabacum* NIOTA	F	*Mamestra brassicae* BARABR	Spray, medium sprayer	~~BBCH 20-85~~ BBCH 30-85	a)1 b)~~2~~ 1	~~7~~	a) 0.265-~~0.550 L/ha~~ ~~b) 0.530-1.100 L/ha~~	a) 53 -~~54 110 g as/ha~~ ~~b) 106-220 g as/ha~~	600-1000	1	~~BBCH 20-85~~ BBCH 30-85	not in the scope of residue section
59	PL	Grass	F	*Oulema* sp.OULESP	Spray, medium sprayer	BBCH 53-69	a) 1 b) 1	-	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	200-400	n/a	Only for seeds	not in the scope of residue section
60	PL	Christmas tree *Picea abies* PIEAB	F	*Collembola* 1COLLO, *Coleophora laricella* COLELA	Spray, medium sprayer	BBCH 11-69	a) 1 b) 1	-	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	200-400	n/a		not in the scope of residue section
61	PL	Forestry tree	F	*Collembola* 1COLLO, *Coleophora laricella* COLELA	Spray, medium sprayer	BBCH 11-69	a) 1 b) 1	-	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	200-400	n/a		not in the scope of residue section
62	PL	Ornamentals	F	*Collembola* 1COLLO, *Coleophora laricella* COLELA	Spray, medium sprayer	BBCH 11-69	a) 1 b) 1	-	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	200-400	n/a		not in the scope of residue section
63	PL	Willow *Salix* sp. SAXSS	F	*Chrysomela populi* CHRSPO, *Phratora vulgatissima* PHRRVU, *Phyllodecta vitellinae* PHRRVI, *Earias clorana* EARICH, *Cecidomyiidae* 1CECIF	Spray, medium sprayer	>BBCH 69	a) 1 b) 1	-	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	200-750	n/a		not in the scope of residue section
64	PL	Energetic tree	F	*Chrysomela populi* CHRSPO, *Phratora vulgatissima* PHRRVU, *Phyllodecta vitellinae* PHRRVI, *Earias clorana* EARICH, *Cecidomyiidae* 1CECIF *Cecidomyiidae*	Spray, medium sprayer	>BBCH 69	a) 1 b) 1	-	a) 0.175 L/ha b) 0.175 L/ha	a) 35 g as/ha b) 35 g as/ha	200-750	n/a		not in the scope of residue section

Minor uses according to Article 51 (interzonal uses) greenhouses													
65	PL	Cucumber *Cucumis sativus* CUMSA 232010	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH 20-49	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	500-1200	1		For not-fully closed greenhouses: Maximum one application of 50 g as/ha
66	PL	Pepper *Capsicum annuum* CPSAN 231020	G	*Autographa gamma* PYTOGA, *Tuta absoluta* GNORAB	Spray, medium sprayer	~~BBCH 12-49~~ BBCH 20-49	a) 1 b) 2	7	a) 0.14-0.215 L/ha b) 0.28-0.43 L/ha	a) 28-43 g as/ha b) 56-86 g as/ha	300-1250	1		For not-fully closed greenhouses: Maximum one application of 50 g as/ha
67	PL	Tomato *Solanum lycopersicum* LYPES 231010	G	*Autographa gamma* PYTOGA, *Tuta absoluta* GNORAB	Spray, medium sprayer	~~BBCH 12-49~~ BBCH 20-49	a) 1 b) 2	7	a) 0.14-0.315 L/ha b) 0.28-0.63 L/ha	a) 28-63 g as/ha b) 56-126 g as/ha	500-1500	1		For not-fully closed greenhouses: Maximum one application of 50 g as/ha
68	PL	Lettuce *Lactuca sativa* LACSA 251020	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed greenhouses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval
69	PL	Corn salad *Valerianella locusta* VLLLO 251010	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed greenhouses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval
70	PL	Endive *Cichorium endivia* CICEN 251030	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed greenhouses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval
71	PL	Garden cress *Lepidium sativum* LEPSA 251040	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed greenhouses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval
72	PL	Arugula *Eruca vesicaria subsp. sativa* ERUVE	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed greenhouses:

		251060												Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval
73	PL	Escaroles Cichorium endivia var. latifolia 251030	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed greenhouses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval
~~74~~	~~PL~~	~~Cresses and other sprouts and shoots~~ ~~0251040-001 Alfalfa/lucerne sprouts Medicago sativa subsp. sativa 0251040-002 Chinese chives/oriental garlic/garlic chives sprouts Allium tuberosum 0251040-003 Broccoli sprouts Brassica oleracea var. italica 0251040-004 Daikon/Japanese radish sprouts Raphanus sativus var. longipinnatus 0251040-005 Ginger shoots Zingiber officinale 0251040-006 Mung bean sprouts Vigna radiata 0251040-007 Peas shoots and sprouts Pisum sativum 0251040-008 Roman rocket/rucola sprouts Eruca sativa 0251040-009 Soyabeans sprouts Glycine max 0251040-010 Sunflower shoots~~	~~G~~	~~*Delia florilega* HYLEFG~~	~~Spray, medium sprayer~~	~~BBCH 12-49~~ ~~BBCH 20-49~~	~~a) 1~~ ~~b) 2~~	~~7~~	~~a) 0.155-0.210 L/ha~~ ~~b) 0.310-0.420 L/ha~~	~~a) 31-42 g as/ha~~ ~~b) 62-84 g as/ha~~	~~500-1000~~	~~1~~		~~For not-fully closed greenhouses:~~ ~~Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval~~ At BBCH 20–49, the plants do not appear as sprouts

		and sprouts Helianthus annuus 0251040-011 Wheat-grass/wheat shoots Triticum aestivum 0251040-990 Other species used for the production of sprouts or shoots												
75	PL	Land cresses *Barbarea verna* BARVE 251050	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 12-49 BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed green-houses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval Not minor crop in PL
76	PL	Roman rocket/rucola *Eruca vesicaria* subsp. *sativa* ERUVE 251060	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 12-49 BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed green-houses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval The same use as in 72
77	PL	Red Mustard *Brassica juncea* BRSJU 251070	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 12-49 BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed green-houses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval
78	PL	Baby leaf crops 0251080-001 Chards/beet leaves Beta vulgaris var. flavescens 0251080-002 Escaroles/broad-leaved endives Cichorium endivia var. latifolia 0251080-003 Indian mustards/mustard	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 12-49 BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed green-houses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval At BBCH 20-49, the plants are not grown for young leaves

		~~greens Brassica juncea 0251080-004 Lettuces Lactuca sativa 0251080-005 Spinaches Spinacia oleracea 0251080-990 Other species harvested at baby leaf stage~~												
79	PL	Spinach *Spinacia oleracea* SPQOL 252010	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed greenhouses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval
80	PL	Swiss Chard *Beta vulgaris subsp. vulgaris var. flavescens* BEAVF 252030	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed greenhouses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval
81	PL	Chards/beet leaves 252030	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed greenhouses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval
82	PL	Purslane *Portulaca oleracea* POROL 252020	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 12-49~~ BBCH 20-49	a) 1 b) 2	7	a) 0.155-0.210 L/ha b) 0.310-0.420 L/ha	a) 31-42 g as/ha b) 62-84 g as/ha	500-1000	1		For not-fully closed greenhouses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval
83	PL	Melon *Cucumis melo* CUMME 233010	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 15-89~~ BBCH 20--89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1		For not-fully closed greenhouses: Maximum one application of 50 g as/ha
84	PL	Aubergine *Solanum melongena* SOLME	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 15-89~~ BBCH 20--89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1		For not-fully closed greenhouses: Maximum one application of

		231030												50 g as/ha
85	PL	Okra/Lady's fingers Abelmoschus esculentus 231040	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89 BBCH 20--89	a) 1 b) 2	7	a) 0.14-0.215 L/ha b) 0.28-0.43 L/ha	a) 28-43 g as/ha b) 56-86 g as/ha	300-1250	1		For not-fully closed greenhouses: Maximum one application of 50 g as/ha Not minor crop in PL
86	PL	Watermelon *Citrullus lanatus* CITLA 233030	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89 BBCH 20--89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1		For not-fully closed greenhouses: Maximum one application of 50 g as/ha
87	PL	Zucchini *Cucurbita pepo var. giromontiina* CUUPG 232030	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89 BBCH 20--89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1		For not-fully closed greenhouses: Maximum one application of 50 g as/ha
88	PL	Gherkins *Cucumis sativus* CUMSA 232020	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89 BBCH 20--89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1		For not-fully closed greenhouses: Maximum one application of 50 g as/ha
89	PL	Curgettes *Cucurbita pepo* CUUPE 232030-008	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89 BBCH 20--89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1		For not-fully closed greenhouses: Maximum one application of 50 g as/ha
90	PL	Spaghetti squash *Cucurbita pepo* subsp. *pepo* CUUPE 232030-008	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89 BBCH 20--89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1		For not-fully closed greenhouses: Maximum one application of 50 g as/ha
91	PL	Giant pumpkin *Cucurbita maxima* CUUMA 0233020-003	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89 BBCH 20--89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1		For not-fully closed greenhouses: Maximum one application of 50 g as/ha
92	PL	Canada crookneck *Cucurbita moschata* CUUMO	G	*Delia florilega* HYLEFG	Spray, medium sprayer	BBCH 15-89 BBCH 20--89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1		For not-fully closed greenhouses:
93	PL	Pumpkin	G	*Delia florilega* HYLEFG	Spray, medi-	BBCH 15-89	a) 1	7	a) 0.14-0.25 L/ha	a) 28-50 g as/ha	200-	1		For not-fully closed green-

		Cucurbita pepo CUUPE 233020-001			um sprayer	BBCH 20--89	b) 2		b) 0.28-0.50 L/ha	b) 56-100 g as/ha	1000			houses: Maximum one application of 50 g as/ha
94	PL	Cucumber *Cucumis sativus* CUMSA 232010	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 15-89~~ BBCH 20--89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1		For not-fully closed greenhouses: Maximum one application of 50 g as/ha
95	PL	Bush squash *Cucurbita melopepo* CUUPM 233990	G	*Delia florilega* HYLEFG	Spray, medium sprayer	~~BBCH 15-89~~ BBCH 20--89	a) 1 b) 2	7	a) 0.14-0.25 L/ha b) 0.28-0.50 L/ha	a) 28-50 g as/ha b) 56-100 g as/ha	200-1000	1		For not-fully closed greenhouses: Maximum one application of 50 g as/ha
~~96~~	~~PL~~	~~Watercresses *Nasturtium officinale* NAAOF~~ ~~254000~~	~~G~~	~~*Delia florilega* HYLEFG~~	~~Spray, medium sprayer~~	~~BBCH 12-49~~ ~~BBCH 20-49~~	~~a) 1~~ ~~b) 2~~	~~7~~	~~a) 0.155-0.210 L/ha~~ ~~b) 0.310-0.420 L/ha~~	~~a) 31-42 g as/ha~~ ~~b) 62-84 g as/ha~~	~~500-1000~~	~~1~~		For not-fully closed greenhouses: Maximum one application of 42 g as/ha or two application of 25 g as/ha with 7 day interval Not minor crop in PL

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading,

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.			

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation CLOROL 200 SC is composed of Chlorantraniliprole.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of chlorantraniliprole

Reference value	Source	Year	Value	Study relied upon	Safety factor
Chlorantraniliprole - Parent compound					
ADI	EFSA 2013	2013	1.56 mg/kg bw/d	Rat, 2-year study, supported by the mouse, 18-month study	100
ARfD	Not relevant				

7.1.2.1 Summary for Chlorantraniliprole

Table 7.1-3: Summary for chlorantraniliprole

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Potato *Solanum tuberosum* SOLTU	Yes	Yes	Yes	Yes	Yes	No	No
2	Maize *Zea mays* ZEAMX	Yes	Yes	Yes	Yes	Yes	No	No
3	Winter oilseed rape *Brassica napus var. napus* BRSNW	Yes	Yes	Yes	Yes	Yes	No	No
5	Apple *Malus domestica* MABSD	Yes	Yes	Yes	Yes	Yes	No	No
65	Cucumber *Cucumis sativus* CUMSA	Yes	Yes	Yes	Yes	Yes	No	No
66	Pepper *Capsicum annuum* CPSAN	Yes	Yes	Yes	Yes	Yes	No	No
67	Tomato *Solanum lycopersicum* LYPES	Yes	Yes	Yes	Yes	Yes	No	No
7	Sugar beet *Beta vulgaris* subsp. *vulgaris* var. *altissima* BEAVA	Yes	Yes	Yes	Yes	Yes	No	No
8	Sweet Potato *Ipomoea batatas* IPOBA	Yes	Yes	Yes	Yes	No	No	No
						Use not accepted		
9	Yams *Dioscorea* L. 1DIUG	Yes	Yes	Yes	Yes	No	No	No
						Use not accepted		

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
10	Carrot *Daucus carota* subsp. *sativus* DAUCS	Yes	Yes	Yes	Yes	Yes	No	No
11	Beetroot *Beta vulgaris s*ubsp. *vulgaris* var. *conditiva* BEAVD	Yes	Yes	Yes	Yes	Yes	No	No
12	Horseradish *Armoracia rusticana* ARWLA	Yes	Yes	Yes	Yes	Yes	No	No
13	Radish *Raphanus sativus* RAPSR	Yes	Yes	Yes	Yes	Yes	No	No
14	Celery *Apium graveolens* APUGV	Yes	Yes	Yes	Yes	Yes	No	No
15	Jerusalem artichoke *Helianthus tuberosus* HELTU	Yes	Yes	Yes	Yes	Yes	No	No
16	Parsley *Petroselinum crispum* PARCR	Yes	Yes	Yes	Yes	Yes	No	No
17	Parsnip *Pastinaca sativa* PAVSA	Yes	Yes	Yes	Yes	Yes	No	No
18	Salsify *Tragopogon porrifolius* TROPS	Yes	Yes	Yes	Yes	Yes	No	No
19	Rutabaga *Brassica napus* subsp. *rapifera* BRSNA	Yes	Yes	Yes	Yes	Yes	No	No
20	Turnip *Brassica rapa* BRSRR	Yes	Yes	Yes	Yes	Yes	No	No
21	Scorzonera *Scorzonera hispanica* SCVHI	Yes	Yes	Yes	Yes	Yes	No	No
22	Sweet Corn *Zea mays* subsp. *saccharata* ZEAMS	Yes	Yes	Yes	Yes	Yes	No	No
23	Sweet cane *Saccharum officinarum* SACOF	Yes	Yes	Yes	Yes	Yes	No	No
						Use not accepted		
24	Sorghum *Sorghum bicolor* SORVU	Yes	Yes	Yes	Yes	Yes	No	No
						Use not accepted		
25	Millet *Panicum miliaceum* PANMI	Yes	Yes	Yes	Yes	Yes	No	No
26	Spring oilseed rape *Brassica napus var. napus* BRSNS	Yes	Yes	Yes	Yes	Yes	No	No
27	Flax *Linum usitatissimum* LIUUT	Yes	Yes	Yes	Yes	Yes	No	No

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
28	Opium poppy *Papaver somniferum* PAPSO	Yes	Yes	Yes	Yes	Yes	No	No
29	White mustard *Sinapis alba* SINAL	Yes	Yes	Yes	Yes	Yes	No	No
30	Winter Turnip rape *Brassica rapa* subsp. *oleifera* BRSRO	Yes	Yes	Yes	Yes	Yes	No	No
31	Sunflower *Helianthus annuus* HELAN	Yes	Yes	Yes	Yes	Yes	No	No
						Use not accepted		
32	Soybean *Glycine max* GLXMA	Yes	Yes	Yes	Yes	Yes	No	No
33	Pumpkin *Cucurbita pepo* CUUPE	Yes	Yes	Yes	Yes	Yes	No	No
34	Hemp *Cannabis sativa* CNISA	Yes	Yes	Yes	Yes	Yes	No	No
35	White cabbage *Brassica oleracea* var. *capitata* f. *alba* BRSOH	Yes	Yes	Yes	Yes	Yes	No	No
36	Red cabbage *Brassica oleracea* var. *capitata* f. *rubra* BRSOR	Yes	Yes	Yes	Yes	Yes	No	No
37	Kale *Brassica oleracea* var. *viridis* BRSOA	Yes	Yes	Yes	Yes	Yes	No	No
						Use not accepted		
38	Chinese cabbage/pe-tsai *Brassica rapa* subsp. *pekinensis* BRSPK	Yes	Yes	Yes	Yes	Yes	No	No
						Use not accepted		
39	Brussels sprout *Brassica oleracea* var. *gemmifera* BRSOF	Yes	Yes	Yes	Yes	Yes	No	No
						Use not accepted		
40	Cauliflower *Brassica oleracea* var. *botrytis* BRSOB	Yes	Yes	Yes	Yes	Yes	No	No
41	Broccoli *Brassica oleracea var. italica* BRSOK	Yes	Yes	Yes	Yes	Yes	No	No
42	Pear *Pyrus communis* PYUCO	Yes	Yes	Yes	Yes	Yes	No	No
43	Plum *Prunus domestic*a PRNDO	Yes	Yes	Yes	Yes	Yes	No	No
44	Common quince *Cydonia oblonga* CYDOB	Yes	Yes	Yes	Yes	Yes	No	No
45	Wild Apple *Malus sylvestris* MABSY	Yes	Yes	Yes	Yes	Yes	No	No

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
46	Chinese Pear *Pyrus pyrifolia* PYUPY	Yes	Yes	Yes	Yes	Yes	No	No
47	Common medlar *Mespilus germanica* MSPGE	Yes	Yes	Yes	Yes	Yes	No	No
48 not minor crop in PL	Loquats/Japanese medlars *Eriobotrya japonica* EIOJA	Yes	Yes	Yes	Yes	Yes	No	No
49	Peach *Prunus persica* PRNPS	Yes	Yes	Yes	Yes	Yes	No	No
50	Apricot *Prunus armeniaca* PRNAR	Yes	Yes	Yes	Yes	Yes	No	No
51	Sour Cherry *Prunus cerasus* PRNCE	Yes	Yes	Yes	Yes	Yes	No	No
52	Sweet cherry *Prunus avium* PRNAV	Yes	Yes	Yes	Yes	Yes	No	No
53	Hazelnuts/cobnuts *Corylus avellana* CYLAV	Yes	Yes	Yes	Yes	Yes	No	No
54	Walnuts *Juglans regia* IUGRE	Yes	Yes	Yes	Yes	Yes	No	No
55	Chestnuts *Castanea sativa* CSNSA	Yes	Yes	Yes	Yes	Yes	No	No
56	Table grape *Vitis vinifera* VITVI	Yes	Yes	Yes	Yes	Yes	No	No
57	Grapevine *Vitis vinifera* VITVI	Yes	Yes	Yes	Yes	Yes	No	No
58	Tobacco *Nicotiana tabacum* NIOTA	Yes	Yes	Yes	Yes	Yes	Consumer exposure assessment not required	
59	Grass	Yes	Yes	Yes	Yes	Yes		
60	Christmas tree *Picea abies* PIEAB	Yes	Yes	Yes	Yes	Yes		
61	Forestry tree	Yes	Yes	Yes	Yes	Yes		
62	Ornamentals	Yes	Yes	Yes	Yes	Yes		
63	Willow *Salix* sp. SAXSS	Yes	Yes	Yes	Yes	Yes		
64	Energetic tree	Yes	Yes	Yes	Yes	Yes		
68	Lettuce *Lactuca sativa* LACSA	Yes	Yes	Yes	Yes	Yes	No	No
69	Corn salad *Valerianella locusta* VLLLO	Yes	Yes	Yes	Yes	Yes	No	No
70	Endive *Cichorium endivia* CICEN	Yes	Yes	Yes	Yes	Yes	No	No
71	Garden cress *Lepidium sativum*	Yes	Yes	Yes	Yes	Yes	No	No

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
	LEPSA							
72	Arugula *Eruca vesicaria subsp. sativa* ERUVE	Yes	Yes	Yes	Yes	Yes	No	No
73	Escaroles Cichorium endivia var. latifolia	Yes	Yes	Yes	Yes	Yes	No	No
74 At BBCH 20–49, the plants do not appear as sprouts	Cresses and other sprouts and shoots	Yes	Yes	Yes	Yes	Yes	No	No
75 At BBCH 49, the plants are not grown for young leaves	Land creses *Barbarea verna* BARVE	Yes	Yes	Yes	Yes	Yes	No	No
~~76~~ The same as in 72	~~Roman rocket/rucola *Eruca vesicaria subsp. sativa* ERUVE~~	~~Yes~~	~~Yes~~	~~Yes~~	~~Yes~~	~~Yes~~	~~No~~	~~No~~
77	Red Mustard *Brassica juncea* BRSJU	Yes	Yes	Yes	Yes	Yes	No	No
78	Baby leaf crops	Yes	Yes	Yes	Yes	Yes	No	No
79	Spinach *Spinacia oleracea* SPQOL	Yes	Yes	Yes	Yes	Yes At stages 20–49, the plants do not appear as sprouts	No	No
80	Swiss Chard *Beta vulgaris subsp. vulgaris var. flavescens* BEAVF	Yes	Yes	Yes	Yes	Yes	No	No
81	Chards/beet leaves	Yes	Yes	Yes	Yes	Yes	No	No
82	Purslane *Portulaca oleracea* POROL	Yes	Yes	Yes	Yes	Yes	No	No
83	Melon *Cucumis melo* CUMME	Yes	Yes	Yes	Yes	Yes	No	No
84	Aubergine *Solanum melongena*	Yes	Yes	Yes	Yes	Yes	No	No

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
	SOLME							
85 not minor crop in PL	Okra/Lady's fingers Abelmoschus esculentus	Yes	Yes	Yes	Yes	Yes	No	No
86	Watermelon *Citrullus lanatus* CITLA	Yes	Yes	Yes	Yes	Yes	No	No
87	Zucchini *Cucurbita pepo var. giromontiina* CUUPG	Yes	Yes	Yes	Yes	Yes	No	No
88	Gherkins *Cucumis sativus* CUMSA	Yes	Yes	Yes	Yes	Yes	No	No
89	Curgettes *Cucurbita pepo* CUUPE	Yes	Yes	Yes	Yes	Yes	No	No
90	Spaghetti squash *Cucurbita pepo* subsp. *pepo* CUUPE	Yes	Yes	Yes	Yes	Yes	No	No
91	Giant pumpkin *Cucurbita maxima* CUUMA	Yes	Yes	Yes	Yes	Yes		No
92	Canada crookneck *Cucurbita moschata* CUUMO	Yes	Yes	Yes	Yes	Yes	No	No
93	Pumpkin *Cucurbita pepo* CUUPE	Yes	Yes	Yes	Yes	Yes	No	No
94	Cucumber *Cucumis sativus* CUMSA	Yes	Yes	Yes	Yes	Yes	No	No
95	Bush squash *Cucurbita melopepo* CUUPM	Yes	Yes	Yes	Yes	Yes	No	No
96 not minor crop in PL	Watercresses *Nasturtium officinale* NAAOF	Yes	Yes	Yes	Yes	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

7.1.2.2 Summary for CLOROL 200 SC

Table 7.1-4: Information on CLOROL 200 SC (KCA 6.8)

Crop	PHI [days] for CLOROL 200 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CLOROL 200 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Chlorantraniliprole		
Potato *Solanum tuberosum* SOLTU	14	Yes		
Maize *Zea mays* ZEAMX	7	Yes		
Winter oilseed rape *Brassica napus var. napus* BRSNW	7	Yes		
Winter oilseed rape *Brassica napus var. napus* BRSNW	7	Yes		
Apple *Malus domestica* MABSD	14	Yes		
Cucumber *Cucumis sativus* CUMSA	1	Yes		
Pepper *Capsicum annuum* CPSAN	1	Yes		
Tomato *Solanum lycopersicum* LYPES	1	Yes		
Sugar beet *Beta vulgaris* subsp. *vulgaris* var. *altissima* BEAVA	28	Yes		
Sweet Potato *Ipomoea batatas* IPOBA	14	Yes		Use not accepted
Yams *Dioscorea* L. 1DIUG	14	Yes		Use not accepted
Carrot *Daucus carota* subsp. *sativus* DAUCS	21	Yes		
Beetroot *Beta vulgaris s*subsp. *vulgaris* var. *conditiva* BEAVD	21	Yes		
Horseradish *Armoracia rusticana* ARWLA	21	Yes		
Radish *Raphanus sativus* RAPSR	21	Yes		
Celery *Apium graveolens* APUGV	21	Yes		
Jerusalem artichoke *Helianthus tuberosus* HELTU	21	Yes		
Parsley *Petroselinum*	21	Yes		

Crop	PHI [days] for CLOROL 200 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CLOROL 200 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Chlorantraniliprole		
crispum PARCR				
Parsnip *Pastinaca sativa* PAVSA	21	Yes		
Salsify *Tragopogon porrifolius* TROPS	21	Yes		
Rutabaga *Brassica napus* subsp. *rapifera* BRSNA	21	Yes		
Turnip *Brassica rapa* BRSRR	21	Yes		
Scorzonera *Scorzonera hispanica* SCVHI	21	Yes		
Sweet Corn *Zea mays* subsp. *saccharata* ZEAMS	7	Yes		
Sweet cane *Saccharum officinarum* SACOF	7	Yes		Use not accepted
Sorghum *Sorghum bicolor* SORVU	7	Yes		Use not accepted
Millet *Panicum miliaceum* PANMI	7	Yes		
Spring oilseed rape *Brassica napus var. napus* BRSNS	7	Yes		
Flax *Linum usitatissimum* LIUUT	7	Yes		
Opium poppy *Papaver somniferum* PAPSO	7	Yes		
White mustard *Sinapis alba* SINAL	7	Yes		
Winter Turnip rape *Brassica rapa* subsp. *oleifera* BRSRO	7	Yes		
Sunflower *Helianthus annuus* HELAN	7	Yes		Use not accepted
Soybean *Glycine max* GLXMA	7	Yes		
Pumpkin *Cucurbita pepo* CUUPE	7	Yes		
Hemp *Cannabis sativa* CNISA	7	Yes		Use not accepted
White cabbage *Brassica oleracea* var. *capitata* f.	1	Yes		

Crop	PHI [days] for CLOROL 200 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CLOROL 200 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Chlorantraniliprole		
alba BRSOH				
Red cabbage *Brassica oleracea* var. *capitata* f. *rubra* BRSOR	1	Yes		
Kale *Brassica oleracea* var. *viridis* BRSOA	1	Yes		Use not accepted
Chinese cabbage/pe-tsai *Brassica rapa* subsp. *pekinensis* BRSPK	1	Yes		Use not accepted
Brussels sprout *Brassica oleracea* var. *gemmifera* BRSOF	1	Yes		Use not accepted
Cauliflower *Brassica oleracea* var. *botrytis* BRSOB	1	Yes		
Broccoli *Brassica oleracea var. italica* BRSOK	1	Yes		
Pear *Pyrus communis* PYUCO	14	Yes		
Plum *Prunus domestic*a PRNDO	14	Yes		
Common quince *Cydonia oblonga* CYDOB	14	Yes		
Wild Apple *Malus sylvestris* MABSY	14	Yes		
Chinese Pear *Pyrus pyrifolia* PYUPY	14	Yes		
Common medlar *Mespilus germanica* MSPGE	14	Yes		
Loquats/Japanese medlars *Eriobotrya japonica* EIOJA	14	Yes		Use not accepted
Peach *Prunus persica* PRNPS	14	Yes		
Apricot *Prunus armeniaca* PRNAR	14	Yes		
Sour Cherry *Prunus cerasus* PRNCE	14	Yes		
Sweet cherry *Prunus avium* PRNAV	14	Yes		

Crop	PHI [days] for CLOROL 200 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CLOROL 200 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Chlorantraniliprole		
Hazelnuts/cobnuts *Corylus avellana* CYLAV	14	Yes		
Walnuts *Juglans regia* IUGRE	14	Yes		
Chestnuts *Castanea sativa* CSNSA	14	Yes		
Table grape *Vitis vinifera* VITVI	30	Yes		
Grapevine *Vitis vinifera* VITVI	30	Yes		
Tobacco *Nicotiana tabacum* NIOTA	N/A			1 (according to GAP)
Grass	N/A			
Christmas tree *Picea abies* PIEAB	N/A			
Forestry tree	N/A			
Ornamentals	N/A			
Willow *Salix* sp. SAXSS	N/A			
Energetic tree	N/A			
Lettuce *Lactuca sativa* LACSA	1	Yes		
Corn salad *Valerianella locusta* VLLLO	1	Yes		
Endive *Cichorium endivia* CICEN	1	Yes		
Garden cress *Lepidium sativum* LEPSA	1	Yes		
Arugula *Eruca vesicaria subsp. sativa* ERUVE	1	Yes		
Escaroles Cichorium endivia var. latifolia	1	Yes		
Cresses and other sprouts and shoots	1	Yes		Use not accepted
Land creses *Barbarea verna* BARVE	1	Yes		Use not accepted
Roman rocket/rucola *Eruca vesicaria* subsp. *sativa* ERUVE	1	Yes		
Red Mustard *Brassica juncea* BRSJU	1	Yes		
Baby leaf crops	1	Yes		Use not accepted

Crop	PHI [days] for CLOROL 200 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CLOROL 200 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Chlorantraniliprole		
Spinach *Spinacia oleracea* SPQOL	1	Yes		
Swiss Chard *Beta vulgaris subsp. vulgaris var. flavescens* BEAVF	1	Yes		
Chards/beet leaves	1	Yes		
Purslane *Portulaca oleracea* POROL	1	Yes		
Melon *Cucumis melo* CUMME	1	Yes		
Aubergine *Solanum melongena* SOLME	1	Yes		
Okra/Lady's fingers Abelmoschus esculentus	1	Yes		Use not accepted
Watermelon *Citrullus lanatus* CITLA	1	Yes		
Zucchini *Cucurbita pepo var. giromontiina* CUUPG	1	Yes		
Gherkins *Cucumis sativus* CUMSA	1	Yes		
Curgettes *Cucurbita pepo* CUUPE	1	Yes		
Spaghetti squash *Cucurbita pepo* subsp. *pepo* CUUPE	1	Yes		
Giant pumpkin *Cucurbita maxima* CUUMA	1	Yes		
Canada crookneck *Cucurbita moschata* CUUMO	1	Yes		
Pumpkin *Cucurbita pepo* CUUPE	1	Yes		
Cucumber *Cucumis sativus* CUMSA	1	Yes		
Bush squash *Cucurbita melopepo* CUUPM	1	Yes		
Watercresses *Nasturtium officinale* NAAOF	1	Yes		Use not accepted

NR: not relevant

* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for CLOROL 200 SC
Crop group	**Led by chlorantraniliprole**	
Leafy vegetables	Not required	
Root vegetables	Not required	
Fruiting vegetable	~~NR~~ Not required	
Pome/stone fruits	Not required	
Cereals	Not required	
Roots and tuber vegetables	Not required	
Oilseeds	Not required	

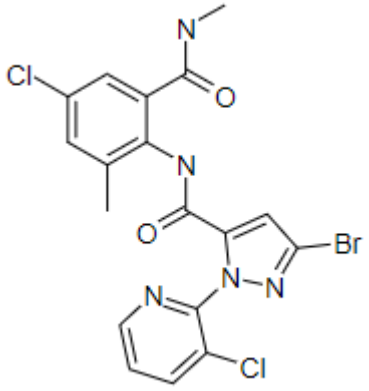
~~NR: not relevant~~

Assessment

7.2 Chlorantraniliprole

General data on chlorantraniliprole are summarized in the table below (last updated 2024/07/22)

Table 7.2-1: General information on chlorantraniliprole

Active substance (ISO Common Name)	Chlorantraniliprole
IUPAC	3-bromo-4'-chloro-1-(3-chloro-2-pyridyl)-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carboxanilide
Chemical structure	
Molecular formula	C18H14BrCl2N5O2

Molar mass	483.15 g/mol
Chemical group	anthranilic diamide insecticide
Mode of action (if available)	Interruption of normal muscle contractions by activating insect ryanodine receptors.
Systemic	No
Company (ies)	DuPont
Rapporteur Member State (RMS)	IE
Approval status	COMMISSION IMPLEMENTING REGULATION ~~(EU) 2020/2007 of 8 December 2020~~ Reg. (EU) 2024/2781
Restriction \	SANCO/12081/2013 rev 2 26 January 2018
Review Report	SANCO/12081/2013 rev 2 26 January 2018
Current MRL regulation	~~Reg. (EU) 2022/1343~~ Reg. (EU) 2024/1355
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	EFSA Journal 2020;18(9):6235
EFSA Journal : Conclusion on the peer review	EFSA Journal 2013;11(6):3143
EFSA Journal: conclusion on article 12	EFSA Journal 2020;18(9):6235
Current MRL applications on intended uses	~~Reg. (EU) 2022/1343~~ Reg. (EU) 2024/1355

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Apple	High water content	24 months for chlorantraniliprole	EFSA Journal 2013;11(6):3143
Grape	High ~~water~~ acid content		
Tomato	High water content		
Lettuce	High water content		
Cauliflower	High water content		
Wheat (grain)	High starch content		
Potato	High starch content		
Cotton	High oil content		

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Straw	Dry		
Alfaalfa hay	Dry		
Apple Juice	Processed fraction	12 months for Chlorantraniliprole and metabolites IN-EQW78, IN-ECD73, IN-F6L99	EFSA Journal 2013;11(6):3143
Tomato ketchup			
Cottonseed oil			
Cottonseed Meal			
Raisins			
Animal Products			
Cattle	Liver	12 months for Chlorantraniliprole and IN-HXH44, IN-K9T00, IN-EQW78, IN-GAZ70	EFSA Journal 2013;11(6):3143
Cattle	Kidney		
Cattle	Milk		
Cattle	Fat		
Cattle	Muscles		

Conclusion on stability of residues during storage

Chlorantraniliprole residues stable at least 24 months when stored frozen at -20 °C in plant matrices with: - high water-content: (apple, grape, tomato, lettuce, cauliflower) - high starch-content: (wheat grain, potato) - high oil content: (cotton seed) - and dry matrices: (straw, alfalfa hay)
Chlorantraniliprole and metabolites IN-EQW78, IN-ECD73, IN-F6L99 residues stable for at least 12 months when stored at -20°C in processed fractions (apple juice, tomato ketchup, cottonseed oil and meal and raisins).
Chlorantraniliprole and IN-HXH44, IN-K9T00, IN-EQW78, IN-GAZ70 residues stable for at least 12 months when stored at -20°C in milk and cattle tissues

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant for this application, in supervised studies evaluated during Annex I inclusion and presented in DAR Chlorantraniliprole - Volume 3, Annex B.7 and new studies, analysis time were less than 24 hours between extraction and analysis.

zRMS comment: The storage stability of chlorantraniliprole was investigated in the framework of the peer review in different groups, including high water, high oil, high starch and high acid content commodities, animal tissues and in some processed commodities. Chlorantraniliprole is stable for 24 months in all matrices and 12 months in processed fractions and animal products. Stability of chlorantraniliprole in honey is not required as residues in honey were determined within 30 days after sampling. No further data is required.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Apple	[BC-14C]-chlorantraniliprole [PC-14C]-chlorantraniliprole	foliar treatment, F	100 g as/ha	3	Immature apple leaves and fruit samples were taken immediately after the first application, before and after the second and third (final) applications and 15 days after the final application. The final (maturity) harvest was taken 30 days after the last application.		EFSA Journal 2013;11(6):3143
	Tomato	[BC-14C]-chlorantraniliprole [PC-14C]-chlorantraniliprole	foliar treatment, F	100 g as/ha	3	Immature treated tomato leaf and fruit samples were taken immediately after the first application. Immature treated tomato leaf and fruit samples were taken before and after the second and		EFSA Journal 2013;11(6):3143

						third (final) applications, and 7 days after the final application. Final (maturity) harvest was 15 days after the last application		
Leafy vegetables	Lettuce	[BC-14C]-chlorantraniliprole [PC-14C]-chlorantraniliprole	foliar treatment, F	100 g as/ha	3	Immature lettuce foliage samples (whole plants) were taken immediately after the first application, before and after the second and third (final) applications and 7 days after the final application. The final (maturity) harvest was taken 15 days after the last application. These sampling points corresponded to BBCH growth stage 13 for the sampling carried out after the first application and BBCH growth stage 19 for all remaining harvests		EFSA Journal 2013;11(6):3143
Pulses and oilseeds	Cotton	[BC-14C]-chlorantraniliprole [PC-14C]-chlorantraniliprole	foliar treatment, F	150 g as/ha	1	All of the excised cotton plants were removed from the uptake solutions at the		EFSA Journal 2013;11(6):3143

						end of Day 4. The uptake solutions recovered after the plant incubation were retained for analysis.		
Cereals	Rice	[BC-14C]-chlorantraniliprole [PC-14C]-chlorantraniliprole	soil treatment, F	300 g as/ha	1	14,28, 56 and 132 days		EFSA Journal 2013;11(6):3143

Summary of plant metabolism studies reported in the EU

a) metabolism in apple:
Chlorantraniliprole was the only quantifiable residue in the apple fruit and leaf samples from all intervals and the majority (84-93% TRR) was found in the surface wash of apples from 15 and 30 days after the last application. Intact chlorantraniliprole was the only major component accounting for 0.089 to 0.126 mg/kg (86.2 to 91.4% TRR) and 0.076 to 0.088 mg/kg (83.1 to 83.5% TRR) in the apple fruit tissue collected 15 and 30 days after the last application, respectively. In apple leaf tissue collected 15 and 30 days after the last application, chlorantraniliprole accounted for 4.814 to 6.162 mg/kg (95.5 to 96.4% TRR) and 3.803 to 4.015 mg/kg (91.7 to 93.7% TRR) respectively. Chlorantraniliprole dissipates through growth dilution and metabolism is not significant rout in apple trees. No metabolites were formed in any significant amounts (>1.7% TRR, >0.004 mg/kg).

b) metabolism in tomato:
Chlorantraniliprole was the only quantifiable residue in the tomato fruit and leaf samples from all intervals. The majority (ca. 76% TRR) of the fruit surface washed radioactivity was identified as parent chlorantraniliprole. Intact chlorantraniliprole was the major component accounting for 0.052 mg/kg (92.8% TRR) and 0.012 mg/kg (92.3% TRR) in the tomato fruit tissue collected 7 and 15 days after the last application, respectively. In tomato leaf collected 7 and 15 days after the last application, chlorantraniliprole accounted for 2.348 mg/kg (97.1% TRR) and 1.340 mg/kg (98.1% TRR), respectively. Chlorantraniliprole dissipates through growth dilution and metabolism is not significant route in tomato plants.

c) metabolism in lettuce:
Chlorantraniliprole was the only quantifiable residue in the lettuce samples from all intervals. The surface residues were 0.237 mg/kg (63.7% TRR) and 0.1193 mg/kg (39.4% TRR) in the lettuce collected 7 days and 15 days (respectively) after the last (third) application that totalled 300 g ai/ha. The majority (ca. 99%) of the surface residue was identified as the parent chlorantraniliprole. Intact chlorantraniliprole was the major component (or residue) accounting for 0.370 mg/kg (99.3% TRR) and 0.268 mg/kg (88.7% TRR) in the lettuce collected 7 and 15 days (respectively) after the last application. The unextracted radioactive residues were <2% TRR. No metabolites were formed in any significant amounts (>1.7% TRR, >0.004 mg/kg). Minor metabolites, individually not exceeding 1.7% TRR or 0.004 mg/kg were also observed

d) metabolism in rice:
Chlorantraniliprole was the principal residue in the grain of rice plants grown in soil which received a single drench application of 14C-chlorantraniliprole at 300 g ai/ha. The grain TRR was 0.155 mg/kg of

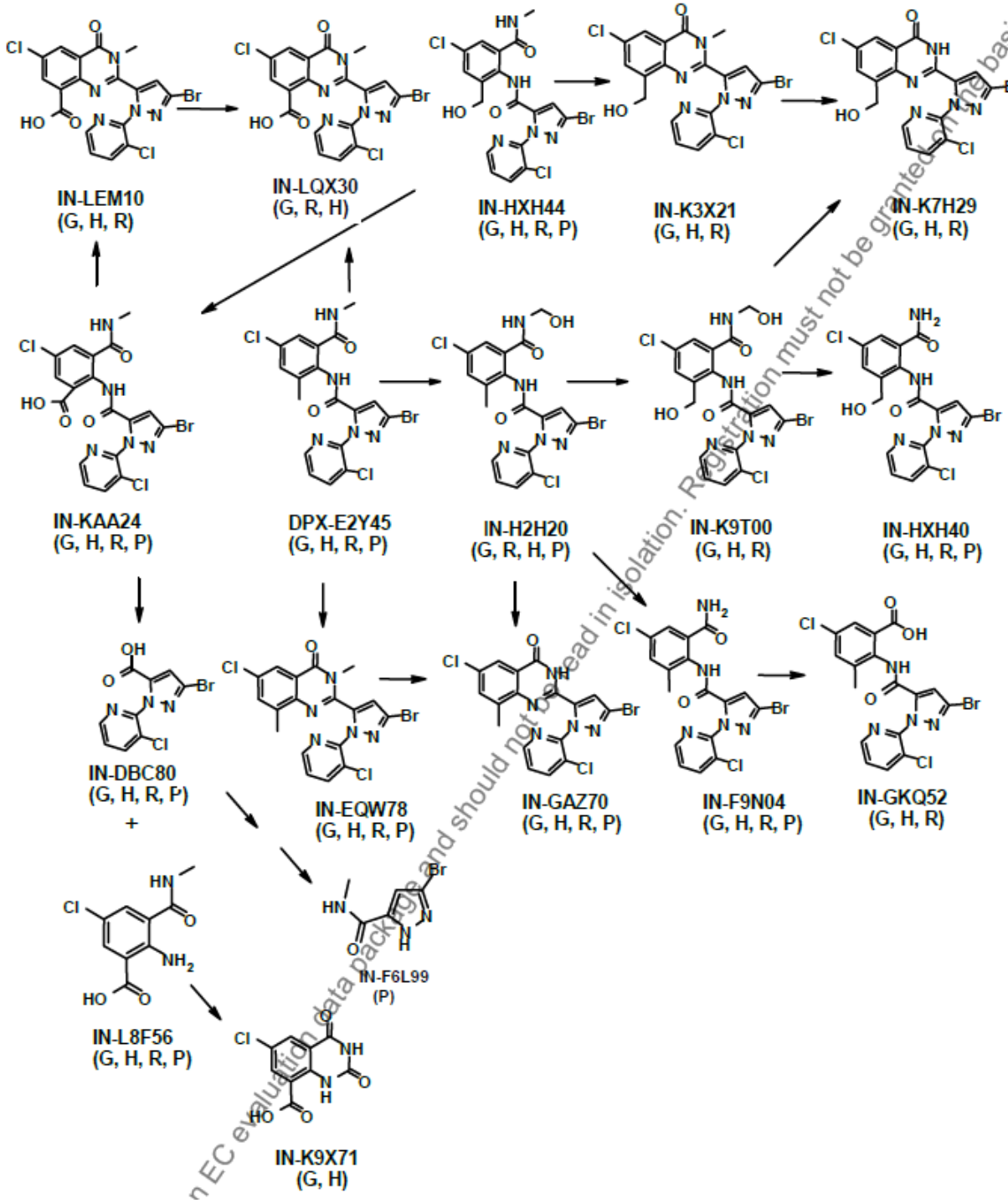
which chlorantraniliprole accounted for 51.4% (0.080 mg/kg). The remaining residue comprised minor components:
identified metabolites including IN-EQW78, IN-KAA24, IN-L8F56 and IN-F6L99 (all ≤1.8% TRR, ≤0.003 mg/kg), two unidentified polar metabolites (≤7.6% TRR, ≤0.011 mg/kg), uncharacterised fractions (≤4.1% TRR, ≤0.006 mg/kg) and the unextracted residue (9.1% TRR, 0.014 mg/kg). TRRs in hulls, leaves, sheaths and straw at maturity were 0.174, 4.056, 0.133 and 0.903 mg/kg respectively. Chlorantraniliprole was the largest residue component present at 0.086 to 2.118 mg/kg (52.3 to 66.3% TRR). Multiple minor metabolites were present in mature leaves at concentrations ranging from 0.037 mg/kg (0.9% TRR) to 0.244 mg/kg (6.1% TRR) and included those identified as IN-GAZ70, IN-EQW78, IN-H2H20, IN-F9N04, IN-KAA24, IN-DBC80, IN-HXH40, IN-HXH44, IN-E5F18, IN-L8F56 and IN-F6L99. Tentatively identified and unidentified metabolites were also present at 0.006 mg/kg (0.1% TRR) to 0.055 mg/kg (1.3% TRR). Chlorantraniliprole dissipates in the soil/sediment and in the rice plants through three major types of metabolic reaction: hydroxylation, N-demethylation, and cyclisation with the loss of a water molecule. The metabolic pathway of chlorantraniliprole in the rice plants was adequately understood

e) metabolism in cotton:
Chlorantraniliprole was the only quantifiable residue in cotton samples (foliage, hulls and seed) at all sampling intervals regardless of the treatment regimen. Minor components were present in immature cotton foliage included IN-EQW78 and IN-GAZ70 (≤2%TRR; ≤0.02 mg/kg) and polar metabolites (≤12% TRR; ≤0.05 mg/kg). There was no potential for the transfer of residues to the cottonseed. Dissipation of chlorantraniliprole through metabolism in the cotton plants was not a significant route

Conclusion on metabolism in primary crops

The metabolic fate of chlorantraniliprole in plants (apple, cotton, lettuce, rice, and tomato) and animal (goat, hen and rat) is adequately understood. Metabolism of chlorantraniliprole in the plants is not a significant route of dissipation when foliar applications were made. However, the metabolic pathway in the rice was complex with the root uptake, as the test substance was applied by a soil drench method.
Crops (apple, cotton, lettuce, rice and tomato) were all foliarly treated, except for the rice metabolism in which a soil drench application was made. The application rate was 300 ai/ha (100 g ai/ha × 3) of [14C]-chlorantraniliprole, with the exception of cotton (150 g ai/ha). The crops were either 5 to 9 weeks old or at mid to late bloom when the first application was made. Chlorantraniliprole was the only quantifiable residue (86.2-92.2% TRR) in the human food (apple, cotton seed, lettuce, rice grain, and tomatoes) and animal feed (apple, cotton and tomato foliage, rice) items. No significant residues (≥0.01 mg/kg) were detected in any of the plant matrices. However, metabolism of chlorantraniliprole in the rice plants was more complicated with root uptake occurring. IN-GAZ70 (0.049 mg/kg) and IN-EQW78 (0.039 mg/kg) were two major metabolites in the rice straw, but were less than 7% of the TRR. Other minor (<0.035 mg/kg) metabolites identified in the rice straw included IN-KAA24, IN-HXH40, IN-H2H20, IN-HXH44, and IN-F6L99.

Figure 3
Proposed metabolic pathways of chlorantraniliprole (DPX-E2Y45) in animals and plants



n EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis o

zRMS comment: Metabolism studies of chlorantraniliprole have been investigated at EU level in four crop categories (fruits, cereals, leafy vegetables and pulses/oilseeds) and the results indicated that the metabolism of chlorantraniliprole is similar in all crops. A residue definition for monitoring and risk assessment is proposed as chlorantraniliprole

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	lettuce	[PC-^{14}C]-chlorantraniliprole	G	0.3	0, 30, 120 and 365	At maturity		Chapleo, S., 2006)
		[BC-^{14}C]-chlorantraniliprole			30			
Root and tuber vegetables	Red beet	[PC-^{14}C]-chlorantraniliprole	G	0.3	0, 30, 120 and 365	At maturity		Chapleo, S., 2006)
		[BC-^{14}C]-chlorantraniliprole			30			
Cereals	Spring wheat	[PC-^{14}C]-chlorantraniliprole	G	0.3	0, 30, 120 and 365	28, 99, 159 and 409 days		Chapleo, S., 2006)
				0.9	0 and 365	28 and 409 days		
		[BC-^{14}C]-chlorantraniliprole		0.3	30 days	99 days		

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

Spring wheat, lettuce, and red beet seeds were sown into a sandy loam at 0, 30, 120, and 365 days following a single spray application of chlorantraniliprole to the soil, at a target application rate of 300 g ai/ha. Samples of early forage, hay, straw, and grain from wheat, foliage, and roots from red beet and lettuce foliage were collected. Crop tissues were pulverized and extracted. Soil cores (0–15 cm and 15–30 cm depths) were also taken, pulverized, and extracted.

1. Human-food commodities
TRRs in the human-food items from soil treated with [PC-14C]-chlorantraniliprole ranged from <0.010-0.041 mg/kg for wheat grain, 0.006–0.013 mg/kg for red beet roots, and 0.024–0.046 mg/kg for lettuceTRRs in food items from the 30-day sowing into soil treated with [BC-14C]-chlorantraniliprole were <0.010 mg/kg for wheat grain and red beet roots, and 0.038 mg/kg for lettuce. Overall the transfer of chlorantraniliprole and its metabolites through root uptake to the human-food commodities was low with 0.1–1.0% of soil-applied radioactivity

2. Animal-feed commodities
The TRRs in wheat commodities taken from the 0-, 30-, and 365-day sowings into soil treated with

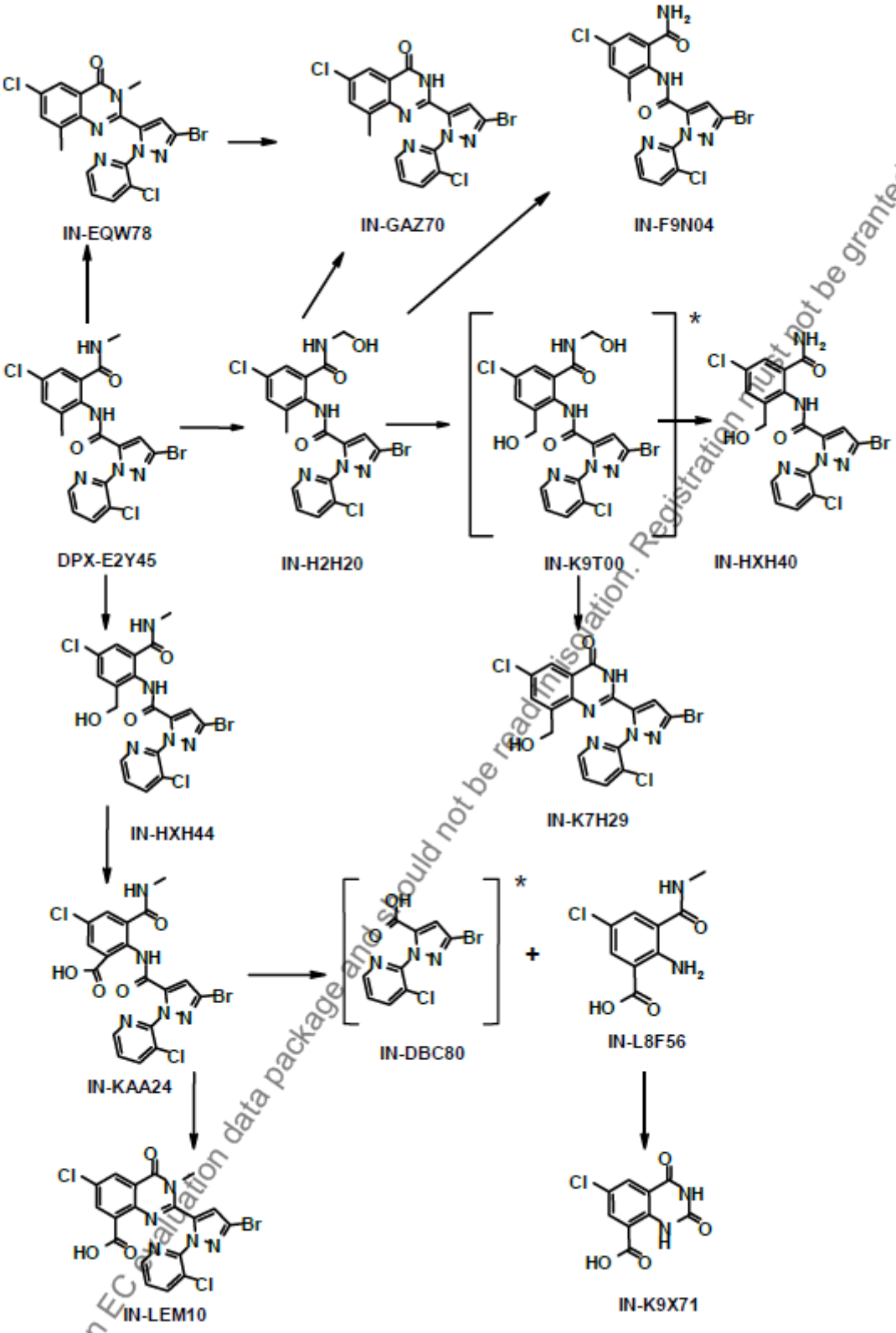
[PC-14C]-chlorantraniliprole ranged from 0.062–0.110 mg/kg for early forage, 0.332–0.572 mg/kg for hay, and 0.355–0.485 mg/kg for straw. Highest residues were found at the 120-day sowing: 0.261, 1.573, and 2.085 mg/kg in early forage, hay, and straw, respectively. The corresponding TRRs in wheat fractions from the 30-day sowing into soil treated with [BC-14C]-chlorantraniliprole were 0.248, 0.903, and 0.339 mg/kg, respectively. TRRs in red beet foliage from soil treated with [PC-14C]-chlorantraniliprole ranged from 0.067–0.122 mg/kg at all intervals; that from the 30-day sowing following [BC-14C]-chlorantraniliprole treatment was 0.045 mg/kg. Overall the transfer of chlorantraniliprole and its metabolites through root uptake to the animal-feed commodities was low with 0.1–1.0% of soil-applied radioactivity

3. Soil
The TRRs in soil treated with [PC-14C]-chlorantraniliprole steadily decreased from 0.258 mg/kg following application (0 days) to 0.079 mg/kg at 365 days (Table 293). Levels decreased more readily in the presence of growing crops and the TRR at 479 days, maturity of the 365-day wheat, was 0.054 mg/kg

Conclusion on metabolism in rotational crops

Transfer of chlorantraniliprole and its metabolites to human-food commodities (wheat grain, lettuce, and red beet roots) was low (<0.01–0.046 mg/kg) when crops were grown in soil aged for various intervals (0, 30, 120, and 365 days) after treatment with 14C-chlorantraniliprole at 300 g ai/ha. Chlorantraniliprole was the principal residue in food items containing >0.01 mg/kg (lettuce and 120-day sowing wheat grain). Minor components (all individually present at ≤0.002 mg/kg; 5.2% TRR) in the lettuce included IN-GAZ70, IN-F9N04, and IN-F6L99.
Transfer of chlorantraniliprole and its metabolites to animal-feed items (0.4–6.6% applied) was higher than observed in the human-food (0.1–1.0% applied) commodities. The total radioactive residues in animal-feed items ranged from 0.045–2.085 mg/kg with chlorantraniliprole present at concentrations of <0.001–1.340 mg/kg
(<0.1–84.1% TRR). Minor metabolites in wheat hay and straw ranging from 0.001 mg/kg (<1% TRR) to 0.067 mg/kg (4.3% TRR) were tentatively identified as IN-EQW78, IN-GAZ70, IN-F9N04, IN-H2H20, IN-K7H29, IN-KAA24, IN-HXH44, IN-HXH40, and IN-F6L99. Metabolism of chlorantraniliprole in red beet foliage was extensive with no more than 13.2% TRR detected as parent together with multiple metabolites present at <0.010 mg/kg.

Proposed metabolic pathway for chlorantraniliprole (DPX-E2Y45) in confined rotational cr



* IN-DBC80 and IN-K9T00 shown in the brackets were not detected

t of an EC evaluation data package and should not be read/misused. Registration must not be granted on

zRMS comment: Metabolism in primary and rotational crops was found to be similar. Therefore, a specific residue definition for rotational crops is not necessary.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

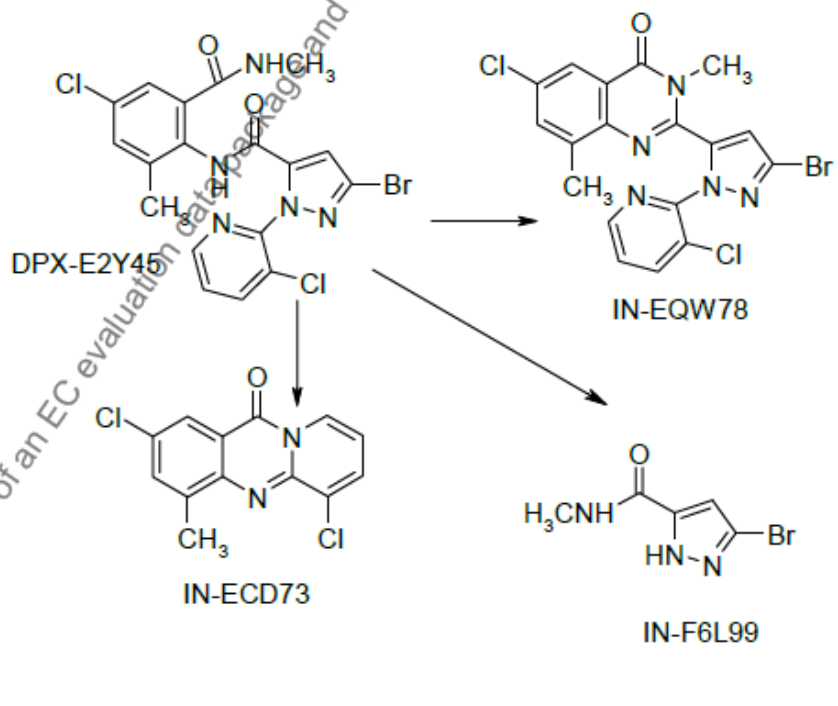
Table 7.2-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	[BC-14C]-chlorantraniliprole: Chlorantraniliprole - 98.35% IN-EQW78 - 0.58% IN-ECD73 – 1.20% [PC-14C]-chlorantraniliprole: Chlorantraniliprole - 99.13% IN-EQW78 - 0.5% IN-F6L99 – 1.26%	Chapleo, S. (2004); DuPont-12994, Revision No. 1
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	[BC-14C]-chlorantraniliprole: Chlorantraniliprole - 87.00% IN-EQW78 – 3.54% IN-F6L99 – 10.93% [PC-14C]-chlorantraniliprole: Chlorantraniliprole - 85.88% IN-EQW78 – 2.85% IN-F6L99 – 13.59%	Chapleo, S. (2004); DuPont-12994, Revision No. 1
Sterilisation (20 minutes, 120°C, pH 6)	[BC-14C]-chlorantraniliprole: Chlorantraniliprole - 96.40% IN-EQW78 - 0.76% IN-F6L99 – 1.61% [PC-14C]-chlorantraniliprole: Chlorantraniliprole - 96.17% IN-EQW78 - 0.48% IN-F6L99 – 2.88%	Chapleo, S. (2004); DuPont-12994, Revision No. 1

Conclusion on nature of residues in processed commodities

This study demonstrated that chlorantraniliprole was stable under hydrolytic processing conditions representative of pasteurisation (90° C for 20 minutes in pH 4 solution) and sterilisation (120° C for 20 minutes in pH 6 solution). During conditions representative of baking, brewing, or boiling, degradation of chlorantraniliprole led to the formation of IN-F6L99, IN-ECD73, and IN-EQW78

Proposed hydrolytic degradation pathway for chlorantraniliprole (DPX-E2Y45) under simulated processing conditions for baking, brewing, or boiling (100°C, pH 5, 60 minutes)



nent forms part of an EC evaluation data package and should

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Fruit crops (apple, tomato) Leafy crops (lettuce) Pulses/Oilseeds (cotton) Cereals (rice)
Rotational crops covered	Cereals (wheat), leafy crops (lettuce) and root/tuber crops (red beet)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Standard hydrolytic conditions representative of: pasteurisation (90°C; 20 min; pH 4) baking/brewing/ boiling (100°C; 60 min; pH 5) sterilisation (120°C; 20 min; pH 6)
Residue pattern in processed commodities similar to pattern in raw commodities?	Chlorantraniliprole stable under pasteurisation and sterilisation conditions but slightly degraded to IN-F6L99, IN-ECD73 and IN-EQW78 under baking/ brewing/boiling conditions (10.9% to 13.6% TRR). However, processing data on apple, grape, tomato, plum and cotton indicate low residues of IN-EQW78, IN-ECD73, and IN-F6L99 (≤0.016 mg/kg) in only few end processed tomato fractions (paste, puree and ketchup), the magnitude of chlorantraniliprole residues being always significantly higher than the magnitude of the degradates
Plant residue definition for monitoring	chlorantraniliprole

Plant residue definition for risk assessment	chlorantraniliprole
Conversion factor from enforcement to RA	Not applicable

zRMS comment: No new studies submitted in the framework of this submission. Chlorantraniliprole is stable under pasteurisation and sterilisation conditions, but it is slightly degraded to IN-F6L99, IN-ECD73 and IN-EQW78 under baking/brewing/boiling conditions (11-14% TRR). Processing studies indicate the presence of low residues of these metabolites in only few processed commodities, being the magnitude of parent chlorantraniliprole always significantly higher than the magnitude of degradates.

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	~~Cow~~ Goat	1. [Benzamide carbonyl–14C] 2. [Pyrazole carbonyl–14C]	2	10	7	Milk	twice daily	DuPont-14377
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	1. [Benzamide carbonyl–14C] 2. [Pyrazole carbonyl–14C]	7	10	14 days	Eggs	Once daily	DuPont-14776
						Excreta	Once daily	
						Tissues	At sacrifice	

Summary of ~~plant~~ metabolism studies in animals reported in the EU

Chlorantraniliprole (DPX-E2Y45), was administered to 5 laying hens as a daily single oral dose of a 1:1 (μCi/μCi) mixture of [benzamide carbonyl-14C]-chlorantraniliprole and [pyrazole carbonyl-14C]-chlorantraniliprole for 14 consecutive days. The nominal dose level was 10 mg/kg of food consumed per day. Excreta and eggs were collected daily. The hens were sacrificed approximately 23 h after last dose and the total radioactive residues (TRR) in liver, muscle composite (breast and thigh), abdominal fat, and skin with fat were determined. The majority (98%) of the dose was eliminated in the excreta. A quantitative mass balance was obtained. The radioactive residues in egg yolk (0.557 μg/g) and egg white (1.327 μg/g) reached steady plateau in 120 and 192 hours after the first dose, respectively. The TRR in whole egg equivalents were low with 0.881 and 0.929 μg/g in the Day 5-8 and Day 9-14 samples, respectively. Tissues retained less than 0.2% of the total dose. TRR values in individual tissues were: liver – 0.515 μg/g, muscle – 0.022 μg/g, fat and skin with fat - 0.035-0.052 μg/g..

Identification was based on HPLC retention time comparison with an authentic standard, and confirmation by liquid chromatography/mass spectroscopy (LC-MS). Overall 13 metabolites and chlorantraniliprole were identified/characterised from eggs, tissues and excreta. Unchanged chlorantraniliprole was the major terminal residue identified in fat samples (0.007-0.009 μg/g), in liver (0.046 μg/g), and in eggs (0.258 μg/g). IN-GAZ70 (up to 0.291μg/g) was a major metabolite in the eggs. Several other metabolites (IN-K9X71, IN-L8F56, IN-HXH40, IN-DBC80, IN-HXH44, IN-KAA24, IN-H2H20, IN-K7H29, IN-F9N04, IN-K3X21, and IN-EQW78) were identified in tissues at concentrations ranging from ≤0.001-0.062 μg/g equivalent in the whole egg. These metabolites in all other tissues were detected in low levels (<0.01 to 0.028 μg/g), except for the IN-GKQ52 that was present in liver at 0.056 μg/g. The metabolism of chlorantraniliprole in laying hens is well understood. The major metabolites resulted from N-demethylation, methyl-phenyl hydroxylation and further oxidation to carboxylic acid. Cyclisation of chlorantraniliprole and/or its hydroxyl metabolites with a loss of water molecule resulted into several quinazolinone derivatives. Hydrolysis of N-methyl amide to form a benzoic acid derivative was also observed. A minor metabolic reaction involved the amidic bridge cleavage between phenyl and heterocyclic rings. Chlorantraniliprole is rapidly eliminated through excreta (>98% of the dose). Edible tissues and fat contained negligible amounts of radioactivity (<1% of the total dose), while eggs contained ca. 3% of the dose

Chlorantraniliprole (DPX-E2Y45) was administered to a lactating goat as a single daily oral dose of a 1:1 (μCi:μCi) mixture of [benzamide carbonyl-14C]-chlorantraniliprole and [pyrazole carbonyl-14C]-chlorantraniliprole for 7 consecutive days. The nominal dose level was 10 mg/kg of food consumed per day. Faeces and urine were collected once daily and milk collected twice daily. The goat was sacrificed approximately 23 hours after the last dose and the total radioactive residues (TRR) in bile, liver, kidney, muscle, omental fat, renal fat, and subcutaneous fat determined. Approximately 95% of the administered dose was recovered, with the majority of this accounted for in excreta (93.57%). TRR values in individual tissues were as follows: liver – 0.640 μg/g, kidney - 0.090 μg/g, muscle - 0.017 μg/g, and fat – 0.067-0.070 μg/g. The TRR values in milk were 0.047 to 0.081 μg/g during the dosing period. Identification was based on HPLC retention time comparison with authentic standards, and confirmation by liquid chromatography/mass spectroscopy (LC/MS). Chlorantraniliprole was found in all tissues together with low levels of oxidised metabolites. Overall 15 metabolites and chlorantraniliprole were identified/characterised from milk, tissues, and excreta. Unchanged chlorantraniliprole was identified in the in liver (0.027 μg/g) and also was the major residue in kidney, muscle, and fat samples (0.007-0.051 μg/g). The metabolite IN-L8F56 was the major component identified in liver at 0.052 μg/g. Several other metabolites (IN-HXH44, IN-H2H20, IN-K9T00, IN-HXH40, IN-LEM10, IN-GAZ70, and IN-EQW78) were identified in tissues at concentrations ranging from <0.001-0.040 μg/g. The major residues detected in milk were identified as chlorantraniliprole (0.016 μg/g), IN-HXH40 (0.004 μg/g), IN-HXH44 (0.018 μg/g), and IN-K9T00 (0.017 μg/g). The metabolism of chlorantraniliprole in the lactating goat is adequately understood. The major metabolites were formed by N-demethylation, methyl-phenyl hydroxylation and further oxidation to carboxylic acids, cyclisation with a loss of water molecule to yield various cyclic metabolites, and hydrolysis of N-methyl amides to form benzoic acid derivatives. The minor metabolic reactions involved the amide bridge cleavage between phenyl and heterocyclic rings. There was no significant transfer of residues of chlorantraniliprole and its metabolites to tissues or milk; as the administered dose was eliminated rapidly by the lactating goat primarily in the excreta (93.57% of the dose). Milk and liver and kidney contained only ca. 1% of the administered total dose.

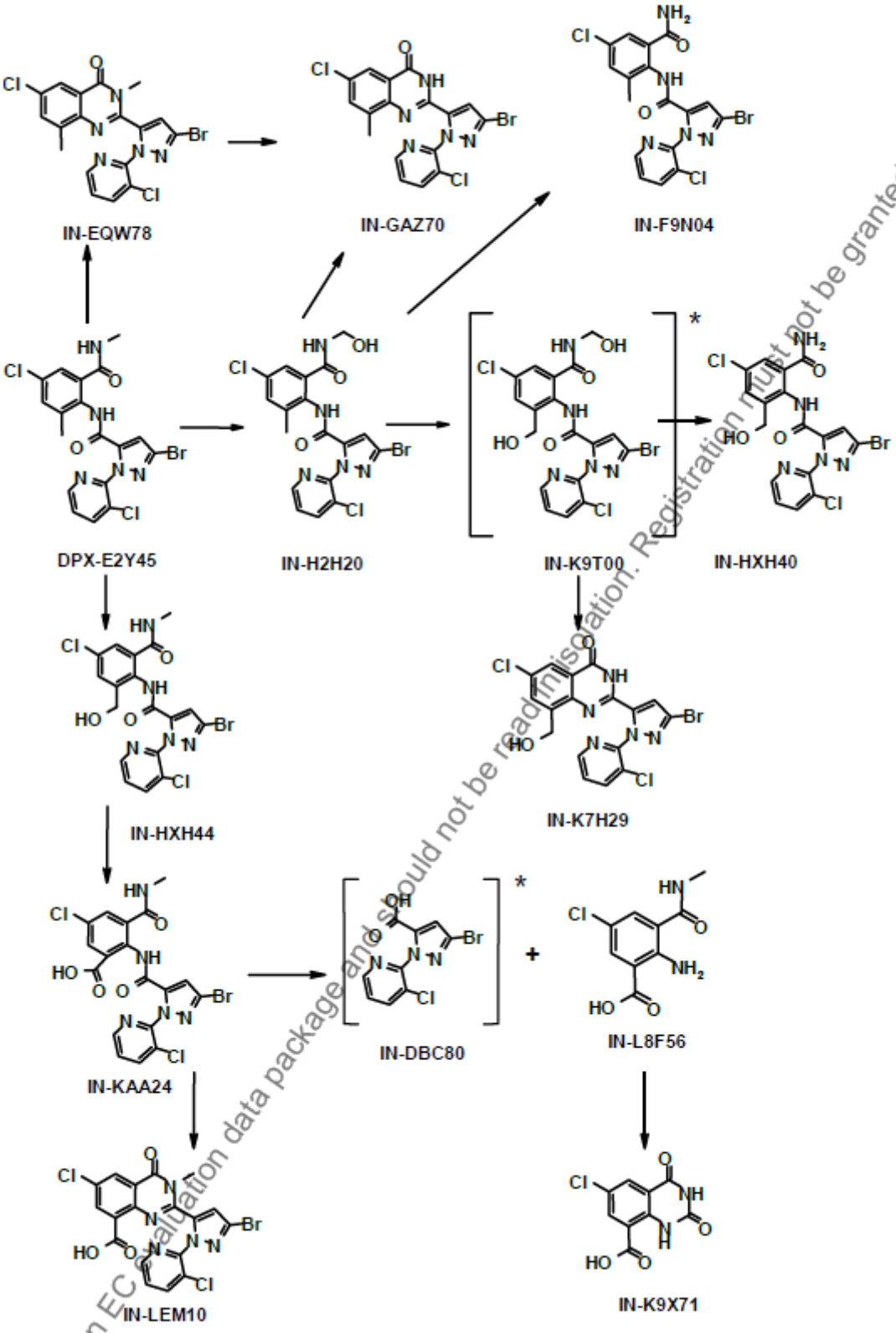
Conclusion on metabolism in livestock

The metabolic fate of chlorantraniliprole in livestock was investigated by the conduct of radiolabelled studies in laying hens and lactating goats.
Following oral administration to laying hens, chlorantraniliprole and its metabolites were eliminated, primarily in the excreta (>98% of the dose). Eggs and edible tissues contained ca. 3% of the total administered dose. A number of metabolites were identified in tissues and eggs, which were formed primarily through three transformation processes:
1) hydroxylation of N-methyl to yield IN-H2H20, hydroxylation of the methyl-phenyl carbon to yield

INHXH44;
2) condensation with a loss of water molecule from DPX-E2Y45 to yield a quinazolinone derivative, IN-EQW78. Similar condensation of the oxidative metabolites (IN-HXH44, IN-H2H20, IN-KAA24, and IN-K9T00) generates corresponding quinazolinone derivatives (IN-K3X21, IN-GAZ70, IN-LEM10, and IN-K7H29);
3) N-demethylation of hydroxymethylamide group in IN-H2H20 to IN-F9N04 and amidic bridge cleavage between phenyl and heterocyclic rings yields IN-L8F56 and IN-DBC80.

The major components of the radioactivity in eggs were parent chlorantraniliprole and IN-GAZ70; in hen tissues, it was parent chlorantraniliprole.
When 14C-chlorantraniliprole was orally administered to a lactating goat at 10 ppm in the feed, a large proportion of the dose was eliminated in the excreta (93.57% of the dose). Milk, liver, and kidney combined contained ca. 1% of the administered total dose. Parent chlorantraniliprole was the major component of the extracted radioactivity identified in kidney, muscle, and fat samples and was also identified in liver. The concentrations of chlorantraniliprole were higher in fat than in muscle, indicating that chlorantraniliprole (and its residues) are likely to be designated as ‘fat-soluble’.
All of the radioactivity in milk was extracted. Three metabolites were identified in addition to chlorantraniliprole in the extracts. Unchanged parent compound accounted for 23.58% TRR (0.016 mg/kg, 0.19% dose). The three metabolites were IN-K9T00 at 26.1% TRR (0.017 mg/kg, 0.21% dose), IN-HXH44 at 26.92% TRR (0.018 mg/kg, 0.21% dose) and IN-HXH40 at 5.87% TRR (0.004 mg/kg; 0.05% dose). The presence of metabolites IN-K9T00 and IN-HXH44 at equal proportions to parent chlorantraniliprole in goat milk, suggests that they may be considered relevant for inclusion in the residue definition for animal commodities if detected in the milk component of the livestock feeding study at similar proportions to parent compound.

Proposed metabolic pathway for chlorantraniliprole (DPX-E2Y45) in confined rotational cr



* IN-DBC80 and IN-K9T00 shown in the brackets were not detected

t of an EC evaluation data package and should not be read/misused. Registration must not be granted on

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Goat (ruminant); hen ~~and rat (monogastric)~~
Time needed to reach a plateau concentration	Milk: 2 to 3 days ~~Egg white 5 days~~ egg: 10-14 ~~Egg yolk 8 days~~
Animal residue definition for monitoring	chlorantraniliprole
Animal residue definition for risk assessment	Sum chlorantraniliprole and metabolites IN-HXH44 and IN-K9T00 expressed as chlorantraniliprole
Conversion factor	Ruminants/pigs: Liver, kidney, muscle: 1.5 Fat: 1 Milk 3 Poultry: not necessary
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes (log Pow <3 [max: 2.86 at pH 7]but residues in milk cream and fat 5 to 6 times higher than in whole milk and muscle)

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of CLOROL 200 SC and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Apple/ Pear	EFSA Journal 2013;11(6):3143 (DuPont-14141 DuPont-16577)	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.06 kg as/ha, BBCH 87, PHI 14d, outdoor <u>≤0.01</u>, 0.010, <u>0.046</u>, 0.054, 0.068, 0.069, <u>0.082, 0.090</u>, 0.091, 0.13 (trials on pear underlined)	N/A				
	Overall supporting data for cGAP	N-EU	<u>≤0.01</u>, 0.010, <u>0.046</u>, 0.054, 0.068, 0.069, <u>0.082, 0.090</u>, 0.091, 0.13 (trials on pear underlined)	0.069	0.13	0.213	0.4	Yes
Potato	EFSA Journal 2013;11(6):3143 (DuPont-14143 DuPont-16565 DuPont-18748)	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.012 kg as/ha, BBCH 69, PHI 14d, outdoor NEU: 6x <0.01	N/A				
	Overall supporting data for cGAP	N-EU	6x <0.01	0.01	0.01	0.01	0.03	Yes
Grape (Wine)	EFSA Journal 2013;11(6):3143 (DuPont-16567, DuPont-19306)	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.054 kg as/ha, BBCH 83, PHI 30d, outdoor 0.014, 0.021, 0.022, 0.030, 0.036, 0.044, 0.068, 0.074, 0.120	N/A				

	Overall supporting data for cGAP	N-EU	0.014, 0.021, 0.022, 0.030, 0.036, 0.044, 0.068, 0.074, 0.120	0.036	0.12	0.178	1	Yes
Tomato (incl. cherry)	EFSA Journal 2013;11(6):3143 (DuPont-14154, DuPont-16582, DuPont-16584 DuPont-18755)	EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.063 kg as/ha, BBCH 89, PHI 1d, indoor 2x <0.01, 0.009, 0.012, 2x 0.015, 0.015, 0.018, 0.028, 0.034, 0.037, 0.061, 0.079, 0.079, 0.090, 0.095, 0.110, 0.150 (trials on cherry tomato underlined)	N/A				
	Overall supporting data for cGAP	EU	2x <0.01, 0.009, 0.012, 2x 0.015, 0.015, 0.018, 0.028, 0.034, 0.037, 0.061, 0.079, 0.079, 0.090, 0.095, 0.110, 0.150 (trials on cherry tomato underlined)	0.031	0.15	0.219	0.6	Yes
Pepper	EFSA Journal 2013;11(6):3143 (DuPont-16579, DuPont-16580, DuPont-16585, DuPont-16586) DuPont-18753 DuPont-18754 DuPont-18757 DuPont-18765)	EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.04375 kg as/ha, BBCH 89, PHI 1d, indoor Pepper (bell): 0.029, 0.036, 0.048, 0.049, 0.052, 0.058, 0.062, 0.072, 0.110 Pepper (hot): 0.064, 0.16, 0.17, 0.39, 0.57	N/A				
	Overall supporting data for cGAP	EU	Pepper (bell): 0.029, 0.036, 0.048, 0.049, 0.052, 0.058, 0.062, 0.072, 0.110 Pepper (hot): 0.064, 0.16, 0.17, 0.39, 0.57	0.063	0.57	0.761	1	Yes
Cucumber and courgette	EFSA Journal 2013;11(6):3143 (DuPont-18760)	EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.0504 kg as/ha, BBCH 89, PHI 1d, indoor <0.01, 0.016, 0.021, 0.039, 0.058, 0.064, 0.083, 0.100, 0.130 (Trials on courgette underlined)	N/A				
	Overall supporting data	EU	<0.01, 0.016, 0.021, 0.039, 0.058, 0.064, 0.083, 0.100, 0.130 (Trials on courgette underlined)	0.058	0.13	0.222	0.3	Yes

	for cGAP							
Melon	EFSA Journal 2013;11(6):3143 (DuPont-18761)	EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.0504 kg as/ha, BBCH 89, PHI 1d, indoor Whole: 0.010, 2x 0.019, 0.023, 0.030, 2x 0.032, 0.038, 0.068 Pulp: 9x <0.01	N/A				
	Overall supporting data for cGAP	EU	Whole: 0.010, 2x 0.019, 0.023, 0.030, 2x 0.032, 0.038, 0.068 Pulp: 9x <0.01	0.01	0.068	0.121	0.3	Yes
Lettuce	EFSA Journal 2013;11(6):3143 (DuPont-18764)	EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.042 kg as/ha, BBCH 49, PHI 1d, indoor 0.09, 0.15, 0.38, 1.30, 1.40, 1.60, 1.80, 2.00, 2.30 (Trials on head lettuce underlined)	N/A				
	Overall supporting data for cGAP	EU	0.09, 0.15, 0.38, 1.30, 1.40, 1.60, 1.80, 2.00, 2.30 (Trials on head lettuce underlined)	1.4	2.3	4.517	20	Yes
Lamb's lettuce	EFSA Journal 2013;11(6):3143 (DuPont-18764)	EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.042 kg as/ha, BBCH 49, PHI 1d, indoor 3.2, 4.1, 4.1, 7.8, 8.0	N/A				
	Overall supporting data for cGAP	EU	3.2, 4.1, 4.1, 7.8, 8.0	4.1	8	16.32	20	Yes
Plum	EFSA Journal 2013;11(6):3143 (DuPont-21714)	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.06 kg as/ha, BBCH 87, PHI 14d, outdoor 2 x <0.01, 0.010, 0.026, 0.034, 0.038, 0.063, 0.081,	N/A				
	Overall supporting data for cGAP	N-EU	2 x <0.01, 0.010, 0.026, 0.034, 0.038, 0.063, 0.081,	0.03	0.081	0.139	1	Yes

Maize	Irleand, 2014 Netherlands, 2014 Poland, 2014 (DuPont-20120 DuPont-21629) EFSA, 2020	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.025 kg as/ha, BBCH 69, PHI 7d, outdoor 9 x <0.01 1 x 0.03 kg/ha, BBCH 87, PHI 7d 5 x <0.01 EFSA (2020): *Reduced data set of 5 overdosed trials on maize grains, performed with 2 instead of 1 application (Ireland, 2018), deemed acceptable as all residues were below LOQ. Extrapolation to sweet corn and common millet is proposed since trials on maize grain were overdosed and no residues were observed.* ***No NEU uses are authorised for sorghum grains.***	N/A				
	Overall supporting data for cGAP	N-EU	9 (14) x <0.01	<0.01	0.01	0.01	0.02	Yes
Sweet Corn	Irleand, 2014 Netherlands, 2014, Poland, 2014 (DuPont-20120 DuPont-21629) EFSA, 2020	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.025 kg as/ha, BBCH 69, PHI 7d, outdoor 9 x <0.01 2 x 0.03 kg/ha, BBCH 71, PHI 10 d 5 x <0.01	N/A				
	Overall supporting data for cGAP	N-EU	9 (14) x <0.01	<0.01	0.01	0.01	0.01	Yes
Carrot	Irleand, 2014 Netherlands, 2014, Poland 2014	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.035 kg as/ha, BBCH 49, PHI 21d, outdoor 5 x <0.01; 0.01; 0.014; 0.021; 0.027	N/A				

	(DuPont-27575) EFSA, 2020							
	Overall supporting data for cGAP	N-EU	5 x <0.01; 0.01; 0.014; 0.021; 0.027	<0.01	0.027	0.039	0.08	Yes
Broccoli	EFSA Journal 2013;11(6):3143 Irleand, 2014 Netherlands, 2014, Poland 2014 (DuPont-18772 DuPont-21338)	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.054 kg as/ha, BBCH 49, PHI 1d, outdoor 0.064; 0.10; 0.12; 0.14	N/A				
	Overall supporting data for cGAP	N-EU	0.064; 0.10; 0.12; 0.14	0.11	0.14	0.318	1.5	Yes
Cauliflower	EFSA Journal 2013;11(6):3143 Irleand, 2014 Netherlands, 2014, Poland 2014 (DuPont-18722 DuPont- 21338	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.025 kg as/ha, BBCH 49, PHI 1d, outdoor 2 x <0.01; 0.019; 0.045; 0.082	N/A				
	Overall supporting data for cGAP	N-EU	2 x <0.01; 0.019; 0.045; 0.082	0.019	0.082	0.156	0.5	Yes
Cauliflowers Broccoli	EFSA, 2020 Combined data set on cauliflowers (9) and broccoli (4)	N-EU	2 x 0.035 g/ha 4 x < 0.01; 0.019; 0.027; 0.047; 0.064; 0.082; 0.10; 2 x 0.12; 0.14	0.14	0.3	0.254	0.5	Yes

Cabbage	EFSA Journal 2013;11(6):3143 Irleand, 2014 Netherlands, 2014, Poland 2014 (DuPont-18770 DuPont-21337 EFSA, 2020	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.025 kg as/ha, BBCH 49, PHI 1d, outdoor 7 x <0.01; 0.012; 0.095 5 x <0.01 mg/kg	N/A				
	Overall supporting data for cGAP	N-EU	7(12) x <0.01; 0.012; 0.095	0.01	0.095	0.107	2	Yes
Oilseed rape	Peda Tomasz, SGS Polska Sp. z o. o. Study code: 24SGS34-24SGS41	N-EU	RAC specimens for analyses were collected: S1 (Seeds) BBCH89, 2 x applications, target dose rate: 0,2 l/ha (40 g of chlorantraniliprole) 4 x <0.01; 0.066; 0.026; 0.093; 0.012	N/A				
	Overall supporting data for cGAP	N-EU	4 x <0.01; 0.066; 0.026; 0.093; 0.012	0.011	0.093	0.158	0.2	Yes
Sugarbeet	Wańczyk K., SGS Polska Sp. z o.o. Study code: 24SGS53-24SGS56	N-EU	RAC specimens for analyses were collected: S (Root and leaves with tops) BBCH49, 1 x applications, target dose rate: 0,1 l/ha (20 g of chlorantraniliprole) Root: 4 x <0.01 Leaves with tops: 0.060; 0.092; 0.043; 0.088	N/A				
	Overall supporting data for cGAP	N-EU	Root: 4 x <0.01	0.010	0.010	0.010	0.010	Yes

* Source of EU MRL: Reg. (EU) ~~2022/1343~~ 2024/1355

According to COMMISSION REGULATION (EU) No 283/2013 point “Magnitude of residue trials in plants” studies shall always be performed where the plant

protection product is to be applied to plants or plant products that are used as food or feed. Tobacco is a crop designed for smoking, not for eating. Tobacco have no edible part therefore residues evaluation isn't necessary according to EU 283/2013.

According to COMMISSION REGULATION (EU) No 283/2013 point "Magnitude of residue trials in plants" studies shall always be performed where the plant protection product is to be applied to plants or plant products that are used as food or feed. Coniferous / deciduous forest nurseries and Ornamental shrubs have no edible part therefore residues evaluation isn't necessary according to EU 283/2013.

According to COMMISSION REGULATION (EU) No 283/2013 point "Magnitude of residue trials in plants" studies shall always be performed where the plant protection product is to be applied to plants or plant products that are used as food or feed. *Salix viminalis and* Wicker are used for crafting and green energy purposes and have no edible part so residues evaluation isn't necessary according to EU 283/2013.

According to COMMISSION REGULATION (EU) No 283/2013 point "Magnitude of residue trials in plants" studies shall always be performed where the plant protection product is to be applied to plants or plant products that are used as food or feed. Ornamentals are used for crafting and green energy purposes and have no edible part so residues evaluation isn't necessary according to EU 283/2013

According to ~~SANCO 7525/VI/95 Rev. 10.2, 23 September 2016~~ SANTE/2019/12752 guidance document, residue data set for sunflower (0401050) soya (0401070), mustard (0401080), breadseed poppy (0401030), sesame (0401040) spring oil seed rape, flax (0401030), pumpkin (0401100), hemp (0401140), castor beans (0401150), safflower (0401110) borage (0401120), gold of pleasure (0401130) can be obtained winter oilseed rape. According to GAP both all crop covered by winter oil seed rape is designed in end phases BBCH 71. The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to sunflower, soya, mustard, breadseed poppy, spring oil seed rape, flax, winter turnip rape. Pumpkin (on seed), hemp (on seed) on residues in winter oil seed rape were reviewed during this registration and were considered to be acceptable and no further data have been generated according to Guidance Document SANTE/2019/12752.

According to SANTE/2019/12752 guidance document, residue data set for whole pome fruits group (0130000) whole stone fruit group (0140000), whole tree nuts group (0120000), can be obtained by apple (0130010), pears (0130020) and plums (0140040). The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to whole pome fruits group (0130000) whole stone fruit group (0140000), whole tree nuts group (0120000)on residues in apples, pears and plums were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANTE/2019/12752.

According to SANTE/2019/12752 guidance document, residue data set for table grapes (0151010) can be obtained by wine grapes (0151020). The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to table grapes on residues in wine grapes were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANTE/2019/12752.

According to SANTE/2019/12752 guidance document, residue data set for subgroup lettuces and salad plants (0251000) can be obtained by lettuces(0251020) and

lamb's lettuces (0251010). The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to subgroup lettuces and salad plants on residues in lettuces and lamb's lettuces were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANTE/2019/12752.

According to SANTE/2019/12752 guidance document, residue data set for subgroup watercresses (0254000) can be obtained by lettuces(0251020) The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to subgroup watercresses on residues in lettuces were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANTE/2019/12752.

According to SANTE/2019/12752 guidance document, residue data set for subgroup spinaches and similar leaves (0252000) can be obtained by lettuces (0251020) The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to subgroup spinaches and similar leaves on residues in lettuces were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANTE/2019/12752.

According to SANTE/2019/12752 guidance document, residue data set for sweet potato (0212020), yams (0212030), subgroup other root and tuber vegetable (0213000), subgroup herbal infusion (dried roots) (0633000) can be obtained by potato (0211000) and carrot (0213020)). The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to subgroup sweet potato (0212020), yams (0212030), subgroup other root and tuber vegetable (0213000), subgroup herbal infusion (dried roots) (0633000) on residues in potato (0211000) and carrot (0213020) were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANTE/2019/12752.

According to SANTE/2019/12752 guidance document, residue data set for aubergines/eggplants (0231030), okra/lady's fingers (0231040), subgroup solanacea (0231000) can be obtained by tomatoes (0231010) and peppers (0231020). The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to aubergines/eggplants (0231030), okra/lady's fingers (0231040), subgroup solanacea (0231000) on residues in tomatoes (0231010) and peppers (0231020) were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANTE/2019/12752.

According to SANTE/2019/12752 guidance document, residue data set for gherkins (0232020), subgroup cucurbits – edible peel (0232000) can be obtained by cucumbers (0231010) and courgette (0232030). The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to gherkins (0232020), subgroup cucurbits – edible peel (0232000) on residues in cucumbers (0231010) and courgette (0232030) were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANTE/2019/12752.

According to SANTE/2019/12752 guidance document, residue data set for pumpkins (0233020), watermelons (0233030) and other cucurbits – inedible peel (0233990) can be obtained by melon (0233010). The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assess-

ment. Data/information which are source of extrapolation to pumpkins (0233020), watermelons (0233030) and other cucurbits – inedible peel (0233990) on residues in melon (0233010) were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANTE/2019/12752

According to SANTE/2019/12752 guidance document, residue data set for subgroup flowering brassica (0241000), subgroup leafy brassica (0243000) and subgroup – head brassica (0242000) can be obtained by broccoli (0241010), cauliflowers (0241020) and cabbage (0242020). The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to subgroup flowering brassica (0241000), subgroup leafy brassica (0243000) and subgroup – head brassica (0242000) on residues in broccoli (0241010), cauliflowers (0241020) and cabbage (0242020) were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANTE/2019/12752.

According to SANTE/2019/12752 guidance document, residue data set for sweet ~~cane~~ corn (0234000), Sorghum (0500080), and millet (050040) can be obtained by maize (0500030),. The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to sweet ~~cane~~ corn (0234000), Sorghum (0500080, and millet (050040) can on residues in maize (0500030) were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANTE/2019/12752

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on apple, pears, potato, grapes, plums, maize, sweet corn, carrot, broccoli, cauliflower, cabbage and other extrapolated crops from mentioned earlier crops are considered acceptable, for outdoor uses.

According to the available data, the intended uses on tomato, pepper, cucumber, courgette, melon, lettuce, lamb's lettuce and other extrapolated crops from mentioned earlier crops are considered acceptable, for indoor uses.

The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

zRMS comment:

Pome fruits:
No new data submitted in the framework of this application. In total, 10 trials (6 on apples and 4 on pears) is available. The residues were below the current MRL of 0.4 mg/kg for pome fruits. According to SANTE/2019/12752 Rev. 01[1], extrapolation from apple and pears (with a minimum of 4 trials on apples) to whole group of pome fruits before and after forming of the edible part is possible.

Plum:
No new data submitted in the framework of this application. In total, 8 trials, conducted according to a more critical GAP (2 x 0.06 kg/ha) are available. The residues were below the current MRL of 1.0 mg/kg for plum.

Possible extrapolation:
from apple and pear to whole group of pome fruits **before and after forming of the edible parts** (BBCH 56, 70-87 and 56-87),
from apple (4 trials) and plum to whole group of tree nuts **before forming of the edible parts** (before BBCH 65),
from apple (4 trials) and plum to whole group of stone fruits **before forming of the edible parts** (before BBCH 65).

Potato:
No new data submitted in the framework of this application. Limited number of residue trials has been submitted. In total, 6 trials, conducted according to a GAP are available. However, taking into account the residues below 0.01 mg/kg, the reduced data set can be accepted.

Carrot:
In total, 9 trials conducted according to a proposed GAP are available. The residues were below the current MRL of 0.08 mg/kg for carrot. According to SANTE/2019/12752 Rev. 01, extrapolation to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Extrapolation from potato (8 trials) and carrot (8 trials) to whole group root and tuber vegetables (0210000) is **not possible for (b) tropical root and tuber vegetables (0212000) as HR in carrot exceeds MRL of 0.02 mg/kg for this subgroup.**

[1] The newest version is SANTE/2019/12752 Rev 02

Grapes:
No new data submitted in the framework of this application. In total, 9 trials, conducted according to a proposed GAP are available. The residues were below the current MRL of 1.0 mg/kg on grapes.

Tomato:
No new data submitted in the framework of this application. In total, 18 trials, conducted according to the' proposed GAP are available. The residues were below the current MRL of 0.6 mg/kg for tomatoes.

Pepper:
No new data submitted in the framework of this application. In total, 14 trials, conducted according to a GAP similar to the proposed GAP are available. The residues were below the current MRL of 1.0 mg/kg for peppers.

Cucumber and courgettes:
No new data submitted in the framework of this application. In total, 9 trials, conducted according to a proposed GAP are available. The residues were below the current MRL of 0.3 mg/kg for cucumber/courgette.

Melon:
No new data submitted in the framework of this application. In total, 9 trials, conducted according to a proposed GAP are available. The residues were below the current MRL of 0.3 mg/kg for melon.

Possible extrapolation:
from tomatoes to aubergines/eggplants (0211030),
from peppers to okra/lady's fingers (0231040),
from cucumbers to whole subgroup (b) cucurbits with edible peel (232000),
from melons to whole subgroup (c) cucurbits with inedible peel (233000),

Lettuce:
No new data submitted in the framework of this application. In total, 9 trials, conducted according to a proposed GAP are available. The residues were below the current MRL of 20 mg/kg for lettuce.

Lamb lettuce:
No new data submitted in the framework of this application. In total, 5 trials, conducted according to a proposed GAP are available. The residues were below the current MRL of 20 mg/kg for lamb's lettuce.

Possible extrapolation:
from lettuces (0251020), trials from open leaf varieties to whole subgroup (a) lettuces and salad plants (0251000), whole subgroup (d) water cresses (0254000), Whole subgroup (b) spinaches and similar leaves (0252000).

Maize:
In total, 14 trials conducted according to a more critical GAP (2 x 0.025 kg/ha) are available. The residues were below the current MRL of 0.02 mg/kg for maize.
According to EFSA, 2020: *Extrapolation to sweet corn and common millet is proposed since trials on maize grain were overdosed and no residues were observed.* ***No NEU uses are authorised for sorghum grains.***

Extrapolation from maize to sweet cane is not possible (maize (whole plant fresh) to sugar canes (0900020) before forming of the edible parts allowed only for herbicides)

Sweet corn:
No new data submitted in the framework of this application. In total, 13 trials, conducted according to a proposed GAP are available. The residues were below the current MRL of 0.01 mg/kg for sweet corn.

Cauliflower/Broccoli:
In total, 13 trials conducted according to a more critical GAP (2 x 0.035 kg/ha) are available. The residues were below the current MRL of 1.5 mg/kg for broccoli and 0.5 for cauliflower.

Cabbage:
In total, 12 trials conducted according to a proposed GAP are available. The residues were below the current MRL of 2.0 mg/kg for cabbage.

Possible extrapolation:
8 trials on head cabbages (0242020) + 8 trials on cauliflower (0241020) (or 4 on cauliflower and 4 on broccoli) to whole subgroups (a) flowering brassica (0241000) and (b) head brassica (0242000), before forming of the edible part (before BBCH 19 except for brussels sprouts as HR for cabbage (cauliflower and broccoli) exceeds MRL of 0.01 mg/kg for brussels sprouts.
Extrapolation from 4 trials on cauliflower (0241020) + 4 trials broccoli (0241010) to whole subgroup (a) flowering brassica (0241000) before and after forming of the edible parts.

Oilseed rape:
8 new trials conducted according to a proposed GAP are available. The residues were below the current MRL of 0.2 mg/kg for oilseed rape.
According to SANTE/2019/12752 Rev. 01, extrapolation to winter turnip rape, linseeds, poppy seeds, mustard seeds and gold of pleasure before and after forming of the edible part is possible.

Sugar beet:
4 new trials conducted according to a proposed GAP are available. The residues were below the LOQ of 0.01 mg/kg, therefore the reduced data set can be accepted.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-10: Input values for the dietary burden calculation

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue chlorantraniliprole				
Cabbage, heads	0.01	Median residue	~~0.1~~ 0.095	HR
Corn, field	0.01	Median residue	0.01	HR
Millet	0.01	Median residue	0.01	HR
Sorghum	0.01	Median residue	0.01	HR
Turnip	0.01	Median residue	0.03	HR
Carrot	~~0.02~~ 0.01	Median residue	0.03	HR
Pottato	0.01	Median residue	0.01	HR

Table 7.2-11: Results of the dietary burden calculation

Animal burden calculation — **Chlorantraniliprole**

According to: "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"

Maximum Intake	Cattle						Sheep					
	Beef (500 kg / 12 kg)			Dairy (650 kg / 25 kg)			Ram/Ewe (75 kg / 2.5 kg)			Lamb (40 kg / 1.7 kg)		
(mg/kg bw/d)	0.073	mg/kg bw/d	%	0.140	mg/kg bw/d	%	0.226	mg/kg bw/d	%	0.114	mg/kg bw/d	%
Contributor 1	Clover	hay	30	Clover	hay	40	Clover	forage	85	Clover	forage	30
Contributor 2	Potato	process wast	40	Potato	process wast	30	Potato	process wast	15	Potato	process wast	20
Contributor 3	Turnip	roots	20	Turnip	roots	20			0	Turnip	roots	30
Contributor 4	Sorghum	grain	10	Sorghum	grain	10			0	Sorghum	grain	20
Median intake	0.0506	mg/kg bw/d		0.0929	mg/kg bw/d		0.1406	mg/kg bw/d		0.0752	mg/kg bw/d	

Maximum Intake	Swine					
	Breeding (260 kg / 6 kg)			Finishing (100 kg / 3 kg)		
(mg/kg bw/d)	0.045	mg/kg bw/d	%	0.005	mg/kg bw/d	%
Contributor 1	Clover	hay	20	Potato	dried pulp	20
Contributor 2	Potato	process wast	20	Turnip	roots	40
Contributor 3	Turnip	roots	40	Sorghum	grain	40
Contributor 4	Sorghum	grain	20			
Median intake	0.031	mg/kg bw/d		0.004	mg/kg bw/d	

Intakes >0.004 mg/kg bw/d are highlighted

Maximum Intake	Poultry								
	Broiler (1.7 kg / 0.12 kg)			Layer (1.9 kg / 0.13 kg)			Turkey (7 kg / 0.5 kg)		
(mg/kg bw/d)	0.008	mg/kg bw/d	%	0.060	mg/kg bw/d	%	0.002	mg/kg bw/d	%
Contributor 1	Potato	dried pulp	20	Clover	hay	10	Carrot	culls	10
Contributor 2	Carrot	culls	10	Potato	dried pulp	15	Sorghum	grain	50
Contributor 3	Sorghum	grain	70	Carrot	culls	10			
Contributor 4				Sorghum	grain	65			
Median intake	0.008	mg/kg bw		0.038	mg/kg bw		0.002	mg/kg bw	

Intakes expressed on the dry mater basis (mg/kg DM)

mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	3.03	3.64	6.8	2.69	1.96	0.16
Median	2.11	2.41	4.22	1.77	1.32	0.13

	Poultry		
	Broiler	Layer	Turkey
Maximum	0.12	0.87	0.03
Median	0.11	0.56	0.02

Intake >0.1 mg/kg DM in red characters

* These categories correspond to those (formerly) assessed at EU level.

Recalculation including corrected cabbage and carrot values

Animal burden calculation — **Chlorantraniliprole**

According to: "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"

Maximum Intake	Cattle								Sheep							
	Beef	500 kg / 12 kg			Dairy	650 kg / 25 kg			Ram/Ewe	75 kg / 2,5 kg			Lamb	40 kg / 1,7 kg		
(mg/kg bw/d)	0,020	mg/kg bw/d	%		0,026	mg/kg bw/d	%		0,026	mg/kg bw/d	%		0,019	mg/kg bw/d	%	
Contributor 1	Potato	process wast	40		Potato	process wast	30		Potato	process wast	40		Potato	process wast	20	
Contributor 2	Cabbage, heads	leaves	20		Cabbage, heads	leaves	20		Cabbage, heads	leaves	10		Cabbage, heads	leaves	10	
Contributor 3	Turnip	roots	20		Turnip	roots	20		Turnip	roots	30		Turnip	roots	30	
Contributor 4	Sorghum	grain	20		Sorghum	grain	30		Sorghum	grain	20		Sorghum	grain	40	
Median intake	0,0167	mg/kg bw/d			0,0204	mg/kg bw/d			0,0232	mg/kg bw/d			0,0155	mg/kg bw/d		

Maximum Intake	Swine						
	Breeding	260 kg / 6 kg			Finishing	100 kg / 3 kg	
(mg/kg bw/d)	0,011	mg/kg bw/d	%		0,005	mg/kg bw/d	%
Contributor 1	Potato	process wast	20		Potato	dried pulp	20
Contributor 2	Cabbage, heads	leaves	10		Turnip	roots	40
Contributor 3	Turnip	roots	40		Sorghum	grain	40
Contributor 4	Sorghum	grain	30				
Median intake	0,009	mg/kg bw/d			0,004	mg/kg bw/d	

Intakes >0.004 mg/kg bw/d are highlighted

Maximum Intake	Poultry									
	Broiler	1,7 kg / 0,12 kg			Layer	1,9 kg / 0,13 kg			Turkey	7 kg / 0,5 kg		
(mg/kg bw/d)	0,008	mg/kg bw/d	%		0,009	mg/kg bw/d	%		0,003	mg/kg bw/d	%	
Contributor 1	Potato	dried pulp	20		Cabbage, heads	leaves	5		Carrot	culls	10	
Contributor 2	Carrot	culls	10		Potato	dried pulp	15		Corn, field	hominy meal	20	
Contributor 3	Sorghum	grain	70		Carrot	culls	10		Sorghum	grain	50	
Contributor 4					Sorghum	grain	70					
Median intake	0,007	mg/kg bw			0,006	mg/kg bw			0,002	mg/kg bw		

Intakes expressed on the dry mater basis (mg/kg DM)

mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	0,83	0,67	0,8	0,46	0,47	0,16
Median	0,70	0,53	0,70	0,37	0,37	0,12

	Poultry		
	Broiler	Layer	Turkey
Maximum	0,12	0,13	0,04
Median	0,10	0,08	0,03

Intake >0.1 mg/kg DM in red characters

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application. According to the chicken metabolism study, laying hens were fed 10 mg chlorantraniliprole/kg feed/day for 14 days. The highest chlorantraniliprole residues in tissues or eggs following plateau in eggs at 5–8 days, were seen in eggs at 0.3 mg/kg. The highest estimated poultry dietary burden is 0.05 mg/kg feed/day. Therefore, the dose rate used in the metabolism study was 200× the highest estimated poultry dietary burden. There is reasonable expectation that the residues of chlorantraniliprole in poultry tissue or eggs would not be be quantifiable (<0.01 mg/kg; e.g., 0.3 mg/kg ÷ 200) and a poultry feeding study was not required or conducted.

According to the study number DuPont-17817 which is available on EU level and assessed during Annex I inclusion there were no average residues greater than 0.010 mg/kg of any analyte in any matrix at the 1-mg/kg feed and 3-mg/kg feed dose levels, with the exception of chlorantraniliprole residues at 0.015 mg/kg in Day 21 cream from the 3-mg/kg feed dose group. Residues of chlorantraniliprole, IN-HXH44, and IN-K9T00 were not detected (<0.003 mg/kg) in whole milk from the lower dose group (1 mg/kg feed) but were dose dependent, increasing with higher doses. Residues in milk reached a plateau within 10 days of dosing.
Residues of chlorantraniliprole, IN-HXH44, and IN-K9T00 were detected in fat, kidney, liver, and muscle. Residues were dose dependent, increasing with higher doses.
Residues of IN-GAZ70 or IN-EQW78 were not detected (<0.003 mg/kg) in any matrix or any dose group with the exception of an average residue of 0.003 mg/kg for IN-EQW78 in fat in the 50-mg/kg-feed dose group. Following cessation of dosing, residues in milk and tissues rapidly declined with no residues detected (<0.003 mg/kg) in the milk samples from 3 days post last dose and in tissue samples collected from the earliest sacrifice at 9 days post dose. It is not expected that consumption of feed commodities treated

with chlorantraniliprole in accordance with the proposed label recommendations, will result in significant residues (<0.01 mg/kg) in milk, milk products, or edible tissues (muscle, fat, liver, kidney) of cattle.

Livestock studies for sheep, pig and fish are covered by poultry and ruminant livestock studies. Therefore, only overview of the values derived from ruminant livestock feeding studies are performed below:

Table 7.2-12: Overview of the values derived from livestock feeding studies

Active substance: Chlorantraniliprole

highest intakes

	Estimated intakes		expressed		feeding levels		N Rate	N Rate
	Maximum	Median	as		mg/kg bw	mg/kg DM	Dairy cattle	Beef cattle
Beef cattle	0.020	0.017	mg/kg bw	Level 1	**1.000**	**1.00**	**39.0**	50.1
Dairy cattle	0.026	0.021	mg/kg bw	Level 2	**3.000**	**2.00**	**117.1**	150.3
				Level 3	**10.000**	**10.00**	**390.3**	501.0
				Level 4	**30.000**	**30.0**	**1170.9**	1503.0

RESET

erase bovine inputs

RD Monitoring

matrices	Muscle	Fat	Liver	Kidney	Milk			
1.000	0.003	0.003	0.004	0.003	0.003			
1.000	0.003	0.003	0.004	0.003	0.003			
1.000	0.003	0.003	0.004	0.003	0.003			
1.000					0.003			
1.000					0.003			
3.000	0.003	0.009	0.010	0.006	0.003			
3.000	0.003	0.009	0.010	0.006	0.003			
3.000	0.003	0.009	0.010	0.006	0.003			
3.000					0.003			
3.000					0.003			
10.000	0.007	0.029	0.029	0.022	0.005			
10.000	0.007	0.029	0.029	0.022	0.005			
10.000	0.007	0.029	0.029	0.022	0.005			
10.000					0.005			
10.000					0.005			
30.000	0.019	0.140	0.130	0.068	0.021			
30.000	0.019	0.140	0.130	0.068	0.021			
30.000	0.019	0.140	0.130	0.068	0.021			
30.000					0.021			
30.000					0.021			

RD Risk assessment

Muscle	Fat	Liver	Kidney	Milk			
0.003	0.003	0.004	0.003	0.003			
0.003	0.003	0.004	0.003	0.003			
0.003	0.003	0.004	0.003	0.003			
				0.003			
				0.003			
0.003	0.009	0.010	0.006	0.003			
0.003	0.009	0.010	0.006	0.003			
0.003	0.009	0.010	0.006	0.003			
				0.003			
				0.003			
0.007	0.029	0.029	0.022	0.005			
0.007	0.029	0.029	0.022	0.005			
0.007	0.029	0.029	0.022	0.005			
				0.005			
				0.005			
0.019	0.140	0.130	0.068	0.021			
0.019	0.140	0.130	0.068	0.021			
0.019	0.140	0.130	0.068	0.021			
				0.021			
				0.021			

MRL & HR Calculations

Matrices	Muscle	Fat	Liver	Kidney	Milk			
Tf Level 1	0.000	0.000	0.000	0.000	0.000			
Tf Level 2	0.000	0.000	0.000	0.000	0.000			
Tf Level 3	0.000	0.000	0.000	0.000	0.000			
Tf Level 4	0.000	0.000	0.000	0.000	0.000			
Interpolation	Burden<L1	Burden<L1	Burden<L1	Burden<L1	Burden<L1			
Linear regression	<30% L1	<30% L1	<30% L1	<30% L1	<30% L1			
R^2								
HR (Tf_{CL}, lt, Ln)	0.000	0.000	0.000	0.000	0.000			
HR (Alternative)								
HR	0.000	0.000	0.000	0.000	0.000			
LOQ (Monitoring)								
MRL proposal	**0.001**	**0.001**	**0.001**	**0.001**	**0.001**			

#: No calculation done as all values <LOQ

Closest level

Conversion Factor for risk assessment (median)

Muscle	Fat	Liver	Kidney	Milk			
1.0	1.0	1.0	1.0	1.0			
1.0	1.0	1.0	1.0	1.0			
1.0	1.0	1.0	1.0	1.0			
1.0	1.0	1.0	1.0	1.0			
1.00	**1.00**	**1.00**	**1.00**	**1.00**			

#: indicates that residues at or close to the LOQ (x2) were included in CF calculation

STMR Calculations

Matrices	Muscle	Fat	Liver	Kidney	Milk			
Tf Level 1	0.000	0.000	0.000	0.000	0.000			
Tf Level 2	0.000	0.000	0.000	0.000	0.000			
Tf Level 3	0.000	0.000	0.000	0.000	0.000			
Tf Level 4	0.000	0.000	0.000	0.000	0.000			
Interpolation	Burden<L1	Burden<L1	Burden<L1	Burden<L1	Burden<L1			
Linear regression	<30% L1	<30% L1	<30% L1	<30% L1	<30% L1			
R^2								
STMR (Tf_{CL}, lt, Ln)	0.000	0.000	0.000	0.000	0.000			
STMR (alternative)								
STMR	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**			

Closest level

Comment	Estimated intakes below 30% lowest feeding level. No values derived by linear regression.

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

7.2.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.

Data/information on a core set of processing parameters were reviewed during the active substance approval process and were considered acceptable. See the Chlorantraniliprole DAR, Volume 3, B7, pages 717-795 (pdf pagination) and the Chlorantraniliprole Final addendum to the DAR, Volume 3, B7 (February 2013) pages 161-164 (pdf pagination). Processing of pome fruit, stone fruit, grapes, potatoes and cabbage were included in the DAR. The apple processing study produced juice, puree, sauce, preserves, canned fruit, washed fruit, peel fruit, blanched fruit and both wet and dry pomaces. The grape processing study produced red and white wines, juice and raisins. The plum processing study produced dried prunes.. The cabbage study produced cabbage trimmed as is common prior to household consumption. An additional follow-up study conducted for cabbage along with a request to waive maize/corn processing based on low residues are summarized below to support the additional uses presented in this document.
Chlorantraniliprole residues in boiled cabbage, sauerkraut, and sauerkraut juice were reduced relative to the unprocessed head cabbage. This observation is consistent with the lower weight outer leaves being physically separated from the heavier weight cabbage head prior to boiling or fermenting as was seen in the trimmed cabbage where residues were reduced with an average processing factor of 0.10. The processing factors determined for the representative-crop processed commodities reviewed in the DAR plus the additional data for cabbage processing reviewed by zonal registration of Coragen 200 SC are provided below:

Table 7.2-13: Overview of the available processing studies

Commodity	Processed commodity	Average processing factor[a] (range)		
		Concentration	No change (approx.)	Reduction
Apple	Wet Pomace	2.6 (1.8–4.2)	--	--
	Dry Pomace	11 (9.3–13)	--	--
	Juice	--	--	0.26 (0.12–0.38)
	Puree	--	--	0.21 (0.086–0.38)
	Sauce	--	--	0.3 (0.18–0.38)
	Preserves	--	--	0.26 (0.12–0.38)
	Canned	--	--	0.26 (0.12–0.38)
	Washed fruit[b]	--	1.5 (1.2-1.9)	--
	Peeled fruit[b]	--	--	0.4 (0.3-0.5)
	Blanched fruit[b]	--	--	0.4 (<0.19-0.6)
Grape	Raisins	4.2 (2.7–7.1)	--	--
	Juice	--	0.88 (0.43–1.7)	--
	Wine, Red	--	1.2 (0.76–1.6)	--
	Wine, White	--	--	0.45 (0.3–0.59)
Tomato	Puree	1.5 (1.2–1.7)	--	--
	Paste	1.5 (0.61–2.4)	--	--
	Ketchup	--	1.0 (0.72–1.6)	--
	Washed	--	--	0.39 (0.38–0.39)
	Canned	--	--	0.44 (0.23–0.65)
	Juice	--	0.84 (0.57–1.1)	--
Potato	Not conducted; chlorantraniliprole residues in 1×- and 5×-treated RAC were <0.01 mg/kg			
Plum	Prune	1.9	--	--
Cottonseed	Refined Oil	--	--	0.25
	Meal	--	--	0.75
	Hulls	2.1		
Cabbage	Trimmed	--	--	0.10 (0.07–0.13)
	Cooked cabbage	--	--	<0.5 (<0.2-<1)
	Sauerkraut	--	--	<0.5 (0.1-<1)
	Sauerkraut juice	--	--	<0.5 (<0.2-<1)
Celery	Trimmed	--	--	0.39 (0.09–0.96)
Head lettuce	Trimmed	--	--	0.16 (0.10–0.19)

[a] Processing factor = Chlorantraniliprole residue in processed fraction/Chlorantraniliprole residue in raw agricultural commodity; Average of four tests (apple, grape, tomato, cooked cabbage, sauerkraut, sauerkraut juice), three tests (trimmed cabbage, celery, head lettuce), or result of one test (plum, cotton)

[b] Processing factor is average of only two tests.

Overview of the processing studies based on EFSA (2020):

Processed commodity	Number of studies	Median PF
Apple, wet pomace	4	2.2
Apple, dry pomace	4	11.6
Apple, juice	4	<0.14
Apple, sauce	4	<0.19
Table Grape, dried raisin	2	5.0

Processed commodity	Number of studies	Median PF
Wine Grape, juice	2	0.72
Wine Grape, red wine (unheated)	2	1.2
Wine Grape, white wine	2	0.45
Wine grape, dry pomace	2	9.0
Wine grape, wet pomace	2	2.7
Wine grapes, must	2	0.97
Plum, dried (prunes)	1	1.9
Tomatoes, peeled and canned	4	0.45
Tomatoes, sauce	4	1.46
Tomatoes, paste	4	1.54
Tomatoes, ketchup	4	0.95
Tomatoes, juice	4	0.83
Melons, peeled	9	<0.33
Cotton seeds, refined oil	1	0.25
Cotton seeds, meal/press cake	1	0.75

7.2.5.2 Conclusion on processing studies

The results of the processing studies show that chlorantraniliprole, upon processing, concentrates only in apple pomace, plum prune raisins, tomato paste, and tomato puree. Chlorantraniliprol upon processing doesn't concentrate in other process commodities. Residues of the metabolites were generally nondetectable in the processed fractions; the RACs were not analyzed for the metabolites.

zRMS comment: No new data submitted in the framework of this application.
Further processing studies are not required as chronic consumer exposure is below the trigger value of 10% of ADI.

7.2.6 Magnitude of residues in representative succeeding crops

Data dealing with magnitude of residues in succeeding crops are available and are summarized hereafter.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Field crop-rotation studies are being conducted at sites in northern and southern EU in the 2005, 2006, and 2007 field seasons to determine the magnitude of residues in representative succeeding crops planted 30-, 60-, 120-, 180-, and 365-days following the last chlorantraniliprole application to a treated field. These studies are being conducted with applications made to cropped plots at the highest application rates

proposed for EU field crops (two applications with a seasonal-application rate of 84 g ai/ha). These rates are considerably lower than the rates studied in the Canadian and the United States field crop rotation trials (one to two applications with a seasonal-application rate of 200–225 g ai/ha). Therefore, the trials conducted in Canada and the United States and summarised below should provide a worst-case picture of potential rotational-crop residues.

Table 7.2-14: Summary of available studies in field rotational crops

Table 1: Residues of chlorantraniliprole in succeeding crops (swiss chard, rad after application of 200 or 600 g ai/ha SC formulation to peas in Donna, Texas, U in 2003.

Treatment Number	Crop/Variety	Matrix/ Commodity	Total Rate g ai/ha (lb ai/A)	PBI (days)	Harvest DAP	Residue (mg/kg)	
						Replicate	Average[1]
1	Clay	Soil	200 (0.18)	40	-	0.042 0.045 0.042	0.043
	Clay	Soil		61	-	0.031 0.033 0.038	0.034
	Swiss Chard/ Silverado	Leaves		61	59	<0.003 <0.003	<0.010
	Radish/ Champion	Root		40	44	0.005 0.004	<0.010
		Tops		40	44	0.066 0.070	0.068
2	Clay	Soil	200 (0.18)	130	-	0.028 0.022 0.030	0.026
	Clay	Soil		151	-	0.025 0.030 0.032	0.029
	Swiss Chard/ Silverado	Leaves		151	59	<0.003 <0.003	<0.010
	Radish/ Champion	Root		130	44	<0.003 0.003	<0.010
		Tops		130	44	0.030 0.030	0.030
3	Clay	Soil	600 (0.54)	40	-	0.103 0.108 0.129	0.11
	Clay	Soil		61	-	0.113 0.085 0.091	0.096
	Swiss Chard/ Silverado	Leaves		61	59	0.010 0.007	<0.010
	Radish/ Champion	Root		40	44	0.009 0.010	0.010
		Tops		40	44	0.17 0.16	0.16
4	Clay	Soil	600 (0.54)	130	-	0.085 0.083 0.073	0.080
	Clay	Soil		151	-	0.067 0.066 0.065	0.066
	Swiss Chard/ Silverado	Leaves		151	59	0.004 0.005	<0.010
	Radish/ Champion	Root		130	44	0.005 0.004	<0.010
		Tops		130	44	0.078 0.061	0.070

n data package and should not be read in isolation. Registration must not be granted

Table 7.2-15: Summary of available studies in field rotational crops

Table 2: Residues of chlorantraniliprole in succeeding crops (wheat, lettuce, be after application of 200 or 600 g ai/ha SC formulation to peas in Madera, Califo USA in 2003.

Treatment Number	Crop/Variety	Matrix/ Commodity	Total Rate g ai/ha (lb ai/A)	PBI (days)	Harvest DAP	Residue (mg/kg)	
						Replicate	Average[1]
1	Loam	Soil	200 (0.18)	31	-	0.17 0.13 0.12	0.14
	Wheat/Yecorro Rogo	Forage		31	95	0.032 0.030	0.031
		Grain		31	192	0.004 0.004	<0.01
		Straw		31	192	0.045 0.033	0.039
		Hay		31	140	0.043 0.042	0.043
	Lettuce/Great Lakes, Head	Leaves		31	141	0.004 0.003	<0.01
	Beets/Detroit Dark Red	Roots		31	142	0.006 0.006	<0.01
		Tops		31	142	0.016 0.013	**0.015**
3	Loam	Soil	200 (0.18)	-	122	0.041 0.047 0.044	0.044
	Wheat/Yecorro Rogo	Forage		122	95	0.032 0.012	0.022
		Grain		192	122	0.003 0.003	<0.01
		Straw		122	192	0.017 0.020	0.018
		Hay		122	140	0.022 0.008	0.015
	Lettuce/Great Lakes, Head	Leaves		122	141	0.003 0.010	<0.01
2	Loam	Soil	600 (0.54)	31	-	0.33 0.30 0.30	0.31
	Wheat/Yecorro Rogo	Forage		31	95	0.086 0.080	0.083
		Grain		31	192	0.005 0.006	<0.01
		Straw		31	192	0.14 0.10	0.12
		Hay		31	140	0.15 0.16	0.15
	Lettuce/Great Lakes, Head	Leaves		31	141	0.014 0.006	0.010
	Beets/Detroit Dark Red	Roots		31	142	0.007 0.009	<0.01
		Tops		31	142	0.028 0.041	0.034
4	Loam	Soil	600 (0.54)	122	-	0.17 0.13 0.12	0.23
	Wheat/Yecorro Rogo	Forage		122	95	0.049 0.055	0.052
		Grain		122	192	0.004 0.007	<0.01
		Straw		122	192	0.086 0.078	0.082
		Hay		122	140	0.098 0.10	0.10
	Lettuce/Great Lakes, Head	Leaves		122	141	0.007 0.003	<0.010

[1] LOQ = 0.010 mg/kg

ation data package and should not be read in isolation. Registration must not be granted)

Table 7.2-16: Summary of available studies in field rotational crops

Table 3: Residues of chlorantraniliprole in succeeding crops (oats, wheat, radish, beets, lettuce, spinach) after application of 200 or 600 g ai/ha SC formulation to peas in Rochelle, Illinois, USA in 2003.

Treatment Number	Crop/Variety	Matrix/ Commodity	Total Rate g ai/ha (lb ai/A)	PBI (days)	Harvest DAP	Residue (mg/kg)	
						Repl	Ave[1]
1	Silty clay loam	Soil	200 (0.18	30	-	0.16 0.13 0.16	0.15
	Oats/Moraine	Forage		30	39	0.014 0.017	0.016
		Grain		30	85	<0.003 <0.003	<0.010
		Straw		30	85	<0.003 0.004	<0.010
		Hay		30	58	0.005 0.005	<0.010
	Lettuce/Green Salad Bowl	Leaves		30	71	<0.003 <0.003	<0.01
	Beets/Detroit Medium Top	Roots		30	73	<0.003 <0.003	<0.010
		Tops		30	73	<0.003 <0.003	<0.010
3	Silty clay loam	Soil	200 (0.18)	123	-	0.075 0.081g 0.071	0.076
	Winter Wheat/Pioneer 25R47	Forage		123	223	0.007 0.009	<0.010
		Grain		123	302	<0.003 <0.003	<0.010
		Straw		123	302	0.016 0.010	0.014
		Hay		123	265	0.015 0.019	0.017
	Spinach/Melody	Leaves		123	69	0.006 0.005	<0.010
	Radish/Champion	Root		123	51	<0.003 <0.003	<0.010
		Tops		123	51	<0.003 <0.003	<0.010
2	Silty clay loam	Soil	600 (0.54)	30	-	0.47 0.39 0.34	0.40
	Oats/Moraine	Forage		30	39	0.040 0.038	0.039
		Grain		30	85	<0.003 <0.003	<0.010
		Straw		30	85	0.011 0.011	0.011
		Hay		30	58	0.027 0.036	0.031
	Lettuce/Green Salad Bowl	Leaves		30	71	<0.003 <0.003	<0.010
	Beets/Detroit Medium Top	Roots		30	73	<0.003 <0.003	<0.010
		Tops		30	73	<0.003 <0.003	<0.010
4	Silty clay loam	Soil	600 (0.54)	123	-	0.25 0.27 0.18	0.23
	Winter Wheat/Pioneer 25R47	Forage		123	223	0.020 0.020	0.020
		Grain		123	302	0.009 0.004	<0.010
		Straw		123	302	0.028 0.035	0.032
		Hay		123	265	0.059 0.057	0.058
	Spinach/Melody	Leaves		123	69	0.011 0.008	0.010
	Radish/Champion	Root		123	51	<0.003 <0.003	<0.010
		Tops		123	51	0.009 0.011	0.010

[1] LOQ = 0.010 mg/kg

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Table 7.2-17: Summary of available studies in field rotational crops

Table 4: Residues of chlorantraniliprole in succeeding crops (oats, turnips, garden beets) after application of 200 g ai/ha WG formulation to bare ground in Corvallis, Oregon, USA in 2004.

Treatment Number	Crop/Variety	Matrix/ Commodity	Total Rate g ai/ha (lb ai/A)	PBI (days)	Harvest DAP	Residue (mg/kg)	
						Rep	Ave[1]
1	Silty clay loam	Soil	200 (0.18)	30	-	0.142 0.128 0.121	0.130
	Oats/Cayuse	Forage		30	49	0.012 0.015	0.013
		Grain		30	99	0.004 0.004	<0.010
		Straw		30	99	0.032 0.028	0.030
		Hay		30	65	0.054 0.049	0.051
	Turnip/Shogoin	Roots		30	72	<0.003 <0.003	<0.010
		Tops		30	72	0.003 0.003	<0.010
	Beets/Red Ace	Roots		30	72	<0.003 <0.003	<0.010
		Tops		30	72	<0.003 <0.003	<0.010

[1] LOQ = 0.010 mg/kg

Registration must not be granted until

Table 7.2-18: Summary of available studies in field rotational crops

Table 5: Residues of chlorantraniliprole in succeeding crops (spinach, soybean, turnip) after application of 225 g ai/ha of a SC formulation to bare ground in Berwick, Nova Scotia, Canada in 2005

Treatment Number	Crop/Variety	Matrix/ Commo -dity	Total Rate g ai/ha (lb ai/A)	PBI (days)	Harvest DAP	Residue (mg/kg)	
						Repl	Ave[2]
1	Loamy sand	Soil	225 (0.201)	-	45[1]	0.073 0.097 0.067	0.079
	Spinach/Longstanding Bloomsdale	Leaves		13	77	0.005 0.004	<0.010
	Soybean/Vista RR	Forage		13	62	0.035 0.019	0.027
		Hay		13	109	0.036 0.038	0.037
		Seed		13	112	0.004 <0.003	<0.010
	Turnip/Purple Top White Globe	Roots		13	77	<0.003 <0.003	<0.010
		Tops		13	77	0.005 0.004	<0.010

[1] Soil samples were not taken at the 13 day PBI, but 60 days after the treatment. Residues from the broccoli plot soils, taken at a 15 day PBI, were in the same range with the average 6% greater.
[2] LOQ = 0.010 mg/kg

Table 6: Residues of chlorantraniliprole in succeeding crops (turnip, soybean, winter and summer wheat) after application of 225 g ai/ha of a SC formulation to a cropped plot in Berwick, Nova Scotia, Canada in 2005.

Treatment Number	Crop/Variety	Matrix/ Commodity	Total Rate g ai/ha (lb ai/A)	PBI[1] (days)	Harvest DAP	Residue (mg/kg)	
						Rep	Ave[2]
1	Loamy sand	Soil	225 (0.2)	15	N/A	0.076, 0.089 0.087	0.084
				238	N/A	0.046, 0.041 0.044	0.044
				279	N/A	0.0083 , 0.035 0.033	0.026
	Turnip/Purple Top White Globe	Roots		279	110	<0.00 3, <0.00 3	<0.003
		Tops		279	110	0.004, 0.003	0.004
	Soybean/Vista RR	Forage			32	0.037, 0.045	0.041
		Hay			73	0.064, 0.045	0.055
		Seed			114	<0.00 3, <0.00 3	<0.003
	Winter wheat/AC Sampson	Forage		15	245	0.021, 0.022	0.022
		Hay			258	0.049, 0.040	0.045
		Grain			301	0.004, 0.004	0.004
		Straw			301	0.062, 0.059	0.061
	Spring wheat/AC Helena	Forage		238	60	0.042, 0.043	0.043
		Hay			71	0.14[3], 0.15[3]	0.14
		Grain			114	0.003, 0.003	0.003
		Straw			114	0.076, 0.080	0.078

[1]Plant-back interval = number of days between the last application to the treated plot and sowing of follow crop. [2]LOQ = 0.01 mg/kg. [3]Average of 3 analyses

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Conclusion on rotational crops studies

The residue data reported in the five studies (4 US and 1 Canada) are appropriate for estimation of the magnitude of residues of chlorantraniliprole in root, leafy, and cereal grain crops when grown rotationally in fields previously treated with chlorantraniliprole insecticide at total seasonal rates of 200 – 600 g ai/ha. Generally, residues at or above the LOQ (0.010 mg/kg) may occur on rotated leafy crops and on the tops of root vegetables at PBIs up to 130 days, ranging between 0.01 and 0.20 mg/kg, whereas residues on grain and root vegetables are anticipated to be below the LOQ. Chlorantraniliprole residues (>0.01 mg/kg) are possible on the livestock only commodities of rotated grain crops (forage, straw, hay), ranging from 0.01 to 0.2 mg/kg for PBIs ranging from 30 to 279 days.

In the US rotational field studies conducted at a dose rate of 200/225 g/ha (ca. 0.8N plateau level in soil), residues of chlorantraniliprole in succeeding crops were ≤0.006 mg/kg in leafy vegetables, roots of root vegetables, cereal grains and soybean seed and mostly ≤0.05 mg/kg in tops of root vegetables, cereal forage, hay and straw for rotational crops grown under realistic field conditions. Chlorantraniliprole residues not expected to be present in significant levels in rotational crops when the active substance is used according to the EU GAPs

zRMS comment: Some of the proposed crops are grown in rotation. In EFSA review (2020) it is concluded: *"In the US rotational field studies conducted at a dose rate of 200–225 or 600 g a.s./ha (ca. 0.8–1.7N plateau level in soil), residues of chlorantraniliprole in succeeding crops were < 0.01 mg/kg in leafy vegetables, roots of roots vegetables, cereal grains and soyabean seeds, and mostly ≤ 0.05 mg/kg in tops of root vegetables, cereal forage, hay and straw for rotational crops grown under realistic field conditions. Significant residue levels of chlorantraniliprole are not expected in succeeding crops, provided that chlorantraniliprole is applied in compliance with the EU GAPs."*

7.2.7 Other / special studies (KCA6.10, 6.10.1)

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Honey	Grzeczka P., SGS Polska Sp. z o.o. Study code: 24SGS44-24SGS47	N-EU	RAC specimens for analyses were collected: S1 (mature honey). 2 x applications, target dose rate: 0,2 l/ha (40 g of chlorantraniliprole) 4 x <0.01;	N/A				
	Overall supporting data for cGAP	N-EU	4x < 0.01;	0.010	0.010	0.010	~~0.010~~ 0.05	Yes

As part of the residue assessment, analyses were conducted to determine the content of the active substance, Chlorantraniliprole, in the product CLOROL 200 SC. The quantitative determination was carried out using LC-MS/MS detection. According to studies conducted by SGS Polska Sp. z o.o., authored by Grzeczak P. (Study codes: 24SGS44–24SGS47), the concentration of residues detected in the analyzed field samples was below the limit of quantification (LOQ = 0.010 mg/kg).

Throughout the testing period, no bee mortality was observed (e.g., dead bees or signs of health impairment), and the tests did not indicate any adverse effects on the bee colonies.

The details of the research conducted are provided in Appendix 2.

zRMS assessment: Clorol 200 SC is predicted to use in melliferous crops. In this dossier a new honey studies were submitted and the results indicated no exceedance of MRL (0.05 mg/kg) in honey. The detailed assessment of the studies by Grzeczka (2024) is presented in Appendix 2.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).
As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-19: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment *
Risk assessment residue: chlorantraniliprole		
Chestnuts	0.03	MRL value from Reg. (EU) 2022/1343
Hazelnuts	0.03	MRL value from Reg. (EU) 2022/1343
Walnuts	0.03	MRL value from Reg. (EU) 2022/1343
Apples	0.4	MRL value from Reg. (EU) 2022/1343
Pears	0.4	MRL value from Reg. (EU) 2022/1343
Quinces	0.4	MRL value from Reg. (EU) 2022/1343
Medlar	0.4	MRL value from Reg. (EU) 2022/1343
Loquats/Japanese medlars	0.4	MRL value from Reg. (EU) 2022/1343
Other pome fruit	0.4	MRL value from Reg. (EU) 2022/1343
Apricots	1	MRL value from Reg. (EU) 2022/1343
Cherries (sweet)	1	MRL value from Reg. (EU) 2022/1343
Peaches	1	MRL value from Reg. (EU) 2022/1343
Plums	1	MRL value from Reg. (EU) 2022/1343
Other stone fruit	1	MRL value from Reg. (EU) 2022/1343

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment *
Table grapes	1	MRL value from Reg. (EU) 2022/1343
Wine grapes	1	MRL value from Reg. (EU) 2022/1343
Potatoes	0.03	MRL value from Reg. (EU) 2022/1343
Sweet potatoes	0.02	MRL value from Reg. (EU) 2022/1343
Yams	0.02	MRL value from Reg. (EU) 2022/1343
Beetroots	0.06	MRL value from Reg. (EU) 2022/1343
Carrots	0.08	MRL value from Reg. (EU) 2022/1343
Celeriacs/turnip rooted celeries	0.06	MRL value from Reg. (EU) 2022/1343
Horseradishes	0.06	MRL value from Reg. (EU) 2022/1343
Jerusalem artichokes	0.06	MRL value from Reg. (EU) 2022/1343
Parsnips	0.06	MRL value from Reg. (EU) 2022/1343
Parsley roots/Hamburg roots parsley	0.06	MRL value from Reg. (EU) 2022/1343
Radishes	0.5	MRL value from Reg. (EU) 2022/1343
Salsifies	0.06	MRL value from Reg. (EU) 2022/1343
Swedes/rutabagas	0.06	MRL value from Reg. (EU) 2022/1343
Turnips	0.06	MRL value from Reg. (EU) 2022/1343
Other other root and tuber vegetables	0.06	MRL value from Reg. (EU) 2022/1343
Tomatoes	0.6	MRL value from Reg. (EU) 2022/1343
Sweet peppers/bell peppers	1	MRL value from Reg. (EU) 2022/1343
Aubergines/egg plants	0.6	MRL value from Reg. (EU) 2022/1343
Okra/lady’s fingers	0.6	MRL value from Reg. (EU) 2022/1343
Cucumbers	0.3	MRL value from Reg. (EU) 2022/1343
Gherkins	0.3	MRL value from Reg. (EU) 2022/1343
Courgettes	0.3	MRL value from Reg. (EU) 2022/1343
Other cucurbits - edible peel	0.3	MRL value from Reg. (EU) 2022/1343
Melons	0.3	MRL value from Reg. (EU) 2022/1343
Pumpkins	0.3	MRL value from Reg. (EU) 2022/1343
Watermelons	0.3	MRL value from Reg. (EU) 2022/1343
Other cucurbits - inedible peel	0.3	MRL value from Reg. (EU) 2022/1343
Sweet corn	0.01	MRL value from Reg. (EU) 2022/1343
Broccoli	1.5	MRL value from Reg. (EU) 2022/1343
Cauliflowers	0.5	MRL value from Reg. (EU) 2022/1343
Head cabbages	2	MRL value from Reg. (EU) 2022/1343

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment *
Chinese cabbages/pe-tsai	20	MRL value from Reg. (EU) 2022/1343
Kales	40	MRL value from Reg. (EU) 2022/1343
Other leafy brassica	20	MRL value from Reg. (EU) 2022/1343
Lamb's lettuce/corn salads	20	MRL value from Reg. (EU) 2022/1343
Lettuces	20	MRL value from Reg. (EU) 2022/1343
Escaroles/broad-leaved endives	20	MRL value from Reg. (EU) 2022/1343
Cress and other sprouts and shoots	20	MRL value from Reg. (EU) 2022/1343
Land cress	20	MRL value from Reg. (EU) 2022/1343
Roman rocket/rucola	20	MRL value from Reg. (EU) 2022/1343
Red mustards	20	MRL value from Reg. (EU) 2022/1343
Baby leaf crops (including brassica species)	20	MRL value from Reg. (EU) 2022/1343
Other lettuce and other salad plants	20	MRL value from Reg. (EU) 2022/1343
Spinaches	20	MRL value from Reg. (EU) 2022/1343
Purslanes	20	MRL value from Reg. (EU) 2022/1343
Chards/beet leaves	20	MRL value from Reg. (EU) 2022/1343
Other spinach and similar	20	MRL value from Reg. (EU) 2022/1343
Watercreess	20	MRL value from Reg. (EU) 2022/1343
Chervil	20	MRL value from Reg. (EU) 2022/1343
Chives	20	MRL value from Reg. (EU) 2022/1343
Celery leaves	20	MRL value from Reg. (EU) 2022/1343
Parsley	20	MRL value from Reg. (EU) 2022/1343
Sage	20	MRL value from Reg. (EU) 2022/1343
Rosemary	20	MRL value from Reg. (EU) 2022/1343
Thyme	20	MRL value from Reg. (EU) 2022/1343
Basil and edible flowers	20	MRL value from Reg. (EU) 2022/1343
Laurel/bay leaves	20	MRL value from Reg. (EU) 2022/1343
Tarragon	20	MRL value from Reg. (EU) 2022/1343
Other herbs	20	MRL value from Reg. (EU) 2022/1343
Poppy seeds	2	MRL value from Reg. (EU) 2022/1343
Sesame seeds	2	MRL value from Reg. (EU) 2022/1343
Sunflower seeds	2	MRL value from Reg. (EU) 2022/1343
Rapeseeds/canola seeds	2	MRL value from Reg. (EU) 2022/1343
Soyabeans	0.05	MRL value from Reg. (EU) 2022/1343

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment *
Mustard seeds	2	MRL value from Reg. (EU) 2022/1343
Pumpkin seeds	2	MRL value from Reg. (EU) 2022/1343
Safflower seeds	2	MRL value from Reg. (EU) 2022/1343
Borage seeds	2	MRL value from Reg. (EU) 2022/1343
Gold of pleasure seeds	2	MRL value from Reg. (EU) 2022/1343
Hemp seeds	2	MRL value from Reg. (EU) 2022/1343
Castor beans	2	MRL value from Reg. (EU) 2022/1343
Maize/corn	0.02	MRL value from Reg. (EU) 2022/1343
Sugar canes	0.5	MRL value from Reg. (EU) 2022/1343
Swine: Muscle/meat	0.030	MRL value from Reg. (EU) 2022/1343
Swine: Fat tissue	0.200	MRL value from Reg. (EU) 2022/1343
Swine: Liver	0.200	MRL value from Reg. (EU) 2022/1343
Swine: Kidney	0.200	MRL value from Reg. (EU) 2022/1343
Swine: Edible offals (other than liver and kidney)	0.200	MRL value from Reg. (EU) 2022/1343
Swine: Other products	0.010	MRL value from Reg. (EU) 2022/1343
Bovine: Muscle/meat	0.030	MRL value from Reg. (EU) 2022/1343
Bovine: Fat tissue	0.200	MRL value from Reg. (EU) 2022/1343
Bovine: Liver	0.200	MRL value from Reg. (EU) 2022/1343
Bovine: Kidney	0.200	MRL value from Reg. (EU) 2022/1343
Bovine: Edible offals (other than liver and kidney)	0.200	MRL value from Reg. (EU) 2022/1343
Bovine: Other products	0.010	MRL value from Reg. (EU) 2022/1343
Sheep: Muscle/meat	0.030	MRL value from Reg. (EU) 2022/1343
Sheep: Fat tissue	0.200	MRL value from Reg. (EU) 2022/1343
Sheep: Liver	0.200	MRL value from Reg. (EU) 2022/1343
Sheep: Kidney	0.200	MRL value from Reg. (EU) 2022/1343
Sheep: Edible offals (other than liver and kidney)	0.200	MRL value from Reg. (EU) 2022/1343
Sheep: other products	0.010	MRL value from Reg. (EU) 2022/1343
Goat: Muscle/meat	0.030	MRL value from Reg. (EU) 2022/1343
Goat: Fat tissue	0.200	MRL value from Reg. (EU) 2022/1343
Goat: Liver	0.200	MRL value from Reg. (EU) 2022/1343
Goat: Kidney	0.200	MRL value from Reg. (EU) 2022/1343
Goat: Edible offals (other tha liver and kindey)	0.200	MRL value from Reg. (EU) 2022/1343

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment *
Goat: other products	0.010	MRL value from Reg. (EU) 2022/1343
Equine: Muscle/meat	0.030	MRL value from Reg. (EU) 2022/1343
Equine: Fat tissue	0.200	MRL value from Reg. (EU) 2022/1343
Equine: Liver	0.200	MRL value from Reg. (EU) 2022/1343
Equine: Kidney	0.200	MRL value from Reg. (EU) 2022/1343
Equine: Edible offals (other than liver and kidney)	0.200	MRL value from Reg. (EU) 2022/1343
Equine: Other products	0.010	MRL value from Reg. (EU) 2022/1343
Poultry: Muscle/meat	0.020	MRL value from Reg. (EU) 2022/1343
Poultry: Fat tissue	0.080	MRL value from Reg. (EU) 2022/1343
Poultry: Liver	0.070	MRL value from Reg. (EU) 2022/1343
Poultry: Kidney	0.010	MRL value from Reg. (EU) 2022/1343
Poultry: Edible offals (other than liver and kideny)	0.080	MRL value from Reg. (EU) 2022/1343
Poultry: Other products	0.010	MRL value from Reg. (EU) 2022/1343
Other farmed animals: Muscle/meat	0.030	MRL value from Reg. (EU) 2022/1343
Other farmed animals: Fat tissue	0.200	MRL value from Reg. (EU) 2022/1343
Other farmed animals: Liver	0.200	MRL value from Reg. (EU) 2022/1343
Other farmed animals: Kidney	0.200	MRL value from Reg. (EU) 2022/1343
Other farmed animals: Edible offals (other than liver and kidney)	0.200	MRL value from Reg. (EU) 2022/1343
Other farmed animals: Other products	0.010	MRL value from Reg. (EU) 2022/1343
Milk: Cattle	0.050	MRL value from Reg. (EU) 2022/1343
Milk: Sheep	0.050	MRL value from Reg. (EU) 2022/1343
Milk: Goat	0.050	MRL value from Reg. (EU) 2022/1343
Milk: Horse	0.050	MRL value from Reg. (EU) 2022/1343
Milk: Others	0.050	MRL value from Reg. (EU) 2022/1343
Eggs: Chicken	0.200	MRL value from Reg. (EU) 2022/1343
Eggs: Duck	0.200	MRL value from Reg. (EU) 2022/1343
Eggs: Goose	0.200	MRL value from Reg. (EU) 2022/1343
Eggs: Quail	0.200	MRL value from Reg. (EU) 2022/1343
Eggs: Others	0.200	MRL value from Reg. (EU) 2022/1343
Honey and other apiculture products	0.050	MRL value from Reg. (EU) 2022/1343

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment *
Amphibians and reptiles	0.010	MRL value from Reg. (EU) 2022/1343
Terrestrial invertebrate animals	0.010	MRL value from Reg. (EU) 2022/1343
Wild terrestrial vertebrate animals	0.010	MRL value from Reg. (EU) 2022/1343

*The current MRL regulation is: Reg. (EU) 2024/1355, however, MRL values for the crops under assessment have not been changed.

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-20: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	2 % (based on NL toddler)

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of chlorantraniliprole in the formulation CLOROL 200 SC do not represent unacceptable chronic risks for the consumer.

zRMS comment: The MRLs values from the Regulation were used in the calculations, not the values obtained from the studies reported in point 7.2.3 Magnitude of residues in plants. As values from the studies are lower or at MRL, the recalculation is considered not necessary and calculations presented by the Applicant are acceptable.
The proposed uses of chlorantraniliprole in the formulation Clorol 200 SC do not represent unacceptable chronic risks for the consumer.
As ARfD is not established, the acute risk assessment is not relevant.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

EFSA Journal 2013;11(6):3143
EFSA Journal 2020;18(9):6235

FRR CORAGEN 200 SC

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3	Peda, T., SGS Polska Sp. z o.o.	2024	*Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one harvest study trial in Northern France – 2024* Study number: 24SGS35	N	PUH Chemirol Sp. z o.o.
KCA 6.3	Peda, T., SGS Polska Sp. z o.o.	2024	*Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one harvest study trial in Denmark – 2024* Study number: 24SGS34	N	PUH Chemirol Sp. z o.o.
KCA 6.3	Peda, T., SGS Polska Sp. z o.o.	2024	*Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one harvest study trial in Poland - 2024* Study number: 24SGS37	N	PUH Chemirol Sp. z o.o.
KCA 6.3	Peda, T., SGS Polska Sp. z o.o.	2024	*Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one harvest study trial in Hungary – 2024* Study number: 24SGS36	N	PUH Chemirol Sp. z o.o.
KCA 6.3	Peda, T., SGS Polska Sp. z o.o.	2024	*Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one decline curve study trialin Northern France – 2024* Study number: 24SGS39	N	PUH Chemirol Sp. z o.o.
KCA 6.3	Peda, T., SGS Polska Sp. z o.o.	2024	*Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one decline curve study trialin Germany – 2024*	N	PUH Chemirol Sp.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Study number: 24SGS40		z o.o.
KCA 6.3	Peda, T., SGS Polska Sp. z o.o.	2024	*Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one decline curve study trial in Poland – 2024* Study number: 24SGS38	N	PUH Chemirol Sp. z o.o.
KCA 6.3	Peda, T., SGS Polska Sp. z o.o.	2024	*Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one decline curve study trial in Hungary - 2024* Study number: 24SGS41	N	PUH Chemirol Sp. z o.o.
KCA 6.3	Wańczyk K., SGS Polska Sp. z o.o.	2024	*Magnitude of residue of Chlorantraniliprole in sugar beet (Raw Agricultural Commodity) after one application of CLOROL 200 SC with adjuvant Asystent+, one harvest study trial in Poland - 2024* Study number: 24SGS53	N	PUH Chemirol Sp. z o.o.
KCA 6.3	Wańczyk K., SGS Polska Sp. z o.o.	2024	*Magnitude of residue of Chlorantraniliprole in sugar beet (Raw Agricultural Commodity) after one application of CLOROL 200 SC with adjuvant Asystent+, one harvest study trial in Denmark – 2024* Study number: 24SGS54	N	PUH Chemirol Sp. z o.o.
KCA 6.3	Wańczyk K., SGS Polska Sp. z o.o.	2024	*Magnitude of residue of Chlorantraniliprole in sugar beet (Raw Agricultural Commodity) after one application of CLOROL 200 SC with adjuvant Asystent+, one decline curve study trial in Germany – 2024* Study number: 24SGS56	N	PUH Chemirol Sp. z o.o.
KCA 6.3	Wańczyk K., SGS Polska Sp. z o.o.	2024	*Magnitude of residue of Chlorantraniliprole in sugar beet (Raw Agricultural Commodity) after one application of CLOROL 200 SC with adjuvant Asystent+, one decline curve study trial in Hungary – 2024* Study number: 24SGS55	N	PUH Chemirol Sp. z o.o.
KCA 6.10, KCA 6.10.1	Grzeczka P., SGS Polska Sp. z o.o.	2024	*Determination of Chlorantraniliprole residues in honey following two foliar applications of CLOROL 200 SC on Phacelia under semi-field conditions in Poland – 2024* Study number: 24SGS45	N	PUH Chemirol Sp. z o.o.
KCA 6.10, KCA 6.10.1	Grzeczka P., SGS Polska Sp. z o.o.	2024	*Determination of Chlorantraniliprole residues in honey following two foliar applications of CLOROL 200 SC on Phacelia under semi-field conditions in Spain – 2024* Study number: 24SGS44	N	PUH Chemirol Sp. z o.o.
KCA 6.10, KCA 6.10.1	Grzeczka P., SGS Polska Sp. z o.o.	2024	*Determination of Chlorantraniliprole residues in honey following two foliar applications of CLOROL 200 SC on Phacelia under semi-field conditions in Poland – 2024* Study number: 24SGS46	N	PUH Chemirol Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.10, KCA 6.10.1	Grzeczka P., SGS Polska Sp. z o.o.	2024	*Determination of Chlorantraniliprole residues in honey following two foliar applications of CLOROL 200 SC on Phacelia under semi-field conditions in Poland – 2024* Study number: 24SGS47	N	PUH Chemirol Sp. z o.o.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1/01	Grant, J.	2006	Stability of DPX-E2Y45 in representative crops stored frozen DuPont-12985 ABC Laboratories, Inc. (Missouri), Columbia, Missouri, USA (48387) GLP Unpublished	N	DuPont
KCA 6.1/02	Cairns, S.D., Hunter, T.M.	2006	Method validation and frozen stability of DPX-E2Y45, IN-ECD73, IN-EQW78 and IN-F6L99 in representative processed crop fractions DuPont-13255 Charles River Laboratories, Tranent, Scotland, UK (208658) GLP Unpublished	N	DuPont
KCA 6.1/03		2007	Storage stability of DPX-E2Y45, IN-HXH44, IN-K9T00, IN-GAZ70 and IN-EQW78 in cattle tissues and milk stored frozen DuPont-17004	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			(209269) GLP Unpublished		
KCA 6.2.1/01	MacDonald, A.M.G., Paterson, K., Coyle, D	2005	The metabolism of [14C]-DPX-E2Y45 in apple trees DuPont-12264 Inveresk Research, Tranent, Scotland, UK (804125) GLP Unpublished	N	DuPont
KCA 6.2.1/02	MacDonald, A.M.G., Gray, J.L.	2005	Metabolism of 14C-DPX-E2Y45 in tomato DuPont-12266 Inveresk Research, Tranent, Scotland, UK (804167) GLP Unpublished	N	DuPont
KCA 6.2.1/03	MacDonald, A.M.G., Paterson, K., Coyle, D.	2007	The metabolism of [14C]-DPX-E2Y45 in lettuce DuPont-12265, Revision No. 1 Inveresk Research, Tranent, Scotland, UK (804172) GLP Unpublished	N	DuPont
KCA 6.2.1/04	Brown, A.M., Young, G.A., Holliday, M.	2004	Metabolism of 14C-DPX-E2Y45 in cotton, excised and whole plant studies DuPont-12698 DuPont Stine-Haskell Research Center, Newark, Delaware, USA Not GLP Unpublished	N	DuPont
KCA 6.2.1/05	Chapleo, S., Gray, J.L.	2006	The metabolism of [14C]-DPX-E2Y45 in rice DuPont-16967 Charles River Laboratories, Tranent, Scotland, UK (806028)	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCA 6.6.1/01	Chapleo, S.	2006	Confined rotational crop study using [14C]DPX-E2Y45 DuPont-12314 Charles River Laboratories, Tranent, Scotland, UK (804214) GLP Unpublished	N	DuPont
KCA 6.5.1/01	Chapleo, S.	2004	High temperature hydrolysis of [14C]-DPX-E2Y45 in buffered aqueous solution at pH 4, 5, and 6 DuPont-12994, Revision No. 1 Inveresk Research, Tranent, Scotland, UK (23264) GLP Unpublished	N	DuPont
KCA 6.2.2-6.2.5/01		2006	Metabolism of [14C]-DPX-E2Y45 in the lactating goat DuPont-14377 GLP Unpublished	Y	DuPont
KCA 6.2.2-6.2.5/02		2006	The distribution and metabolism of [14C]-DPX-E2Y45 in the laying hen DuPont-14776 (207041) GLP Unpublished	Y	DuPont
KCA 6.3/01	Foster, A.C., Cairns, S.D.	2005	Decline of DPX-E2Y45 residues in apple fruit (pome fruit) following foliar applications of DPX-E2Y45 35WG or DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - Europe, 2004 DuPont-14141 Inveresk Research, Tranent, Scotland, UK (685368) GLP Unpublished	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3/02	Foster, A.C., Cairns, S.D.	2007	Magnitude and decline of DPX-E2Y45 residues in apples and pears (pome fruit) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - Northern and Southern Europe, 2005 DuPont-16577, Revision No. 1 Charles River Laboratories, Tranent, Scotland, UK (687543) GLP Unpublished	N	DuPont
KCA 6.3/03	Foster, A.C., Davidson, J., Cairns, S.D.	2005	Decline of DPX-E2Y45 residues in potato tubers following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - Northern Europe, 2004 DuPont-14143 Charles River Laboratories (formerly Inveresk Research), Tranent, Scotland, UK (685373) GLP Unpublished	N	DuPont
KCA 6.3/04	Foster, A.C., Cairns, S.D.	2006	Magnitude of DPX-E2Y45 residues in potatoes (potato group) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - northern and southern Europe, 2005 DuPont-16565 Charles River Laboratories, Tranent, Scotland, UK (687517) GLP Unpublished	N	DuPont
KCA 6.3/05	Foster, A.C., Cairns, S.D.	2007	Magnitude of DPX-E2Y45 residues in potatoes (potato group) following foliar applications of DPX-E2Y45 20SC [200 g as/L (w/v); 18.5% (w/w)] - northern and southern Europe, 2006 DuPont-18748 Charles River Laboratories, Tranent, Scotland, UK (689561) GLP Unpublished	N	DuPont
KCA	Foster, A.C., Cairns,	2006	Magnitude and decline of DPX-E2Y45 residues in table grapes (berries and small fruit) following foliar	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.3/06	S.D.		applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - Southern Europe, 2005 DuPont-16566 Inveresk Research, Tranent, Scotland, UK (687522) GLP Unpublished		
KCA 6.3/07	Foster, A.C., Cairns, S.D.	2007	Magnitude and decline of DPX-E2Y45 residues in table grapes (berries and small fruit) following foliar applications of DPX-E2Y45 20SC [200 g as/L (w/v); 18.5% (w/w)] and DPX-E2Y45 35WG formulated products - southern Europe, 2006 DuPont-18751 Charles River Laboratories, Tranent, Scotland, UK (689645) GLP Unpublished	N	DuPont
KCA 6.3/08	Foster, A.C., Cairns, S.D., Davidson, J.	2005	Decline of DPX-E2Y45 residues in protected tomatoes (solanacea vegetables) following foliar applications of DPX-E2Y45 35WG – southern Europe, 2004 DuPont-14154 Inveresk Research, Tranent, Scotland, UK (684956) GLP Unpublished	N	DuPont
KCA 6.3/09	Foster, A.C., Cairns, S.D.	2006	Magnitude and decline of DPX-E2Y45 residues in protected tomatoes (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2005 DuPont-16582 Charles River Laboratories, Tranent, Scotland, UK (687653) GLP Unpublished	N	DuPont
KCA 6.3/10	Foster, A.C., Cairns, S.D., Hunter, T.M.	2006	Magnitude and decline of DPX-E2Y45 residues in protected cherry tomatoes (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2005	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			DuPont-16584 Charles River Laboratories, Tranent, Scotland, UK (687648) GLP Unpublished		
KCA 6.3/11	Foster, A.C., Cairns, S.D.	2007	Magnitude and decline of DPX-E2Y45 residues in protected tomatoes (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2006 DuPont-18755 Charles River Laboratories, Tranent, Scotland, UK (689598) GLP Unpublished	N	DuPont
KCA 6.3/12	Foster, A.C., Cairns, S.D.	2007	Magnitude and decline of DPX-E2Y45 residues in protected cherry tomatoes (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2006 DuPont-18769 Charles River Laboratories, Tranent, Scotland, UK (689729) GLP Unpublished	N	DuPont
KCA 6.3/13	Foster, A.C., Cairns, S.D., Hunter, T.M.	2006	Magnitude and decline of DPX-E2Y45 residues in field peppers (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2005 DuPont-16579 Charles River Laboratories GLP Unpublished	N	DuPont
KCA 6.3/14	Foster, A.C., Cairns, S.D.	2006	Magnitude and decline of DPX-E2Y45 residues in protected peppers (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2005 DuPont-16580 Charles River Laboratories GLP	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA 6.3/15	Foster, A.C., Cairns, S.D., Hunter, T.M.	2006	Magnitude and decline of DPX-E2Y45 residues in protected hot peppers Capsicum fructescens (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2005 DuPont-16586 Charles River Laboratories GLP Unpublished	N	DuPont
KCA 6.3/16	Foster, A.C., Cairns, S.D.	2007	Magnitude and decline of DPX-E2Y45 residues in field hot peppers (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - southern Europe, 2006 DuPont-18765 Charles River Laboratories GLP Unpublished	N	Dupont
KCA 6.3/17	Foster, A.C., Cairns, S.D.	2007	Magnitude and decline of DPX-E2Y45 residues in protected peppers (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2006 DuPont-18754 Charles River Laboratories GLP Unpublished	N	DuPont
KCA 6.3/18	Foster, A.C., Cairns, S.D.	2007	Magnitude and decline of DPX-E2Y45 residues in protected hot peppers (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2006 DuPont-18757 Charles River Laboratories GLP Unpublished	N	DuPont
KCA 6.3/19	Foster, A.C., Cairns, S.D., Hansford, R.J.	2007	Magnitude and decline of DPX-E2Y45 residues in protected cucumbers and courgettes (fruiting vegetables, edible peel cucurbits) following foliar applications of DPX-E2Y45 35WG - Europe, 2006 DuPont-18760 Charles River Laboratories GLP	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA 6.3/20	Foster, A.C., Cairns, S.D., Hansford, R.J.	2007	Magnitude and decline of DPX-E2Y45 residues in protected melons (fruiting vegetables, inedible-peel cucurbits) following foliar applications of DPX-E2Y45 35WG - Europe, 2006 DuPont-18761 Charles River Laboratories GLP Unpublished	N	DuPont
KCA 6.3/21	Foster, A.C., Cairns, S.D.	2007	Magnitude and decline of DPX-E2Y45 residues in protected lettuce including lambs lettuce (leaf vegetables) following foliar applications of DPX-E2Y45 35WG - Europe, 2006 DuPont-18764 Charles River Laboratories GLP Unpublished	N	DuPont
KCA 6.3/22	Foster, A.C., Cairns, S.D., Hunter, T.M.	2006	Magnitude and decline of DPX-E2Y45 residues in field lettuce (leaf vegetables) following foliar applications of DPX-E2Y45 35WG - southern Europe, 2005 DuPont-16573 Charles River Laboratories GLP Unpublished	N	DuPont
KCA 6.3/23	Foster, A.C., Cairns, S.D., Hansford, R.J.	2007	Magnitude and decline of DPX-E2Y45 residues in field lettuce (leaf vegetables) following foliar applications of DPX-E2Y45 35WG - France and southern Europe, 2006 DuPont-18750 Charles River Laboratories GLP Unpublished	N	DuPont
KCA 6.3/24	Foster, A.C., Cairns, S.D.	2007	Magnitude and decline of DPX-E2Y45 residues in protected lettuce including lambs lettuce (leaf vegetables) following foliar applications of DPX-E2Y45 35WG - Europe, 2006 DuPont-18764 Charles River Laboratories GLP	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA 6.3/25	Foster, Andrew C., Cairns, Scott D	2009	Magnitude and decline of chlorantraniliprole residues in plums (stone fruit) following foliar applications of DPX-E2Y45 20SC [200 g as/l (w/v); 18.5% (w/w)] – Northern and Southern Europe, 2007 and 2008 DuPont-21714 Charles River Laboratories GLP Unpublished	N	DuPont
KCA 6.3/26		2006	Magnitude and decline of DPX-E2Y45 residues in maize following foliar applications of DPX-E2Y45 20 SC [200 g as/L (w/w); 18.5% (w/w)] – Northern and South Europe, 2006 DuPont-20120 Charles River Laboratories GLP Unpublished	N	DuPont
KCA 6.3/27		2007	Magnitude and decline of DPX-E2Y45 residues in maize following foliar applications of DPX-E2Y45 20 SC [200 g as/L (w/w); 18.5% (w/w)] and DPX-E2Y45 35WG formulated products – Europe, 2007 Charles River Laboratories DuPont-21629 GLP Unpublished	N	DuPont
KCA 6.3/28		2008	Magnitude and decline of chlorantraniliprole residues in cabbage (head brassicas) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] and DPX-E2Y45 35WG formulated products - Europe, 2007 Charles River Laboratories DuPont-21337 GLP Unpublished	N	DuPont
KCA 6.3/29		2008	Magnitude and decline of chlorantraniliprole residues in cabbage (head brassicas) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] and DPX-E2Y45 35WG formulated products - Europe, 2007 Charles River Laboratories	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			DuPont-21337 GLP Unpublished		
KCA 6.3/30	Foster, A.C., Cairns, S.D.,	2008	Magnitude and decline of chlorantraniliprole residues in cauliflower and broccoli (flowering brassicas) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] and DPX-E2Y45 35WG formulated products - Europe, 2007 Charles River Laboratories DuPont-21338 GLP Unpublished	N	DuPont
KCA 6.3/31	Foster, A.C., Cairns, S.D.,	2007	Magnitude and decline of DPX-E2Y45 residues in cauliflower and broccoli (flowering brassicas) following foliar applications of DPX-E2Y45 35WG - northern and southern Europe, 2006 Charles River Laboratories DuPont-18772 GLP Unpublished	N	DuPont
KCA 6.3/32	Foster, A.C., Cairns, S.D.,	2007	Magnitude and decline of DPX-E2Y45 residues in cabbage (head brassicas) following foliar applications of DPX-E2Y45 35WG - northern and southern Europe, 2006 Charles River Laboratories DuPont-18770 GLP Unpublished	N	DuPont
KCA 6.3/33	Cairns, S., Hoskins, M., Foster, A.	2011	Magnitude and decline of chlorantraniliprole residues in carrots following foliar applications of Chlorantraniliprole 35WG - Europe 2009 and 2010 Charles River Laboratories DuPont-27575 GLP Unpublished	N	DuPont
KCA 6.3/34	Foster, A.C., Cairns, S.D., Hansford, R.J.	2007	Magnitude and decline of DPX-E2Y45 residues in wine grapes (berries and small fruit) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] – northern and southern Europe,	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			2006 Charles River Laboratories DuPont-19306 GLP Unpublished		
KCA 6.3/35	Foster, A.C., Cairns, S.D., Hunter, T.M	2006	Decline of DPX-E2Y45 residues in wine grapes (berries and small fruit) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - northern and southern Europe, 2005 Charles River Laboratories DuPont-16567 GLP Unpublished	N	DuPont
KCA 6.3/36	Foster, A.C., Cairns, S.D.	2005	Decline of DPX-E2Y45 residues in wine grapes (berries and small fruits) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - Europe, 2004 Charles River Laboratories DuPont-14139 GLP Unpublished	N	DuPont
KCA 6.3/37	Foster, A.C., Cairns, S.D.	2007	Magnitude and decline of DPX-E2Y45 residues in field peppers (fruiting vegetables, Solanacea) following foliar applications of DPX-E2Y45 35WG - southern Europe, 2006 Charles River Laboratories DuPont-18753 GLP Unpublished	N	DuPont
KCA 6.3/38	Foster, A.C., Cairns, S.D.	2006	Magnitude and decline of DPX-E2Y45 residues in field hot peppers (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Southern Europe, 2005 Charles River Laboratories DuPont-16585 GLP Unpublished	N	DuPont
KCA	Grant, J. and Koch,	2005	Crop rotation study with DPX-E2Y45 20SC insecticide - EPA cropping region 6; U.S.A.; 2003	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.6.2/01	D.		DuPont-12775 ABC Laboratories, Inc. (Missouri) GLP Unpublished		
KCA 6.6.2/02	Grant, J., Koch, D.A.	2005	Crop rotation study with DPX-E2Y45 20SC insecticide - EPA cropping region 10; U.S.A.; 2003 DuPont-12776 ABC Laboratories, Inc. (Missouri) GLP Unpublished	N	DuPont
KCA 6.6.2/03	Grant, J., Koch, D.A.	2005	Crop rotation study with DPX-E2Y45 20SC insecticide - EPA cropping region 5, U.S.A., 2003 DuPont-12777 ABC Laboratories, Inc. (Missouri) GLP Unpublished	N	DuPont
KCA 6.6.2/04	Grant, J., Carringer, S.J.	2005	Crop rotation study with DPX-E2Y45 35WG insecticide - EPA cropping region 12 - 2004, USA The Carringers, Inc.; DuPont-14818 ABC Laboratories, Inc. (Missouri) GLP Unpublished	N	DuPont
KCA 6.6.2/05	Rice, F., Rodgers, C.A.	2007	Crop rotation study with DPX-E2Y45 20SC insecticide - NAFTA growing zone 1A, Canada, 2005 DuPont-17045 Final Report ABC Laboratories, Inc. (Missouri) GLP Unpublished	N	DuPont

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Chlorantraniliprole

A 2.1.1 Stability of residues

Not relevant..

A 2.1.2 Nature of residues in plants, livestock and processed commodities

Not relevant.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Magnitude of residues in Oilseed rape

A 2.1.3.1.1 Study 1

Comments of zRMS:	The study was conducted according to relevant guidances, and GLP requirements and in line with the requested GAP. Study is accepted. The objective of the study was to determine the residue level of chlorantraniliprole in oilseed rape in one harvest study trial following two applications of the formulated product CLOROL 200 SC. Two applications of CLOROL 200 SC were performed at the target dose rate of 40 g of chlorantraniliprole at BBCH 65 and 71. The residue concentration detected was <LOQ in rape seeds.

Reference:	KCA 6.3
Report	Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one harvest study trial in Northern France – 2024; Peda Tomasz, SGS Polska Sp. z o.o., Study numer: 24SGS35
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997; OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021); SANTE/2020/12830 Rev.2, 14 February 2023;

Deviations: Yes
One deviation occurred during field phase. Minimum sample size of 2kg (seeds) were not.

GLP: Yes

Acceptability: YES

Materials and methods

- Test Item:

Name		CLOROL 200 SC
Trade name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		chlorantraniliprole
CAS Number		500008-45-7
Formulation Type		SC
Formulation Name		Suspension Concentrate
Main uses		Insecticide
Content of a.s.	nominal	20 % w/v
	analyzed	19,9 % w/v
Density analyzed :		1,0908 g/cm^3
Certificate of Analysis dated:		17/10/2023
Expiry date		05/2025

- Test System:

Crop	Oil seed rape (*Brassica napus*)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex alimentarius: SO 0088
RACs harvested	Seeds

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed only with water. The target dose rate of test item was 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Target water volume was 200-300 l/ha according to Good Agricultural Practice.

- Field Phase:

Harvest study trial (HS) was established in Northern France. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study. Two typical for insecticide applications of CLOROL 200 SC were performed with boom sprayer on the treated plot at the target dose rate of 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Spray volume was 200-300 l/ha according to Good Agricultural Practice.
Reported dose rates:
Application 1: 0,209 l/ha; 260,6 l/ha of water.
Application 2: 0,197 l/ha; 246,7 l/ha of water.
Applications were performed at:
Application 1: BBCH 65
Application 2: BBCH 71
Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify the delivery rate. Deviations from the target rate were:
Application 1: +4,5%

Application 2: -1,5%
RAC specimens for analyses were collected:
S1 (Seeds) BBCH89 / CH

Table 1 Identification of the field trial

Trial number	Study type	Zone	Country (region)	Trial site	Postal code	GPS coordinates
24SGS35-01	HS	Western Europe	Northern France (Grand Est)	Fraillicourt	08220	N 49.659878 E 4.169034

Table 2 Test system information

Crop	Variety	Sowing date	Row spacing [cm]	Plant spacing [cm]	Crop density [/ha]	Main Flowering Date	Commercial Harvest Date
Oilseed rape	LG Austin	21/08/2023	30	-	2,5 kg	01/04/2024 – 01/05/2024	24/07/2024

Table 3 Soil characterisation

Soil texture	Organic matter content (%)	pH (water)
Clay	2,7	8,4

Table 4 Source of trial weather data

Air temperature and precipitation			
Current year		Historical data – average from past 5 years	
Source of data	Distance to field site (km)	Source of data	Distance to field site (km)
Banogne-Recouvrance [08220]	11	Banogne-Recouvrance [08220]	11

Table 5 Temperature data

Month	Current year		Historical data – average from past 5 years	
	Average minimum air temperature (°C)	Average maximum air temperature (°C)	Average minimum air temperature (°C)	Average maximum air temperature (°C)
April	7	16	5,2	16,4
May	11	20	8,4	20
June	12	22	13,6	25,1
July	15	25	14,1	25,9

Table 6 Rainfall data

Month	Rainfall (mm)	
	Current year	Historical data - average from past 5 years
April	64	41,8
May	119,7	52
June	48,8	72,9
July	96	67,2

Table 7 Experimental design

Plot ID	Plot width [m]	Plot length [m]	Plot area [m²]	Slope [%]	Distance between plots [m]
U, T	6	15	90	5	20

Table 8 Application equipment data

Trial number	Application Number	Sprayer Configuration	Nozzle Brand	Number of Nozzles	Nozzle Spacing [cm]
24SGS35-01	A1	Boom Sprayer	TTVP 11002	6	50
	A2	Boom Sprayer	TTVP 11002	6	50

Table 9 Application data

Application number	Date	Time	BBCH	Actual rate of test item (l/ha)	Actual rate a.s. (g /ha)	Deviation (%)	Spray volume (l/ha)	Treated area (m²)	Spray mixture (g)	Test item (g)	Spray mixture remaining (g)	Spray mixture applied (g)
A1	25/04/2024	12:13	65	0,209	42	+4,5	260,6	90	2750	2,4	405	2345
A2	09/05/2024	12:39	71	0,197	39	-1,5	246,7	90	2750	2,4	530	2220

Table 10 Environmental conditions at application

Application number	Foliage moisture	Soil moisture	Soil temperature at 10 depth (°C)	Air temperature (°C)	Relative humidity (%)	Cloud cover (%)	Wind speed (m/s)	Wind direction (origin)	Rainfall within 3 hours
A1	Dry	Moist	8,3	10,5	73	100	1,2	W	0
A2	Dry	Dry	11,3	22,4	65	60	1,5	W	0

Table 11 Cultivation practices

Date	Operation type	Equipment
21/08/2023	Superficial work	Rotary harrow

Results:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	BBCH 89 / CH	24SGS35-01 1	oilseed rape (seeds)	DPL/54/2024/01U	< LOD
2		24SGS35-01 2	oilseed rape (seeds)	DPL/54/2024/02T	<LOQ

BBCH – according to BBCH scale; CH – commercial harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Conclusions
This study was fully performed as anticipated, in accordance with the study plan and the amendment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s). The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70-120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seeds). There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of chlorantraniliprole in oilseed rape (seeds) meets the criteria of SANTE/2020/12830, Rev. 2 guidelines in terms of precision, accuracy and uncertainty.

Analytical phase:

- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in oilseed rape RAC (seeds) following two applications of CLOROL 200 SC.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in oilseed rape (seeds) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-84 Determination of residues of Chlorantraniliprole in oilseed rape (seed, plant) using QuEChERS method and LC-MS/MS tandem mass spectrometry, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC-and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method.

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18 oC before analysis. After removal from the freezer the samples were homogenized at Test Facility, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/54/2024), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18 oC until beginning of analysis.

- Extraction

5 g of the sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile and 10 mL of deionized water was added together with 50 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogen citrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18 oC for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.3 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples as well as control and fortified samples was performed on 24.10.2024. After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.
Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence. The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 24.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed, sample blank	<LOD	-
OSR seed, PK1 0,010 mg-kg	0.010	103.2
OSR seed, PK1 0,10 mg-kg	0.10	100.0
OSR seed, PK2 0,010 mg-kg	0.010	100.1
OSR seed, PK2 0,10 mg-kg	0.10	103.2
OSR seed, cal 100 ppb'	0.10	-

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure. 24.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 608 minutes (10.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.3.1.2 Study 2

Comments of zRMS:	The study was conducted according to relevant guidances, and GLP requirements and in line with the requested GAP. Study is

	accepted. The objective of the study was to determine the residue level of chlorantraniliprole in oilseed rape in one harvest study trial following two applications of the formulated product CLOROL 200 SC. Two applications of CLOROL 200 SC were performed at the target dose rate of 40 g of chlorantraniliprole at BBCH 65 and 71. The residue concentration detected was 0.012 mg/kg (much below of the current MRL in rape seed – 2.0 mg/kg).

Reference:	KCA 6.3
Report	Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one harvest study trial in Denmark - 2024; Peda Tomasz, SGS Polska Sp. z o.o., Study numer: 24SGS34
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997; OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021); SANTE/2020/12830 Rev.2, 14 February 2023;
Deviations:	No
GLP:	Yes
Acceptability:	YES

Materials and methods

- Test Item:

Name		CLOROL 200 SC
Trade name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		chlorantraniliprole
CAS Number		500008-45-7
Formulation Type		SC
Formulation Name		Suspension Concentrate
Main uses		Insecticide
Content of a.s.	nominal	20 % w/v
	analyzed	19,9 % w/v
Density analyzed :		1,0908 g/cm^3
Certificate of Analysis dated:		17/10/2023
Expiry date		05/2025

- Test System:

Crop	Oil seed rape (*Brassica napus*)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex alimentarius: SO 0088
RACs harvested	Seeds

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed only with water. The target dose rate of test item was 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Target water volume was 200-300 l/ha according to Good Agricultural Practice.

- Field Phase:

Harvest study trial (HS) was established in Denmark. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the
crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.
Two typical for insecticide applications of CLOROL 200 SC were performed with boom sprayer on the treated plot at the target dose rate of 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Spray volume was 200-300 l/ha according to Good Agricultural Practice.
Reported dose rates:
Application 1: 0,191 l/ha of test item; 238,33 l/ha of water.
Application 2: 0,208 l/ha of test item; 260 l/ha of water.
Applications were performed at:
Application 1: BBCH 67
Application 2: BBCH 71
Remaining spray mixture after application was measured and the volume applied to the treated
plot was calculated to verify the delivery rate. Deviations from the target rate were:
Application 1: -4,4%
Application 2: +4%
RAC specimens for analyses were collected:
S1 (Seeds) BBCH89 / CH

Table 1 Identification of the field trial

Trial number	Study type	Zone	Country (region)	Trial site	Postal code	GPS coordinates
24SGS34-01	HS	North Europe	Denmark (Syddanmark)	Sonderborg	6400	N 54.972509 E 9.652119

Table 2 Test system information

Crop	Variety	Sowing date	Row spacing [cm]	Plant spacing [cm]	Crop density	Main Flowering Date	Commercial Harvest Date
Oilseed rape	DK Expose	15/08/2023	12,5	-	35 seeds/m^2	12/05/2024 – 24/05/2024	25/07/2024

Table 3 Soil characterisation

Soil texture	Organic matter content (%)	pH ($CaCl_2$)
Loamy sand	2,4	6,4

Table 4 Source of trial weather data

Air temperature and precipitation			
Current year		Historical data – average from past 5 years	
Source of data	Distance to field site (km)	Source of data	Distance to field site (km)
Felsted-Aabenraa [6200]	5,7	Felsted-Aabenraa [6200]	4,7

Table 5 Temperature data

Month	Current year		Historical data – average from past 5 years	
	Average minimum air temperature (°C)	Average maximum air temperature (°C)	Average minimum air temperature (°C)	Average maximum air temperature (°C)
May	10,3	20,3	5,7	15,4
June	10,4	19,5	11,1	21,2
July	12,2	21,9	12,3	22

Table 6 Rainfall data

Month	Rainfall (mm)	
	Current year	Historical data - average from past 5 years
May	141,2	38
June	206,1	52,2
July	185	54,3

Table 7 Experimental design

Plot ID	Plot width [m]	Plot length [m]	Plot area [m²]	Slope [%]	Distance between plots [m]
U, T	3	10	30	0	20

Table 8 Application equipment data

Trial number	Application Number	Sprayer Configuration	Nozzle Brand	Number of Nozzles	Nozzle Spacing [cm]
24SGS34-01	A1	Boom Sprayer	IDK 120-02	6	50
	A2	Boom Sprayer	IDK 120-02	6	50

Table 9 Application data

Application number	Date	Time	BBCH	Actual rate of test item (l/ha)	Actual rate a.s. (g /ha)	Deviation (%)	Spray volume (l/ha)	Treated area (m²)	Spray mixture (g)	Test item (g)	Spray mixture remaining (g)	Spray mixture applied (g)
A1	14/05/2024	09:18	67	0,191	38	-4,4	238,33	30	2000	1,747	1285	715
A2	27/05/2024	08:35	71	0,208	42	4	260	30	2000	1,745	1220	780

Table 10 Environmental conditions at application

Application number	Foliage moisture	Soil moisture	Soil temperature at 10 depth (°C)	Air temperature (°C)	Relative humidity (%)	Cloud cover (%)	Wind speed (m/s)	Wind direction (origin)	Rainfall within 3 hours
A1	Dry	Moist	13,2	14,7	70	0	2	E	0
A2	Dry	Moist	15,8	16,1	78	60	1,8	W	0

Table 11 Cultivation practices

Date	Operation type	Equipment
20/08/2023	Deep work	Plough

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	BBCH 89 / CH	24SGS34-01 1	oilseed rape (seeds)	DPL/53/2024/01U	< LOD
2		24SGS34-01 2	oilseed rape (seeds)	DPL/53/2024/02T	0.012

BBCH – according to BBCH scale; CH – commercial harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Results:

Conclusions

This study was fully performed as anticipated, in accordance with the study plan and the amendment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s). The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70-120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seeds). There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of chlorantraniliprole in oilseed rape (seeds) meets the criteria of SANTE/2020/12830, Rev. 2 guidelines in terms of precision, accuracy and uncertainty.

Analytical phase:

- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in oilseed rape RAC (seeds) following two applications of CLOROL 200 SC.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in oilseed rape (seeds) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.

ANALYTICAL PROCEDURE DPL-84 Determination of residues of Chlorantraniliprole in oilseed rape (seed, plant) using QuEChERS method and LC-MS/MS tandem mass spectrometry, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC-and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method.

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18ºC before analysis. After removal from the freezer the samples were homogenized at Test Facility, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/53/2024), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18ºC until beginning of analysis.

- Extraction

5 g of the sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile and 10 mL of deionized water was added together with 50 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogen citrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18ºC for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.3 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples as well as control and fortified samples was performed on 24.10.2024. After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.
Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence. The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 24.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed, sample blank	<LOD	-
OSR seed, PK1 0,010 mg-kg	0.010	103.2
OSR seed, PK1 0,10 mg-kg	0.10	100.0
OSR seed, PK2 0,010 mg-kg	0.010	100.1
OSR seed, PK2 0,10 mg-kg	0.10	103.2
OSR seed, cal 100 ppb'	0.10	-

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure. 24.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 608 minutes (10.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.3.1.3 Study 3

Comments of zRMS:	The study was conducted according to relevant guidances, and GLP require-ments and in line with the requested GAP. Study

	is accepted. The objective of the study was to determine the residue level of chlorantraniliprole in oilseed rape in one harvest study trial following two applications of the formulated product CLOROL 200 SC. Two applications of CLOROL 200 SC were performed at the target dose rate of 40 g of chlorantraniliprole at BBCH 65 and 71. The residue concentration detected was 0.066 mg/kg (much below of the cur-rent MRL in rape seed – 2.0 mg/kg).

Reference:	KCA 6.3
Report	Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one harvest study trial in Poland - 2024; Peda Tomasz, SGS Polska Sp. z o.o., Study numer: 24SGS37
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997; OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021); SANTE/2020/12830 Rev.2, 14 February 2023;
Deviations:	No
GLP:	Yes
Acceptability:	YES

Materials and methods

- Test Item:

Name		CLOROL 200 SC
Trade name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		chlorantraniliprole
CAS Number		500008-45-7
Formulation Type		SC
Formulation Name		Suspension Concentrate
Main uses		Insecticide
Content of a.s.	nominal	20 % w/v
	analyzed	19,9 % w/v
Density analyzed :		1,0908 g/cm^3
Certificate of Analysis dated:		17/10/2023
Expiry date		05/2025

- Test System:

Crop	Oil seed rape (*Brassica napus*)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex alimentarius: SO 0088
RACs harvested	Seeds

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed only with water. The target dose rate of test item was 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Target water volume was 200-300 l/ha according to Good Agricultural Practice.

- Field Phase:

Harvest study trial (HS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study. Two typical for insecticide applications of CLOROL 200 SC were performed with boom sprayer on the treated plot at the target dose rate of 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Spray volume was 200-300 l/ha according to Good Agricultural Practice.
Reported dose rates:
Application 1: 0,194 l/ha; 290,7 l/ha water.
Application 2: 0,205 l/ha; 307 l/ha water.
Applications were performed at:
Application 1: BBCH 65
Application 2: BBCH 71
Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify the delivery rate. Deviations from the target rate were:
Application 1: -3%
Application 2: +2,5%
RAC specimens for analyses were collected:
S1 (Seeds) BBCH89 / CH

Table 1 Identification of the field trial

Trial number	Study type	Zone	Country (region)	Trial site	Postal code	GPS coordinates
24SGS37-01	HS	Northern Europe	Poland (Kujawsko-pomorskie)	Kolonia Bodzanowska	87-707	N 52°43'04,1" E 18°39'33,8"

Table 2 Test system information

Crop	Variety	Sowing date	Row spacing [cm]	Plant spacing [cm]	Crop density [/ha]	Main Flowering Date	Commercial Harvest Date
Oilseed rape	Chopin	23/08/2023	25	NAP	3,5 kg	28/04/2024 – 18/05/2024	16/07/2024

Table 3 Soil characterisation

Soil texture	Organic matter content (%)	pH (KCl)
Sandy loam	2,8	6,7

Table 4 Source of trial weather data

Air temperature and precipitation			
Current year		Historical data – average from past 5 years	
Source of data	Distance to field site (km)	Source of data	Distance to field site (km)
Zakrzewo [87-707]	5	Zakrzewo [87-707]	5

Table 5 Temperature data

Month	Current year		Historical data – average from past 5 years	
	Average minimum air temperature (°C)	Average maximum air temperature (°C)	Average minimum air temperature (°C)	Average maximum air temperature (°C)
May	10,3	21,5	12,2	16,2
June	12,7	22,5	19,5	23,8
July	14,7	24,6	19,2	23,2

Table 6 Rainfall data

Month	Rainfall (mm)	
	Current year	Historical data - average from past 5 years
May	44,2	32,3
June	89,9	30,9
July	74,7	20,4

Table 7 Experimental design

Plot ID	Plot width [m]	Plot length [m]	Plot area [m²]	Slope [%]	Distance between plots [m]
U, T	3	10	30	0	20

Table 8 Application equipment data

Application Number	Sprayer Configuration	Nozzle Brand	Number of Nozzles	Nozzle Spacing [cm]
A1	Boom Sprayer	TeeJet AIXR 11002	6	50
A2	Boom Sprayer	TeeJet AIXR 11002	6	50

Table 9 Application data

Application number	Date	Time	BBCH	Actual rate of test item (l/ha)	Actual rate a.s. (g /ha)	Deviation (%)	Spray volume (l/ha)	Treated area (m²)	Spray mixture (g)	Test item (g)	Spray mixture remaining (g)	Spray mixture applied (g)
A1	06/05/2024	06:20	65	0,194	39	-3,0	290,7	30	1400	1,018	528	872
A2	20/05/2024	16:22	71	0,205	41	+2,5	307	30	1400	1,018	479	921

Table 10 Environmental conditions at application

Application number	Foliage moisture	Soil moisture	Soil temperature at 10 depth (°C)	Air temperature (°C)	Relative humidity (%)	Cloud cover (%)	Wind speed (m/s)	Wind direction (origin)	Rainfall within 3 hours
A1	Dry	Dry	12	10,1	69,2	50	0,6	NE	0
A2	Dry	Moist	14	16,5	85,5	60	0,9	E	0

Table 11 Cultivation practices

Date	Operation type	Equipment
20/08/2023	Deep work	Plough
23/08/2023	Superficial work	Field cultivator

Results:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	BBCH 89 / CH	24SGS37-01 1	oilseed rape (seeds)	DPL/56/2024/01U	< LOD
2		24SGS37-01 2	oilseed rape (seeds)	DPL/56/2024/02T	0.066

BBCH – according to BBCH scale; CH – commercial harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Conclusions

This study was fully performed as anticipated, in accordance with the study plan and the amendment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s). The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70-120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seeds). There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of chlorantraniliprole in oilseed rape (seeds) meets the criteria of SANTE/2020/12830, Rev. 2 guidelines in terms of precision, accuracy and uncertainty.

Analytical phase:

- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in oilseed rape RAC (seeds) following two applications of CLOROL 200 SC.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in oilseed rape (seeds) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.

ANALYTICAL PROCEDURE DPL-84 Determination of residues of Chlorantraniliprole in oilseed rape (seed, plant) using QuEChERS method and LC-MS/MS tandem mass spectrometry, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC-and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method.

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18ºC before analysis. After removal from the freezer the samples were homogenized at Test Facility, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/56/2024), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18ºC until beginning of analysis.

- Extraction

5 g of the sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile and 10 mL of deionized water was added together with 50 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogen citrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18ºC for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.3 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples as well as control and fortified samples was performed on 24.10.2024. After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.
Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence. The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 24.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed, sample blank	<LOD	-
OSR seed, PK1 0,010 mg-kg	0.010	103.2
OSR seed, PK1 0,10 mg-kg	0.10	100.0
OSR seed, PK2 0,010 mg-kg	0.010	100.1
OSR seed, PK2 0,10 mg-kg	0.10	103.2
OSR seed, cal 100 ppb'	0.10	-

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure. 24.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 608 minutes (10.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.3.1.4 Study 4

Comments of zRMS:	The study was conducted according to relevant guidances, and GLP requirements and in line with the requested GAP. Study is

	accepted. The objective of the study was to determine the residue level of chlorantraniliprole in oilseed rape in one decline study trial following two applications of the formulated product CLOROL 200 SC. Two applications of CLOROL 200 SC were performed at the target dose rate of 40 g of chlorantraniliprole at BBCH 67 and 71. The residue concentration detected was <LOQ mg/kg in rape seeds.

Reference:	KCA 6.3
Report	Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one decline curve study trial in Hungary - 2024; Peda Tomasz, SGS Polska Sp. z o.o., Study numer: 24SGS41
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997; OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021); SANTE/2020/12830 Rev.2, 14 February 2023;
Deviations:	No
GLP:	Yes
Acceptability:	YES

Materials and methods

- Test Item:

Name		CLOROL 200 SC
Trade name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		chlorantraniliprole
CAS Number		500008-45-7
Formulation Type		SC
Formulation Name		Suspension Concentrate
Main uses		Insecticide
Content of a.s.	nominal	20 % w/v
	analyzed	19,9 % w/v
Density analyzed :		1,0908 g/cm^3
Certificate of Analysis dated:		17/10/2023
Expiry date		05/2025

- Test System:

Crop	Oil seed rape (*Brassica napus*)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex alimentarius: SO 0088
RACs harvested	Seeds

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed only with water. The target dose rate of test item was 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Target water volume was 200-300 l/ha according to Good Agricultural Practice.

- Field Phase:

Decline curve study (DCS) was established in Hungary. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the
crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study. Two typical for insecticide applications of CLOROL 200 SC were performed with boom sprayer on the treated plot at the target dose rate of 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Spray volume was 200-300 l/ha according to Good Agricultural Practice.
Reported dose rates:
Application 1: 0,198 l/ha; 296,7 l/ha water.
Application 2: 0,197 l/ha; 295 l/ha water.
Applications were performed at:
Application 1: BBCH 67
Application 2: BBCH 71
Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify the delivery rate. Deviations from the target rate were:
Application 1: -1%
Application 2: -1,6%
RAC specimens for analyses were collected according to schedule:
S1 (Whole plant without root) - 0 DALA
S2 (Whole plant without root) - 7 DALA
S3 (Whole plant without root) - DALA
S4 (Whole plant without root) - 21 DALA
S5 (Seeds) BBCH 89 / CH

Table 1 Identification of the field trial

Trial number	Study type	Zone	Country (region)	Trial site	Postal code	GPS coordinates
24SGS41-01	DCS	Northern Europe	Hungary (Szabolcs-szatmár-bereg)	Nyiregyhaza	H-4445	N 47°57'38,3" E 21°32'17,5"

Table 2 Test system information

Crop	Variety	Sowing date	Row spacing [cm]	Plant spacing [cm]	Crop density [/ha]	Main Flowering Date	Commercial Harvest Date
Oilseed rape	Duplo	06/09/2023	30	8,13	410 000 plants	05/04/2024 – 05/05/2024	16/07/2024

Table 3 Soil characterisation

Soil texture	Organic matter content (%)	pH (water)
Silty clay loam	2,08	7,22

Table 4 Source of trial weather data

Air temperature and precipitation			
Current year		Historical data – average from past 5 years	
Source of data	Distance to field site (km)	Source of data	Distance to field site (km)
Nyírtelek [H-4461]	9	Nyírtelek [H-4461]	9

Table 5 Temperature data

Month	Current year		Historical data – average from past 5 years	
	Average minimum air temperature (°C)	Average maximum air temperature (°C)	Average minimum air temperature (°C)	Average maximum air temperature (°C)
April	6,5	21,3	3,6	17
May	10,6	25,4	9	22
June	15,1	27,8	14,7	28,4
July	16,6	31,9	15,5	29,4

Table 6 Rainfall data

Month	Rainfall (mm)	
	Current year	Historical data - average from past 5 years
April	15,1	34,7
May	38,4	49,1
June	140,4	95,4
July	3,4	57,3

Table 7 Experimental design

Plot ID	Plot width [m]	Plot length [m]	Plot area [m²]	Slope [%]	Distance between plots [m]
U, T	3	20	60	1	20

Table 8 Application equipment data

Application Number	Sprayer Configuration	Nozzle Brand	Number of Nozzles	Nozzle Spacing [cm]
A1	Boom Sprayer	AIRMIX 110-04	6	50
A2	Boom Sprayer	AIRMIX 110-04	6	50

Table 9 Application data

Application number	Date	Time	BBCH	Actual rate of test item (l/ha)	Actual rate a.s. (g /ha)	Deviation (%)	Spray volume (l/ha)	Treated area (m²)	Spray mixture (g)	Test item (g)	Spray mixture remaining (g)	Spray mixture applied (g)
A1	23/04/2024	14:32	67	0,198	40	-1	296,7	60	3000	2,183	1220	1780
A2	07/05/2024	11:16	71	0,197	39	-1,6	295	60	3000	2,182	1230	1770

Table 10 Environmental conditions at application

Application number	Foliage moisture	Soil moisture	Soil temperature at 10 depth (°C)	Air temperature (°C)	Relative humidity (%)	Cloud cover (%)	Wind speed (m/s)	Wind direction (origin)	Rainfall within 3 hours
A1	Dry	Moist	18	21,4	41	20	2,4	N	0
A2	Dry	Dry	17,8	22,4	31	25	0,8	NE	0

Table 11 Cultivation practices

Date	Operation type	Equipment
17/08/2023	Deep work	Chisel plough
01/09/2023	Superficial work	Field cultivator

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	0 DALA	24SGS41-01 1	oilseed rape (whole plant without root)	DPL/60/2024/01U	< LOD
2		24SGS41-01 2	oilseed rape (whole plant without root)	DPL/60/2024/02T	0.70
3	7 DALA	24SGS41-01 3	oilseed rape (whole plant without root)	DPL/60/2024/03T	0.50
4	14 (±1) DALA	24SGS41-01 4	oilseed rape (whole plant without root)	DPL/60/2024/04T	0.42
5	21 (±1) DALA	24SGS41-01 5	oilseed rape (whole plant without root)	DPL/60/2024/05T	0.26
6	BBCH 89 / CH	24SGS41-01 6	oilseed rape (seeds)	DPL/60/2024/06U	< LOD
7		24SGS41-01 7	oilseed rape (seeds)	DPL/60/2024/07T	< LOQ

DALA – days after last application; BBCH – according to BBCH scale; CH – commercial harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,

Results: **LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg**

Conclusions

This study was fully performed as anticipated, in accordance with the study plan and the amendment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s). The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70-120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seeds). There were no interfering signals at retention time of analyzed compound in exam-

ined control matrix. The analytical method for determining the residues of chlorantraniliprole in oilseed rape (seeds) meets the criteria of SANTE/2020/12830, Rev. 2 guidelines in terms of precision, accuracy and uncertainty.
Analytical phase:

- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in oilseed rape RAC (seeds) following two applications of CLOROL 200 SC.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in oilseed rape (whole plant without root, seeds) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-84 *Determination of residues of Chlorantraniliprole in oilseed rape (seed, plant) using QuEChERS method and LC-MS/MS tandem mass spectrometry*, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC-and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method.

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18ºC before analysis. After removal from the freezer the samples were homogenized at Test Facility, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/60/2024), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18ºC until beginning of analysis.

- Extraction

5 g of the sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile and 10 mL of deionized water was added together with 50 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogen citrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18ºC for 1.5 h. After that, the extract (organic phase) was fil-

tered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.3 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples as well as control and fortified samples was performed on 24.10.2024. After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence. The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 24.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed, sample blank	<LOD	-
OSR seed, PK1 0,010 mg-kg	0.010	103.2
OSR seed, PK1 0,10 mg-kg	0.10	100.0
OSR seed, PK2 0,010 mg-kg	0.010	100.1
OSR seed, PK2 0,10 mg-kg	0.10	103.2
OSR seed, cal 100 ppb'	0.10	-

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 25.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant, sample blank	< LOD	-
OSR plant, PK1 0,010 mg-kg	0.011	111.3
OSR plant, PK1 0,10 mg-kg	0.11	106.2
OSR plant, PK2 0,010 mg-kg	0.011	108.5
OSR plant, PK2 0,10 mg-kg	0.10	103.5
OSR plant, cal 100 ppb'	0.11	-

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 28.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant, sample blank	< LOD	-
OSR plant, PK1 0,010 mg-kg	0.010	101.5
OSR plant, PK1 0,10 mg-kg	0.10	100.6
OSR plant, PK2 0,010 mg-kg	0.011	106.6
OSR plant, PK2 0,10 mg-kg	0.10	102.8
OSR plant, cal 100 ppb'	0.10	-

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure.
24.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 608 minutes (10.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
25.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 684 minutes (11.4 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
28.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 513 minutes (8.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
Extract stability is not considered to be an issue, since working standard that were used for quantification
were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.3.1.5 Study 5

Comments of zRMS:	The study was conducted according to relevant guidances, and GLP requirements and in line with the requested GAP. Study is accepted. The objective of the study was to determine the residue level of chlorantraniliprole in oilseed rape in one harvest study trial following two applications of the formulated product CLOROL 200 SC. Two applications of CLOROL 200 SC were performed at the target dose rate of 40 g of chlorantraniliprole at BBCH 67 and 71. The residue concentration detected was <LOQ in rape seeds.

Reference:	KCA 6.3
Report	Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one harvest study trial in Hungary - 2024; Peda Tomasz, SGS Polska Sp. z o.o., Study numer: 24SGS36
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997; OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021); SANTE/2020/12830 Rev.2, 14 February 2023;
Deviations:	No
GLP:	Yes
Acceptability:	YES

Materials and methods

- Test Item:

Name		CLOROL 200 SC
Trade name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		chlorantraniliprole
CAS Number		500008-45-7
Formulation Type		SC
Formulation Name		Suspension Concentrate
Main uses		Insecticide
Content of a.s.	nominal	20 % w/v
	analyzed	19,9 % w/v
Density analyzed :		1,0908 g/cm^3
Certificate of Analysis dated:		17/10/2023
Expiry date		05/2025

- Test System:

Crop	Oil seed rape (*Brassica napus*)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex alimentarius: SO 0088
RACs harvested	Seeds

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed only with water. The target dose rate of test item was 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Target water volume was 200-300 l/ha according to Good Agricultural Practice.

- Field Phase:

Harvest study trial (HS) was established in Hungary. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the
crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study. Two typical for insecticide applications of CLOROL 200 SC were performed with boom sprayer on the treated plot at the target dose rate of 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Spray volume was 200-300 l/ha according to Good Agricultural Practice.
Reported dose rates:
Application 1: 0,205 l/ha; 308,3 l/ha water.
Application 2: 0,198 l/ha; 296,7 l/ha water.
Applications were performed at:
Application 1: BBCH 67
Application 2: BBCH 71
Remaining spray mixture after application was measured and the volume applied to the treated
plot was calculated to verify the delivery rate. Deviations from the target rate were:
Application 1: +2,7%
Application 2: -1,1%
RAC specimens for analyses were collected:
S1 (Seeds) BBCH89 /CH

Table 1 Identification of the field trial

Trial number	Study type	Zone	Country (region)	Trial site	Postal code	GPS coordinates
24SGS36-01	HS	Northern Europe	Hungary (Borsod-Abaúj-Zemplén)	Monok	H-3905	N 48°12'26,2" E 21°11'02,4"

Table 2 Test system information

Crop	Variety	Sowing date	Row spacing [cm]	Plant spacing [cm]	Crop density [/ha]	Main Flowering Date	Commercial Harvest Date
Oilseed rape	DK Excited	27/08/2023	30	9,5	350 000 seeds	15/04/2024 – 10/05/2024	16/07/2024

Table 3 Soil characterisation

Soil texture	Organic matter content (%)	pH (water)
Silty clay	2,88	5,05

Table 4 Source of trial weather data

Air temperature and precipitation			
Current year		Historical data – average from past 5 years	
Source of data	Distance to field site (km)	Source of data	Distance to field site (km)
Edeleny [H-3780]	30	Edeleny [H-3780]	30

Table 5 Temperature data

Month	Current year		Historical data – average from past 5 years	
	Average minimum air temperature (°C)	Average maximum air temperature (°C)	Average minimum air temperature (°C)	Average maximum air temperature (°C)
April	6,2	20	3,4	17
May	9,3	24,3	8,4	21,4
June	15	26	14,3	27,9
July	16,3	30,9	15,5	29,2

Table 6 Rainfall data

Month	Rainfall (mm)	
	Current year	Historical data - average from past 5 years
April	27,8	48,9
May	36,3	63,3
June	142,4	75,5
July	20,6	58,3

Table 7 Experimental design

Plot ID	Plot width [m]	Plot length [m]	Plot area [m²]	Slope [%]	Distance between plots [m]
U, T	3	10	30	0	20

Table 8 Application equipment data

Application Number	Sprayer Configuration	Nozzle Brand	Number of Nozzles	Nozzle Spacing [cm]
A1	Boom Sprayer	AIRMIX 110-04	6	50
A2	Boom Sprayer	AIRMIX 110-04	6	50

Table 9 Application data

Application number	Date	Time	BBCH	Actual rate of test item (l/ha)	Actual rate a.s. (g /ha)	Deviation (%)	Spray volume (l/ha)	Treated area (m²)	Spray mixture (g)	Test item (g)	Spray mixture remaining (g)	Spray mixture applied (g)
A1	29/04/2024	09:55	67	0,205	41	+2,7	308,3	30	2000	1,454	1075	925
A2	13/05/2024	10:27	71	0,198	40	-1,1	296,7	30	2000	1,454	1110	890

Table 10 Environmental conditions at application

Application number	Foliage moisture	Soil moisture	Soil temperature at 10 depth (°C)	Air temperature (°C)	Relative humidity (%)	Cloud cover (%)	Wind speed (m/s)	Wind direction (origin)	Rainfall within 3 hours
A1	Dry	Dry	19,2	20,5	39	10	1,3	E	0
A2	Dry	Dry	14,2	18,7	34	10	0,6	E	0

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	BBCH 89 / CH	24SGS36-01 1	oilseed rape (seeds)	DPL/55/2024/01U	< LOD
2		24SGS36-01 2	oilseed rape (seeds)	DPL/55/2024/02T	< LOQ

BBCH – according to BBCH scale; CH – commercial harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Results:
Conclusions
The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70–120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seeds).
There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of chlorantraniliprole in oilseed rape (seeds) meets the criteria of SANTE/2020/12830, Rev. 2 guidelines in terms of precision, accuracy and uncertainty.

Analytical phase:

- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in OSR (seeds) following two applications of CLOROL 200 SC.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in oilseed rape (seeds) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-84 *Determination of residues of Chlorantraniliprole in oilseed rape (seed, plant) using QuEChERS method and LC-MS/MS tandem mass spectrometry*, based on:

EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC-and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method.

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18ºC before analysis. After removal from the freezer the samples were homogenized at Test Facility, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/55/2024), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18ºC until beginning of analysis.

- Extraction

5 g of the sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile and 10 mL of deionized water was added together with 50 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogen citrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18ºC for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.3 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples as well as control and fortified samples was performed on 24.10.2024. After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.
Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence. The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 24.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed, sample blank	<LOD	-
OSR seed, PK1 0,010 mg-kg	0.010	103.2
OSR seed, PK1 0,10 mg-kg	0.10	100.0
OSR seed, PK2 0,010 mg-kg	0.010	100.1
OSR seed, PK2 0,10 mg-kg	0.10	103.2
OSR seed, cal 100 ppb'	0.10	-

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure.
24.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 608 minutes (10.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.3.1.6 Study 6

Comments of zRMS:	The study was conducted according to relevant guidances, and GLP requirements and in line with the requested GAP. Study is accepted. The objective of the study was to determine the residue level of chlorantraniliprole in oilseed rape in one decline study trial following two applications of the formulated product CLOROL 200 SC. Two applications of CLOROL 200 SC were performed at the target dose rate of 40 g of chlorantraniliprole at BBCH 65/67 and 71. The residue concentration detected was 0.026 mg/kg in rape seeds (MRL=2.0 mg/kg).

Reference:	KCA 6.3
Report	Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one decline curve study trial in Germany - 2024; Peda Tomasz, SGS Polska Sp. z o.o., Study number: 24SGS40
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997; OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021); SANTE/2020/12830 Rev.2, 14 February 2023;
Deviations:	No
GLP:	Yes
Acceptability:	YES

Materials and methods

- Test Item:

Name		CLOROL 200 SC
Trade name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		chlorantraniliprole
CAS Number		500008-45-7
Formulation Type		SC
Formulation Name		Suspension Concentrate
Main uses		Insecticide
Content of a.s.	nominal	20 % w/v
	analyzed	19,9 % w/v
Density analyzed :		1,0908 g/cm^3
Certificate of Analysis dated:		17/10/2023
Expiry date		05/2025

- Test System:

Crop	Oil seed rape (*Brassica napus*)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex alimentarius: SO 0088
RACs harvested	Seeds

- Application equipment:

The application equipment consisted of boom sprayer.

The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed only with water. The target dose rate of test item was 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Target water volume was 200-300 l/ha according to Good Agricultural Practice.

- Field Phase:

Decline curve study trial (DCS) was established in Germany. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study. Two typical for insecticide applications of CLOROL 200 SC were performed with boom sprayer on the treated plot at the target dose rate of 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Spray volume was 200-300 l/ha according to Good Agricultural Practice.
Reported dose rates:
Application 1: 0,218 l/ha test item; 217,78 l/ha water.
Application 2: 0,198 l/ha test item; 197,78 l/ha water.
Applications were performed at:
Application 1: BBCH 65-67
Application 2: BBCH 71
Remaining spray mixture after application was measured and the volume applied to the treated
plot was calculated to verify the delivery rate. Deviations from the target rate:
Application 1: +9,1%
Application 2: -0,9%
RAC specimens for analyses were collected:
S1 (Whole plant without root) 0 DALA
S2 (Whole plant without root) 7 DALA
S3 (Whole plant without root) – 14 (±1) DALA
S4 (Whole plant without root) – 21 (±1) DALA
S5 (Seeds) BBCH89 / CH

Table 1 Identification of the field trial

Trial number	Study type	Zone	Country (region)	Trial site	Postal code	GPS coordinates
24SGS40-01	DCS	Northern Europe	Germany (Schleswig-Holstein)	Galmsbull	25899	N 54.766954 E 8.735345

Table 2 Test system information

Crop	Variety	Sowing date	Row spacing [cm]	Plant spacing [cm]	Crop density	Main Flowering Date	Commercial Harvest Date
Oilseed rape	Architect	31/08/2023	12,5	NAP	45 seeds/m^2	05/05/2024 – 22/05/2024	20/07/2024

Table 3 Soil characterisation

Soil texture	Organic matter content (%)	pH ($CaCl_2$)
Loam	2,5	6,6

Table 4 Source of trial weather data

Air temperature and precipitation			
Current year		Historical data – average from past 5 years	
Source of data	Distance to field site (km)	Source of data	Distance to field site (km)
Niebull [25899]	3,6	Husum Schobull [25813]	30

Table 5 Temperature data

Month	Current year		Historical data – average from past 5 years	
	Average minimum air temperature (°C)	Average maximum air temperature (°C)	Average minimum air temperature (°C)	Average maximum air temperature (°C)
May	11,2	20,9	6,4	15,1
June	14	23,3	11,2	21,6
July	13,8	21,6	12,7	21

Table 6 Rainfall data

Month	Rainfall (mm)	
	Current year	Historical data - average from past 5 years
May	56,6	63,8
June	17,2	62,2
July	107,4	71,9

Table 7 Experimental design

Plot ID	Plot width [m]	Plot length [m]	Plot area [m²]	Slope [%]	Distance between plots [m]
U, T	3	15	45	0	20

Table 8 Application equipment data

Application Number	Sprayer Configuration	Nozzle Brand	Number of Nozzles	Nozzle Spacing [cm]
A1	Boom Sprayer	IDK 120-02	6	50
A2	Boom Sprayer	IDK 120-02	6	50

Table 9 Application data

Application number	Date	Time	BBCH	Actual rate of test item (l/ha)	Actual rate a.s. (g /ha)	Deviation (%)	Spray volume (l/ha)	Treated area (m²)	Spray mixture (g)	Test item (g)	Spray mixture remaining (g)	Spray mixture applied (g)
A1	14/05/2024	11:02	65-67	0,218	44	+9,1	217,78	45	2000	2,183	1020	980
A2	27/05/2024	12:08	71	0,198	40	-0,9	197,78	45	2000	2,182	1110	890

Table 10 Environmental conditions at application

Application number	Foliage moisture	Soil moisture	Soil temperature at 10 depth (°C)	Air temperature (°C)	Relative humidity (%)	Cloud cover (%)	Wind speed (m/s)	Wind direction (origin)	Rainfall within 3 hours
A1	Dry	Dry	14,8	20,6	61	0	1,8	E	0
A2	Dry	Moist	17,2	21,2	78	40	2,7	W	0

Table 11 Cultivation practices

Date	Operation type	Equipment
26/08/2023	Deep work	Plough

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	0 DALA	24SGS40-01 1	oilseed rape (whole plant without root)	DPL/59/2024/01U	< LOD
2		24SGS40-01 2	oilseed rape (whole plant without root)	DPL/59/2024/02T	0.63
3	7 DALA	24SGS40-01 3	oilseed rape (whole plant without root)	DPL/59/2024/03T	0.20
4	14 (±1) DALA	24SGS40-01 4	oilseed rape (whole plant without root)	DPL/59/2024/04T	0.12
5	21 (±1) DALA	24SGS40-01 5	oilseed rape (whole plant without root)	DPL/59/2024/05T	0.16
6	BBCH 89 / CH	24SGS40-01 6	oilseed rape (seeds)	DPL/59/2024/06U	< LOD
7		24SGS40-01 7	oilseed rape (seeds)	DPL/59/2024/07T	0.026

DALA – days after last application; BBCH – according to BBCH scale; CH – commercial harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Results:

Conclusions

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70–120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seeds).

There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of chlorantraniliprole in oilseed rape (seeds) meets the criteria of SANTE/2020/12830, Rev. 2 guidelines in terms of precision, accuracy and uncertainty.

Analytical phase:

- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in OSR (whole plant without root, seeds), following two applications of CLOROL 200 SC.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in oilseed rape (whole plant without root, seeds) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-84 *Determination of residues of Chlorantraniliprole in oilseed rape (seed, plant) using QuEChERS method and LC-MS/MS tandem mass spectrometry*, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC-and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method.

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18ºC before analysis. After removal from the freezer the samples were homogenized at Test Facility, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/59/2024), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18ºC until beginning of analysis.

- Extraction

5 g of the sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile and 10 mL of deionized water was added together with 50 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogen citrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18ºC for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.3 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples as well as control and fortified samples was performed on 24.10.2024. After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.
Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence. The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 24.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed, sample blank	<LOD	-
OSR seed, PK1 0,010 mg-kg	0.010	103.2
OSR seed, PK1 0,10 mg-kg	0.10	100.0
OSR seed, PK2 0,010 mg-kg	0.010	100.1
OSR seed, PK2 0,10 mg-kg	0.10	103.2
OSR seed, cal 100 ppb'	0.10	-

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 25.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant, sample blank	< LOD	-
OSR plant, PK1 0,010 mg-kg	0.011	111.3
OSR plant, PK1 0,10 mg-kg	0.11	106.2
OSR plant, PK2 0,010 mg-kg	0.011	108.5
OSR plant, PK2 0,10 mg-kg	0.10	103.5
OSR plant, cal 100 ppb'	0.11	-

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 28.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant, sample blank	< LOD	-
OSR plant, PK1 0,010 mg-kg	0.010	101.5
OSR plant, PK1 0,10 mg-kg	0.10	100.6
OSR plant, PK2 0,010 mg-kg	0.011	106.6
OSR plant, PK2 0,10 mg-kg	0.10	102.8
OSR plant, cal 100 ppb'	0.10	-

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure.
24.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 608 minutes (10.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
25.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 684 minutes (11.4 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
28.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 513 minutes (8.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
Extract stability is not considered to be an issue, since working standard that were used for quantification
were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.3.1.7 Study 7

Comments of zRMS:	The study was conducted according to relevant guidances, and GLP requirements and in line with the requested GAP. Study is accepted. The objective of the study was to determine the residue level of chlorantraniliprole in oilseed rape in one decline study trial following two applications of the formulated product CLOROL 200 SC. Two applications of CLOROL 200 SC were performed at the target dose rate of 40 g of chlorantraniliprole at BBCH 65 and 71. The residue concentration detected was <LOQ in rape seeds.

Reference:	KCA 6.3
Report	Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 SC one decline curve study trial in Poland - 2024; Peda Tomasz, SGS Polska Sp. z o.o., Study numer: 24SGS38
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997; OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021); SANTE/2020/12830 Rev.2, 14 February 2023;
Deviations:	No
GLP:	Yes
Acceptability:	YES

Materials and methods

- Test Item:

Name		CLOROL 200 SC
Trade name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		chlorantraniliprole
CAS Number		500008-45-7
Formulation Type		SC
Formulation Name		Suspension Concentrate
Main uses		Insecticide
Content of a.s.	nominal	20 % w/v
	analyzed	19,9 % w/v
Density analyzed :		1,0908 g/cm^3
Certificate of Analysis dated:		17/10/2023
Expiry date		05/2025

- Test System:

Crop	Oil seed rape (*Brassica napus*)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex alimentarius: SO 0088
RACs harvested	Seeds

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed only with water. The target dose rate of test item was 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Target water volume was 200-300 l/ha according to Good Agricultural Practice.

- Field Phase:

Decline curve study trial (DCS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study. Two typical for insecticide applications of CLOROL 200 SC were performed with boom sprayeron the treated plot at the target dose rate of 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Spray volume was 200-300 l/ha according to Good Agricultural Practice.
Reported dose rates:
Application 1: 0,198 l/ha test item; 296,4 l/ha water.
Application 2: 0,197 l/ha test item; 296,2 l/ha water.
Applications were performed at:
Application 1: BBCH 65
Application 2: BBCH 71
Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify the delivery rate. Deviations from the target rate:
Application 1: -1%
Application 2: -1,5%
RAC specimens for analyses were collected:
S1 (Whole plant without root) 0 DALA
S2 (Whole plant without root) 7 DALA
S3 (Whole plant without root) – 14 (±1) DALA
S4 (Whole plant without root) – 21 (±1) DALA
S5 (Seeds) BBCH89 / CH

Table 1 Identification of the field trial

Trial number	Study type	Zone	Country (region)	Trial site	Postal code	GPS coordinates
24SGS40-01	DCS	Northern Europe	Germany (Schleswig-Holstein)	Galmsbull	25899	N 54.766954 E 8.735345

Table 2 Test system information

Crop	Variety	Sowing date	Row spacing [cm]	Plant spacing [cm]	Crop density	Main Flowering Date	Commercial Harvest Date
Oilseed rape	Architect	31/08/2023	12,5	NAP	45 seeds/m^2	05/05/2024 – 22/05/2024	20/07/2024

Table 3 Soil characterisation

Soil texture	Organic matter content (%)	pH ($CaCl_2$)
Loam	2,5	6,6

Table 4 Source of trial weather data

Air temperature and precipitation			
Current year		Historical data – average from past 5 years	
Source of data	Distance to field site (km)	Source of data	Distance to field site (km)
Niebull [25899]	3,6	Husum Schobull [25813]	30

Table 5 Temperature data

Month	Current year		Historical data – average from past 5 years	
	Average minimum air temperature (°C)	Average maximum air temperature (°C)	Average minimum air temperature (°C)	Average maximum air temperature (°C)
May	11,2	20,9	6,4	15,1
June	14	23,3	11,2	21,6
July	13,8	21,6	12,7	21

Table 6 Rainfall data

Month	Rainfall (mm)	
	Current year	Historical data - average from past 5 years
May	56,6	63,8
June	17,2	62,2
July	107,4	71,9

Table 7 Experimental design

Plot ID	Plot width [m]	Plot length [m]	Plot area [m²]	Slope [%]	Distance between plots [m]
U, T	3	15	45	0	20

Table 8 Application equipment data

Application Number	Sprayer Configuration	Nozzle Brand	Number of Nozzles	Nozzle Spacing [cm]
A1	Boom Sprayer	IDK 120-02	6	50
A2	Boom Sprayer	IDK 120-02	6	50

Table 9 Application data

Application number	Date	Time	BBCH	Actual rate of test item (l/ha)	Actual rate a.s. (g /ha)	Deviation (%)	Spray volume (l/ha)	Treated area (m²)	Spray mixture (g)	Test item (g)	Spray mixture remaining (g)	Spray mixture applied (g)
A1	14/05/2024	11:02	65-67	0,218	44	+9,1	217,78	45	2000	2,183	1020	980
A2	27/05/2024	12:08	71	0,198	40	-0,9	197,78	45	2000	2,182	1110	890

Table 10 Environmental conditions at application

Application number	Foliage moisture	Soil moisture	Soil temperature at 10 depth (°C)	Air temperature (°C)	Relative humidity (%)	Cloud cover (%)	Wind speed (m/s)	Wind direction (origin)	Rainfall within 3 hours
A1	Dry	Dry	14,8	20,6	61	0	1,8	E	0
A2	Dry	Moist	17,2	21,2	78	40	2,7	W	0

Table 11 Cultivation practices

Date	Operation type	Equipment
26/08/2023	Deep work	Plough

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	0 DALA	24SGS38-01 1	oilseed rape (whole plant without root)	DPL/57/2024/01U	<LOD
2		24SGS38-01 2	oilseed rape (whole plant without root)	DPL/57/2024/02T	0.56
3	7 DALA	24SGS38-01 3	oilseed rape (whole plant without root)	DPL/57/2024/03T	0.35
4	14 (±1) DALA	24SGS38-01 4	oilseed rape (whole plant without root)	DPL/57/2024/04T	0.24
5	21 (±1) DALA	24SGS38-01 5	oilseed rape (whole plant without root)	DPL/57/2024/05T	0.31
6	BBCH 89 / CH	24SGS38-01 6	oilseed rape (seeds)	DPL/57/2024/06U	< LOD
7		24SGS38-01 7	oilseed rape (seeds)	DPL/57/2024/07T	0.093

DALA – days after last application; BBCH – according to BBCH scale; CH – commercial harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Results:

Conclusions

This study was fully performed as anticipated, in accordance with the study plan and the amend-ment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s). The results acquired during validation of the analytical method (accuracy and repeatabi-lity) were in the range of 70-120% and RSD ≤ 20% for average recovery. The limit of quantifica-tion of the method was established at 0.010 mg/kg for oilseed rape (seeds). There were no interfer-ing signals at retention time of analyzed compound in

examined control matrix. The analytical met-hod for determining the residues of chlorantraniliprole in oilseed rape (seeds) meets the criteria of SANTE/2020/12830, Rev. 2 guidelines in terms of precision, accuracy and uncertainty.
Analytical phase:

- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in OSR (whole plant without root, seeds), following two applications of CLOROL 200 SC.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in oilseed rape (whole plant without root, seeds) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-84 *Determination of residues of Chlorantraniliprole in oilseed rape (seed, plant) using QuEChERS method and LC-MS/MS tandem mass spectrometry*, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC-and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method.

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18ºC before analysis. After removal from the freezer the samples were homogenized at Test Facility, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/57/2024), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18ºC until beginning of analysis.

- Extraction

5 g of the sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile and 10 mL of deionized water was added together with 50 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogen citrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18ºC for 1.5 h. After that, the extract (organic phase) was fil-

tered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.3 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples as well as control and fortified samples was performed on 24.10.2024. After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence. The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 24.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed, sample blank	<LOD	-
OSR seed, PK1 0,010 mg-kg	0.010	103.2
OSR seed, PK1 0,10 mg-kg	0.10	100.0
OSR seed, PK2 0,010 mg-kg	0.010	100.1
OSR seed, PK2 0,10 mg-kg	0.10	103.2
OSR seed, cal 100 ppb'	0.10	-

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 25.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant, sample blank	< LOD	-
OSR plant, PK1 0,010 mg-kg	0.011	111.3
OSR plant, PK1 0,10 mg-kg	0.11	106.2
OSR plant, PK2 0,010 mg-kg	0.011	108.5
OSR plant, PK2 0,10 mg-kg	0.10	103.5
OSR plant, cal 100 ppb'	0.11	-

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 28.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant, sample blank	< LOD	-
OSR plant, PK1 0,010 mg-kg	0.010	101.5
OSR plant, PK1 0,10 mg-kg	0.10	100.6
OSR plant, PK2 0,010 mg-kg	0.011	106.6
OSR plant, PK2 0,10 mg-kg	0.10	102.8
OSR plant, cal 100 ppb'	0.10	-

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure.
24.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 608 minutes (10.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
25.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 684 minutes (11.4 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
28.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 513 minutes (8.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
Extract stability is not considered to be an issue, since working standard that were used for quantification
were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.3.1.8 Study 8

Comments of zRMS:	The study was conducted according to relevant guidances, and GLP requirements and in line with the requested GAP. Study is accepted. The objective of the study was to determine the residue level of chlorantraniliprole in oilseed rape in one decline study trial following two applications of the formulated product CLOROL 200 SC. Two applications of CLOROL 200 SC were performed at the target dose rate of 40 g of chlorantraniliprole at BBCH 68 and 71. The residue concentration detected was <LOQ in rape seeds.

Reference:	KCA 6.3
Report	Magnitude of residue of Chlorantraniliprole in oilseed rape (Raw Agricultural Commodity) after two applications of CLOROL 200 S.C. - one decline curve study trial in Northern France - 2024; Peda Tomasz, SGS Polska Sp. z o.o., Study numer: 24SGS39
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997; OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021); SANTE/2020/12830 Rev.2, 14 February 2023;
Deviations:	No
GLP:	Yes
Acceptability:	YES

Materials and methods

- Test Item:

Name		CLOROL 200 SC
Trade name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		chlorantraniliprole
CAS Number		500008-45-7
Formulation Type		SC
Formulation Name		Suspension Concentrate
Main uses		Insecticide
Content of a.s.	nominal	20 % w/v
	analyzed	19,9 % w/v
Density analyzed :		1,0908 g/cm^3
Certificate of Analysis dated:		17/10/2023
Expiry date		05/2025

- Test System:

Crop	Oil seed rape (*Brassica napus*)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex alimentarius: SO 0088
RACs harvested	Seeds

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed only with water. The target dose rate of test item was 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Target water volume was 200-300 l/ha according to Good Agricultural Practice.

- Field Phase:

Decline curve study (DCS) was established in Northern France. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study. Two typical for insecticide applications of CLOROL 200 SC were performed with boom sprayer on the treated plot at the target dose rate of 0,2 l/ha, equivalent to 40 g of chlorantraniliprole. Spray volume was 200-300 l/ha according to Good Agricultural Practice.
Reported dose rates:
Application 1: 0,215 l/ha; 268,8 l/ha of water.
Application 2: 0,217 l/ha; 270,8 l/ha of water.
Applications were performed at:
Application 1: BBCH 68
Application 2: BBCH 71
Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify the delivery rate. Deviations from the target rate were:
Application 1: +7,5%
Application 2: +8,5%
RAC specimens for analyses were collected:
S1 (Whole plant without root) 0 DALA
S2 (Whole plant without root) 7 DALA
S3 (Whole plant without root) – 14 (±1) DALA
S4 (Whole plant without root) – 21 (±1) DALA
S5 (Seeds) BBCH89 / CH

Table 1 Identification of the field trial

Trial number	Study type	Zone	Country (region)	Trial site	Postal code	GPS coordinates
24SGS39-01	DCS	Northern Europe	France (Grand Est)	Bourgogne-Fresne	51110	N 49.337649 E 4.072984

Table 2 Test system information

Crop	Variety	Sowing date	Row spacing [cm]	Plant spacing [cm]	Crop density [/ha]	Main Flowering Date	Commercial Harvest Date
Oilseed rape	LG Aviron	27/08/2023	45	-	30 000	01/04/2024 – 30/04/2024	17/07/2024

Table 3 Soil characterisation

Soil texture	Organic matter content (%)	pH (water)
Loam	3	8,5

Table 4 Source of trial weather data

Air temperature and precipitation			
Current year		Historical data – average from past 5 years	
Source of data	Distance to field site (km)	Source of data	Distance to field site (km)
SGS Demeter Aumenancourt [51110]	3,5	SGS Demeter Aumenancourt [51110]	3,5

Table 5 Temperature data

Month	Current year		Historical data – average from past 5 years	
	Average minimum air temperature (°C)	Average maximum air temperature (°C)	Average minimum air temperature (°C)	Average maximum air temperature (°C)
April	7	16	3,4	15,9
May	10	20	6,7	19,2
June	11	22	11,5	24,8
July	13	25	12,1	25,7

Table 6 Rainfall data

Month	Rainfall (mm)	
	Current year	Historical data - average from past 5 years
April	75,8	45,2
May	56	59
June	48,6	59,7
July	124,6	46,6

Table 7 Experimental design

Plot ID	Plot width [m]	Plot length [m]	Plot area [m²]	Slope [%]	Distance between plots [m]
U, T	6	8	48	0	40

Table 8 Application equipment data

Trial number	Application Number	Sprayer Configuration	Nozzle Brand	Number of Nozzles	Nozzle Spacing [cm]
24SGS39-01	A1	Boom Sprayer	TTVP 11002	6	50
	A2	Boom Sprayer	TTVP 11002	6	50

Table 9 Application data

Application number	Date	Time	BBCH	Actual rate of test item (l/ha)	Actual rate a.s. (g /ha)	Deviation (%)	Spray volume (l/ha)	Treated area (m²)	Spray mixture (g)	Test item (g)	Spray mixture remaining (g)	Spray mixture applied (g)
A1	23/04/2024	10:10	68	0,215	43	+7,5	268,8	48	1800	1,571	510	1290
A2	07/05/2024	09:40	71	0,217	43	+8,5	270,8	48	1800	1,572	500	1300

Table 10 Environmental conditions at application

Application number	Foliage moisture	Soil moisture	Soil temperature at 10 depth (°C)	Air temperature (°C)	Relative humidity (%)	Cloud cover (%)	Wind speed (m/s)	Wind direction (origin)	Rainfall within 3 hours
A1	Moist	Moist	7	5,9	93	5	0,8	W	0
A2	Moist	Moist	11	11,8	95	5	1	W	0

Table 11 Cultivation practices

Date	Operation type	Equipment
27/08/2023	Superficial work	Rotary harrow

Results:

Residues concentration detected in analysed field samples:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	0 DALA	24SGS39-01 1	oilseed rape (whole plant without root)	DPL/58/2024/01U	<LOD
2		24SGS39-01 2	oilseed rape (whole plant without root)	DPL/58/2024/02T	1.47
3	7 DALA	24SGS39-01 3	oilseed rape (whole plant without root)	DPL/58/2024/03T	1.22
4	14 (±1) DALA	24SGS39-01 4	oilseed rape (whole plant without root)	DPL/58/2024/04T	0.39
5	21 (±1) DALA	24SGS39-01 5	oilseed rape (whole plant without root)	DPL/58/2024/05T	0.53
6	BBCH 89 / CH	24SGS39-01 6	oilseed rape (seeds)	DPL/58/2024/06U	< LOD
7		24SGS39-01 7	oilseed rape (seeds)	DPL/58/2024/07T	<LOQ

DALA – days after last application; BBCH – according to BBCH scale; CH – commercial harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values.
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Conclusions

This study was not-fully performed as anticipated, in accordance with the study plan and the amendment issued (please see deviation). However the collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application tim-ing(s) and rate(s).The results acquired during validation of the analytical method (accuracy and repeatabi-lity) were in the range of 70-120% and RSD ≤ 20% for

average recovery. The limit of quantifica-tion of the method was established at 0.010 mg/kg for oilseed rape (seeds). There were no interfer-ing signals at reten-tion time of analyzed compound in examined control matrix. The analytical met-hod for determining the residues of chlorantraniliprole in oilseed rape (seeds) meets the criteria of SANTE/2020/12830, Rev. 2 guidelines in terms of precision, accuracy and uncertainty.

Analytical phase:

- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in OSR (whole plant without root, seeds), following two applications of CLOROL 200 SC.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in oilseed rape (whole plant without root, seeds) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-84 *Determination of residues of Chlorantraniliprole in oilseed rape (seed, plant) using QuEChERS method and LC-MS/MS tandem mass spectrometry*, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC-and LC-based analysis following acetonitrile extrac-tion/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method.

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18ºC before analysis. After removal from the freezer the samples were homogenized at Test Facility, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/58/2024), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18ºC until beginning of analysis.

- Extraction

5 g of the sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile and 10 mL of deionized water was added together with 50 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g

sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogen citrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18°C for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.3 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples as well as control and fortified samples was performed on 24.10.2024. After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very

end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.
Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence. The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 24.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed, sample blank	<LOD	-
OSR seed, PK1 0,010 mg-kg	0.010	103.2
OSR seed, PK1 0,10 mg-kg	0.10	100.0
OSR seed, PK2 0,010 mg-kg	0.010	100.1
OSR seed, PK2 0,10 mg-kg	0.10	103.2
OSR seed, cal 100 ppb'	0.10	-

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 25.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant, sample blank	< LOD	-
OSR plant, PK1 0,010 mg-kg	0.011	111.3
OSR plant, PK1 0,10 mg-kg	0.11	106.2
OSR plant, PK2 0,010 mg-kg	0.011	108.5
OSR plant, PK2 0,10 mg-kg	0.10	103.5
OSR plant, cal 100 ppb'	0.11	-

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 28.10.2024:

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant, sample blank	< LOD	-
OSR plant, PK1 0,010 mg-kg	0.010	101.5
OSR plant, PK1 0,10 mg-kg	0.10	100.6
OSR plant, PK2 0,010 mg-kg	0.011	106.6
OSR plant, PK2 0,10 mg-kg	0.10	102.8
OSR plant, cal 100 ppb'	0.10	-

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure.
24.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 608 minutes (10.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
25.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 684 minutes (11.4 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
28.10.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 513 minutes (8.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
Extract stability is not considered to be an issue, since working standard that were used for quantification
were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.3.2 Magnitude of residues in Sugar beet

A 2.1.3.2.1 Study 9

Comments of zRMS:	The study was conducted according to relevant guidances, GLP requirements and in line with the requested GAP. Study is accepted. The objective of the study was to determine the residue level of chlorantraniliprole in sugar beet in one harvest study trial following one applications of the formulated product CLOROL 200 SC. One applications of CLOROL 200 SC was performed at the target dose rate of 20 g of chlorantraniliprole at BBCH 49. The residue concentration detected was <LOD of 0.001 mg/kg in sugar beet roots.

Reference:	KCA 6.3
Report	Magnitude of residue of Chlorantraniliprole in sugar beet (Raw Agricultural Commodity) after one application of CLOROL 200 SC with adjuvant Asystent+, one harvest study trial in Denmark - 2024; Wańczyk K., SGS Polska Sp. z o.o., Study numer: 24SGS54
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997; OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021); SANTE/2020/12830 Rev.2, 14 February 2023;
Deviations:	No
GLP:	Yes
Acceptability:	YES

Materials and methods

- Test Item:

Name		CLOROL 200 SC
Trade name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		chlorantraniliprole
CAS Number		500008-45-7
Formulation Name		SC
Formulation Type		Suspension Concentrate
Main uses		Insecticide
Content of a.s.	nominal	20 % w/v
	analyzed	19,9 % w/v
Density analyzed:		1,0908 g/cm^3
Date of production:		05/04/2023
Certificate of Analysis dated:		17/10/2023
Expiry date		05/04/2025

- Adjuvant

Name	Asystent+
Trade name	Asystent+
Batch No.	P4.2022
Density analyzed	1,03 g/cm^3
Certificate of Analysis dated	10/02/2022
Production date	02/2022
Expiry date	02/2026

- Test System:

Crop	Sugar beet (*Beta vulgaris* L., 1753)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex Alimentarius: VR 0596
RACs harvested	Leaves with tops; roots

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed with adjuvant Asystent + and water. The target dose rate of test item is 0,1 l/ha, equivalent to 20 g of chlorantraniliprole. Dose rate of adjuvant is 0,1 l/ha. Target water volume is 150-200 l/ha according to Good Agricultural Practice.

- Field Phase:

Harvest Study (HS) was established in Denmark. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.
One typical for insecticide application of CLOROL 200 SC with adjuvant Asystent+ was performed with boom sprayer on the treated plot at the target dose rate of 0,1 l/ha, equivalent to 20 g of chlorantraniliprole. Spray volume was 150-200 l/ha according to Good Agricultural Practice. The reported dose rate of test item was 0,105 l/ha, adjuvant was 0,105 l/ha (210,0 l/ha of water).

Application was performed at BBCH 49.

Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was +5,0 %.
RAC specimens for analyses were collected:
- S1 Leaves with tops; Root - CH/28(±1) DAA

Table 1 Identification of the field trial

Trial number	Study type	Zone	Country (region)	Trial site	Postal code	GPS coordinates
24SGS54-01	HS	Central Europe	Denmark (Syddanmark)	Tinglev	6360	N 54,886203 E 9,129005

Table 2 Test system information

Crop	Variety	Sowing date	Row spacing [cm]	Plant spacing [cm]	Crop density [/ha]	Commercial Harvest Date
Sugar beet	Strauß	21/04/2024	45	26	85 000 plants	05/11/2024

Table 3 Soil characterisation

Soil texture	Organic matter content (%)	pH (CaCl)
Sandy loam	2,8	6,3

Table 4 Source of trial weather data

Air temperature and precipitation			
Current year		Historical data – past 5 years	
Source of data	Distance to field site (km)	Source of data	Distance to field site (km)
Schafflund [24980]	14,34	Schafflund [24980]	14,34

Table 5 Temperature data

Month	Current year		Historical data – past 5 years	
	Average minimum air temperature (°C)	Average maximum air temperature (°C)	Average minimum air temperature (°C)	Average maximum air temperature (°C)
October	7,2	14,4	8,3	14,6
November	5,7	10,9	4,5	9,0

Table 6 Rainfall data

Month	Rainfall (mm)	
	Current year	Historical data (average past 5 years)
October	63,3	105,0
November	1,0	65,5

Table 7 Experimental design

Plot ID	Plot width [m]	Plot length [m]	Plot area [m²]	Slope [%]	Distance between plots [m]
U, T	3	10	30	0	20

Table 8 Application equipment data

Trial number	Plot ID	Application Number	Sprayer Configuration	Nozzle Brand	Number of Nozzles	Nozzle Spacing [cm]
24SGS54-01	T	A1	Boom Sprayer	IDK 120-02	6	50

Table 9 Application data

Date	Time	BBCH	Actual rate of test item (l/ha)	Actual rate a.i. (g /ha)	Actual rate adjuvant (l/ha)	Deviation (%)	Actual spray volume (l/ha)	Treated area (m^2)	Spray mixture (g)	Test item (g)	Adjuvant (g)	Spray mixture remaining (g)	Spray mixture applied (g)
07/10/2024	18:35	49	0,105	21,0	0,105	+5,0	210	30	2000	1,093	1,033	1370	630

Table 10 Environmental conditions at application

Application number	Foliage moisture	Soil moisture	Soil temperature at 10 depth (°C)	Air temperature (°C)	Relative humidity (%)	Cloud cover (%)	Wind speed (m/s)	Wind direction (origin)	Rainfall within 3 hours
A1	Dry	Moist	11,3	15,8	77	0	1,0	SW	0

Table 11 Cultivation practices

Date	Operation type	Equipment
15/04/2024	Deep work	Mold board plough
20/04/2024	Superficial work	Harrow

Table 12 Cultivation practices – Fertiliser

Date applied	Product	Fertilizer composition				Amount (/ha)
		% N	% P_2O_5	% K_2O	% Other	
No fertiliser applied						

Results:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result *[mg/kg]
1	CH/28(±1) DAA	24SGS54-01 1	sugar beet (leaves with tops)	DPL/84/2024/01U	<LOD
2		24SGS54-01 2	sugar beet (roots)	DPL/84/2024/02U	<LOD
3		24SGS54-01 3	sugar beet (leaves with tops)	DPL/84/2024/03T	0.043
4		24SGS54-01 4	sugar beet (roots)	DPL/84/2024/04T	<LOD

DAA – days after application; CH – commercial harvest
*
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Conclusions
This study was fully performed as anticipated, in accordance with the study plan and the amendment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s).
The method for determination of chlorantraniliprole in sugar beet (leaves with tops, roots) was validated at Test Site SGS Polska Sp. z o.o., ul. Cieszyńska 52A, Pszczyna, according to SANTE/2020/12830 Rev. 2, 14 February 2023. Validation criteria and results were summarized in study VAL/17/2024.
The method was validated according to SANTE/2020/12830 Rev. 2, 14 February 2023. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg. The performance of the method during the analytical study complies with SANTE/2020/12830 Rev. 2 criteria (accuracy in the range 70–120%).
Analytical phase:

- Study objective:

The objective of the study is to magnitude of residue of chlorantraniliprole in sugar beet (Raw Agricultural Commodity) after one application of CLOROL 200 SC with adjuvant Asystent+.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in sugar beet (leaves with tops, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-85 *Determination of residues of Chlorantraniliprole in plant material using QuEChERS method and LC-MS/MS tandem mass spectrometry*, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC- and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method.

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18°C before analysis. After removal from the freezer the samples were homogenized at Test Facility, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/84/2024), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18°C until beginning of analysis.

- Extraction

10 g of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile was added together with 100 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18°C for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 10 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.6 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	100.0
PK 0.10 mg/kg (10xLOQ)	100.0	-

Extraction of all field samples as well as control and fortified samples was performed on 20.11.2024 (leaves with tops, roots). After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow. Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence. The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 20.11.2024:

Sample Name	Result [mg/kg]	Recovery [%]
beet leaves, sample blank	<LOD	-
beet leaves, PK1 0,010 mg-kg	0.010	101.8
beet leaves, PK1 0,10 mg-kg	0.11	107.2
beet leaves, PK2 0,010 mg-kg	0.010	101.2
beet leaves, PK2 0,10 mg-kg	0.10	102.2
beet leaves, cal 100 ppb'	0.10	-

Sample Name	Result [mg/kg]	Recovery [%]
beet roots, sample blank	<LOD	-
beet roots, PK1 0,010 mg-kg	0.011	105.6
beet roots, PK1 0,10 mg-kg	0.10	101.8
beet roots, PK2 0,010 mg-kg	0.010	99.8
beet roots, PK2 0,10 mg-kg	0.10	101.3
beet roots, cal 100 ppb'	0.10	-

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure. 20.11.2024 (leaves with tops) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 608 minutes (10.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. 20.11.2024 (roots) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 570 minutes (9.5 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.3.2.2 Study 10

Comments of zRMS:	The study was conducted according to relevant guidances, GLP requirements and in line with the requested GAP. Study is accepted. The objective of the study was to determine the residue level of chlorantraniliprole in sugar beet in one dedcline study trial following one applications of the formulated product CLOROL 200 SC. One applications of CLOROL 200 SC was performed at the target dose rate of 20 g of chlorantraniliprole at BBCH 49. The residue concentration detected was <LOD of 0.001 mg/kg in sugar beet roots.

Reference:	KCA 6.3
Report	Magnitude of residue of Chlorantraniliprole in sugar beet (Raw Agricultural Commodity) after one application of CLOROL 200 SC with adjuvant Asystent+, one decline curve study trial in Hungary - 2024; Wańczyk K., SGS Polska Sp. z o.o., Study numer: 24SGS55
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997; OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021); SANTE/2020/12830 Rev.2, 14 February 2023;
Deviations:	No
GLP:	Yes
Acceptability:	YES

Materials and methods

- Test Item:

Name		CLOROL 200 SC
Trade name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		chlorantraniliprole
CAS Number		500008-45-7
Formulation Name		SC
Formulation Type		Suspension Concentrate
Main uses		Insecticide
Content of a.s.	nominal	20 % w/v
	analyzed	19,9 % w/v
Density analyzed:		1,0908 g/cm^3
Date of production:		05/04/2023
Certificate of Analysis dated:		17/10/2023
Expiry date		05/04/2025

- Adjuvant

Name	Asystent+
Trade name	Asystent+
Batch No.	P4.2022
Density analyzed	1,03 g/cm^3
Certificate of Analysis dated	10/02/2022
Production date	02/2022
Expiry date	02/2026

- Test System:

Crop	Sugar beet (*Beta vulgaris* L., 1753)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex Alimentarius: VR 0596
RACs harvested	Leaves with tops; roots

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed with adjuvant Asystent + and water. The target dose rate of test item is 0,1 l/ha, equivalent to 20 g of chlorantraniliprole. Dose rate of adjuvant is 0,1 l/ha. Target water volume is 150-200 l/ha according to Good Agricultural Practice.

- Field Phase:

Decline Curve Study (DCS) was established in Hungary. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the
crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.
One typical for insecticide application of CLOROL 200 SC with adjuvant Asystent+ was performed with boom sprayer on the treated plot at the target dose rate of 0,1 l/ha, equivalent to 20 g of Chlorantraniliprole. Spray volume was 150-200 l/ha according to Good Agricultural Practice. The reported dose rate of test item was 0,098 l/ha, adjuvant was 0,098 l/ha (195,0 l/ha of water).

Application was performed at BBCH 49.
Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was – 2,4 %. RAC specimens for analyses were collected:
- S1 (Leaves with tops; Root) – +0/-0 DAA
- S2 (Leaves with tops; Root) –7(±1) DAA
- S3 Leaves with tops; Root)- 14(±1) DAA
- S4 Leaves with tops; Root)- CH/28(±1) DAA

Table 1 Identification of the field trial

Trial number	Study type	Zone	Country (region)	Trial site	Postal code	GPS coordinates
24SGS55-01	DCS	Central Europe	Hungary (Hajdú–Bihar)	Hajdúnánás	H-4080	N 47° 46' 51,1" E 21° 26' 02,7"

Table 2 Test system information

Crop	Variety	Sowing date	Row spacing [cm]	Plant spacing [cm]	Crop density [/ha]	Commercial Harvest Date
Sugar beet	Gazeta	24/03/2024	45	17,1	130 000 seeds	19/09/2024-25/09/2024

Table 3 Soil characterisation

Soil texture	Organic matter content (%)	pH (water)
Silt clay	2,47	8,2

Table 4 Source of trial weather data

Air temperature and precipitation			
Current year		Historical data – past 5 years	
Source of data	Distance to field site (km)	Source of data	Distance to field site (km)
Debrecan-Józsa [H-4225]	21,0	Debrecan-Józsa [H-4225]	21,0

Table 5 Temperature data

Month	Current year		Historical data – past 5 years	
	Average minimum air temperature (°C)	Average maximum air temperature (°C)	Average minimum air temperature (°C)	Average maximum air temperature (°C)
August	17,8	32,5	17,2	30,6
September	13,4	24,9	11,9	23,8

Table 6 Rainfall data

Month	Rainfall (mm)	
	Current year	Historical data (average past 5 years)
August	7,0	36,0
September	85,4	55,8

Table 7 Experimental design

Plot ID	Plot width [m]	Plot length [m]	Plot area [m²]	Slope [%]	Distance between plots [m]
U, T	3	20	60	0	20

Table 8 Application equipment data

Trial number	Plot ID	Application Number	Sprayer Configuration	Nozzle Brand	Number of Nozzles	Nozzle Spacing [cm]
24SGS55-01	T	A1	Boom Sprayer	AIRMIX 110-04	6	50

Table 9 Application data

Date	Time	BBCH	Actual rate of test item (l/ha)	Actual rate a.i. (g /ha)	Actual rate adjuvant (l/ha)	Deviation (%)	Actual spray volume (l/ha)	Treated area (m^2)	Spray mixture (g)	Test item (g)	Adjuvant (g)	Spray mixture remaining (g)	Spray mixture applied (g)
23/08/2024	10:25	49	0,098	19,6	0,098	-2,0	195	60	2200	1,201	1,133	1030	1170

Table 10 Environmental conditions at application

Application number	Foliage moisture	Soil moisture	Soil temperature at 10 depth (°C)	Air temperature (°C)	Relative humidity (%)	Cloud cover (%)	Wind speed (m/s)	Wind direction (origin)	Rainfall within 3 hours
A1	Dry	Dry	22,9	24,6	45	10	0,8	NE	0

Table 11 Cultivation practices

Date	Operation type	Equipment
16/11/2023	Deep work	Mold board plough
20/03/2024	Superficial work	Field cultivator

Table 12 Cultivation practices – Fertiliser

Date applied	Product	Fertilizer composition				Amount (/ha)
		% N	% P_2O_5	% K_2O	% Other	
20/03/2024	N-P-K 8-24-24	8	24	24	-	300 kg
20/03/2024	Pétisó 27%	27	-	-	7-CaO, 5 - MgO	200 kg

Results:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	+0/-0 DAA	24SGS55-01 1	sugar beet (leaves with tops)	DPL/85/2024/01U	<LOD
2		24SGS55-01 2	sugar beet (roots)	DPL/85/2024/02U	<LOD
3		24SGS55-01 3	sugar beet (leaves with tops)	DPL/85/2024/03T	0.25*
4		24SGS55-01 4	sugar beet (roots)	DPL/85/2024/04T	<LOD
5	7(±1) DAA	24SGS55-01 5	sugar beet (leaves with tops)	DPL/85/2024/05T	0.32*
6		24SGS55-01 6	sugar beet (roots)	DPL/85/2024/06T	<LOD
7	14(±1) DAA	24SGS55-01 7	sugar beet (leaves with tops)	DPL/85/2024/07T	0.33*
8		24SGS55-01 8	sugar beet (roots)	DPL/85/2024/08T	<LOD
9	CH/28(±1) DAA	24SGS55-01 9	sugar beet (leaves with tops)	DPL/85/2024/09U	<LOD
10		24SGS55-01 10	sugar beet (roots)	DPL/85/2024/10U	<LOD
11		24SGS55-01 11	sugar beet (leaves with tops)	DPL/85/2024/11T	0.060
12		24SGS55-01 12	sugar beet (roots)	DPL/85/2024/12T	<LOD

DAA – days after application; CH – commercial harvest
*diluted samples
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,

Conclusions
This study was fully performed as anticipated, in accordance with the study plan and the amendment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s).
The method for determination of chlorantraniliprole in sugar beet (leaves with tops, roots) was validated at Test Site SGS Polska Sp. z o.o., ul. Cieszyńska 52A, Pszczyna, according to SANTE/2020/12830 Rev. 2, 14 February 2023. Validation criteria and results were summarized in study VAL/17/2024.
The method was validated according to SANTE/2020/12830 Rev. 2, 14 February 2023. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg. The performance of the method during the analytical study complies with SANTE/2020/12830 Rev. 2 criteria (accuracy in the range 70–120%).

Analytical phase:

- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in sugar beet RAC (leaves with tops, roots), following one application of CLOROL 200 SC with adjuvant Asystent+.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in sugar beet (leaves with tops, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-85 *Determination of residues of Chlorantraniliprole in plant material using QuEChERS method and LC-MS/MS tandem mass spectrometry*, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC- and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method.

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18°C before analysis. After removal from the freezer the samples were homogenized at Test Facility, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/85/2024), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18°C until beginning of analysis.

- Extraction

10 g of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile was added together with 100 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18°C for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 10 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.6 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	100.0
PK 0.10 mg/kg (10xLOQ)	100.0	-

Extraction of all field samples as well as control and fortified samples was performed on 20.11.2024 (leaves with tops, roots) and 21.11.2024 (leaves with tops, diluted samples). After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow. Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence. The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 20.11.2024:

Sample Name	Result [mg/kg]	Recovery [%]
beet leaves, sample blank	<LOD	-
beet leaves, PK1 0,010 mg-kg	0.010	101.8
beet leaves, PK1 0,10 mg-kg	0.11	107.2
beet leaves, PK2 0,010 mg-kg	0.010	101.2
beet leaves, PK2 0,10 mg-kg	0.10	102.2
beet leaves, cal 100 ppb'	0.10	-

Sample Name	Result [mg/kg]	Recovery [%]
beet roots, sample blank	<LOD	-
beet roots, PK1 0,010 mg-kg	0.011	105.6
beet roots, PK1 0,10 mg-kg	0.10	101.8
beet roots, PK2 0,010 mg-kg	0.010	99.8
beet roots, PK2 0,10 mg-kg	0.10	101.3
beet roots, cal 100 ppb'	0.10	-

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of treated samples 21.11.2024:

Sample Name	Result [mg/kg]	Recovery [%]
beet leaves, sample blank	<LOD	-
beet leaves, PK1 0,010 mg-kg	0.010	104.7
beet leaves, PK1 0,10 mg-kg	0.10	101.5
beet leaves, PK2 0,010 mg-kg	0.010	102.2
beet leaves, PK2 0,10 mg-kg	0.10	99.9
beet leaves, cal 100 ppb'	0.11	-

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure. 20.11.2024 (leaves with tops) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 608 minutes (10.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. 20.11.2024 (roots) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 570 minutes (9.5 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. 21.11.2024 (leaves with tops, diluted samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 399 minutes (6.7 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.3.2.3 Study 11

Comments of zRMS:	The study was conducted according to relevant guidances, GLP requirements and in line with the requested GAP. Study is accepted. The objective of the study was to determine the residue level of chlorantraniliprole in sugar beet in one study trial following one applications of the formulated product CLOROL 200 SC. One applications of CLOROL 200 SC was performed at the target dose rate of 20 g of chlorantraniliprole at BBCH 49. The residue concentration detected was <LOD of 0.001 mg/kg in sugar beet roots.

Reference:	KCA 6.3
Report	Magnitude of residue of Chlorantraniliprole in sugar beet (Raw Agricultural Commodity) after one application of CLOROL 200 SC with adjuvant Asystent+, one harvest study trial in Poland - 2024; Wańczyk K., SGS Polska Sp. z o.o., Study numer: 24SGS53
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997; OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021); SANTE/2020/12830 Rev.2, 14 February 2023;
Deviations:	Yes One deviation occurred during field phase. Top with leaves sample in sampling S1 (sample no 1,1R, 3,3R,) was smaller than required in the study plan (1,6; 1,8; 1,4 and 1,4 instead 2 kg). This deviation has no impact on the study, because the samples volume was enough and representative to do residues analysis.
GLP:	Yes
Acceptability:	Yes/No/Supplementary

Materials and methods

- Test Item:

Name		CLOROL 200 SC
Trade name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		chlorantraniliprole
CAS Number		500008-45-7
Formulation Name		SC
Formulation Type		Suspension Concentrate
Main uses		Insecticide
Content of a.s.	nominal	20 % w/v
	analyzed	19,9 % w/v
Density analyzed:		1,0908 g/cm^3
Date of production:		05/04/2023
Certificate of Analysis dated:		17/10/2023
Expiry date		05/04/2025

- Adjuvant

Name	Asystent+
Trade name	Asystent+
Batch No.	P4.2022
Density analyzed	1,03 g/cm^3
Certificate of Analysis dated	10/02/2022
Production date	02/2022
Expiry date	02/2026

- Test System:

Crop	Sugar beet (*Beta vulgaris* L., 1753)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex Alimentarius: VR 0596
RACs harvested	Leaves with tops; roots

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed with adjuvant Asystent + and water. The target dose rate of test item is 0,1 l/ha, equivalent to 20 g of chlorantraniliprole. Dose rate of adjuvant is 0,1 l/ha. Target water volume is 150-200 l/ha according to Good Agricultural Practice.

- Field Phase:

Harvest Study (HS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study. One typical for insecticide application of CLOROL 200 SC with adjuvant Asystent+ was performed with boom sprayer on the treated plot at the target dose rate of 0,1 l/ha, equivalent to 20 g of chlorantraniliprole. Spray volume was 150-200 l/ha according to Good Agricultural Practice. The reported dose rate of test item was 0,098 l/ha, adjuvant was 0,098 l/ha (194,7 l/ha of water).
Application was performed at BBCH 49.
Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was -2,0 %. RAC specimens for analyses were collected:
- S1 Leaves with tops; Root - CH/28(±1) DAA

Table 1 Identification of the field trial

Trial number	Study type	Zone	Country (region)	Trial site	Postal code	GPS coordinates
24SGS53-01	HS	Central Europe	Poland (Dolny Śląsk)	Krzelków	57-220	N 50^0 37' 25,4" E 17^0 00' 02,1"

Table 2 Test system information

Crop	Variety	Sowing date	Row spacing [cm]	Plant spacing [cm]	Crop density [/ha]	Commercial Harvest Date
Sugar beet	Silesia	26/03/2024	45	18	90 000 seeds	10/09/2024

Table 3 Soil characterisation

Soil texture	Organic matter content (%)	pH (CaCl)
Silt loam	2,3	6,4

Table 4 Source of trial weather data

Air temperature and precipitation			
Current year		Historical data – past 5 years	
Source of data	Distance to field site (km)	Source of data	Distance to field site (km)
Ząbkowice Śląskie [57-213]	13,5	Ząbkowice Śląskie [57-213]	13,5

Table 5 Temperature data

Month	Current year		Historical data – past 5 years	
	Average minimum air temperature (°C)	Average maximum air temperature (°C)	Average minimum air temperature (°C)	Average maximum air temperature (°C)
August	15,0	25,9	14,6	23,9
September	11,3	21,1	10,4	19,8

Table 6 Rainfall data

Month	Rainfall (mm)	
	Current year	Historical data (average past 5 years)
August	85,2	140,2
September	282,8	63,6

Table 7 Experimental design

Plot ID	Plot width [m]	Plot length [m]	Plot area [m²]	Slope [%]	Distance between plots [m]
U, T	3	20	60	0	20

Table 8 Application equipment data

Trial number	Plot ID	Application Number	Sprayer Configuration	Nozzle Brand	Number of Nozzles	Nozzle Spacing [cm]
24SGS53-01	T	A1	Boom Sprayer	TEE JET AIXR 11002 VP	6	50

Table 9 Application data

Date	Time	BBCH	Actual rate of test item (l/ha)	Actual rate a.i. (g /ha)	Actual rate adjuvant (l/ha)	Deviation (%)	Actual spray volume (l/ha)	Treated area (m^2)	Spray mixture (g)	Test item (g)	Adjuvant (g)	Spray mixture remaining (g)	Spray mixture applied (g)
13/08/2024	19:24	49	0,098	19,6	0,098	-2,0	194,7	60	2000	1,091	1,030	832	1168

Table 10 Environmental conditions at application

Application number	Foliage moisture	Soil moisture	Soil temperature at 10 depth (°C)	Air temperature (°C)	Relative humidity (%)	Cloud cover (%)	Wind speed (m/s)	Wind direction (origin)	Rainfall within 3 hours
A1	Dry	Dry	19,2	21,3	64	20	0	NAP	0

Table 11 Cultivation practices

Date	Operation type	Equipment
20/10/2023	Deep work	Plough
26/03/2024	Superficial work	Disking

Table 12 Cultivation practices – Fertiliser

Date applied	Product	Fertilizer composition				Amount (/ha)
		% N	% P_2O_5	% K_2O	% Other	
26/03/2024	Polifoska 6	6	20	30	7-SO3	300
09/05/2024	Urea 46%	46	-	-	-	200

Results:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result *[mg/kg]
1	CH/28(±1) DAA	24SGS53-01 1	sugar beet (leaves with tops)	DPL/83/2024/01U	<LOD
2		24SGS53-01 2	sugar beet (roots)	DPL/83/2024/02U	<LOD
3		24SGS53-01 3	sugar beet (leaves with tops)	DPL/83/2024/03T	0.088
4		24SGS53-01 4	sugar beet (roots)	DPL/83/2024/04T	<LOD

DAA – days after application; CH – commercial harvest
*
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Conclusions
This study was fully performed as anticipated, in accordance with the study plan and the amendment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s).
The method for determination of chlorantraniliprole in sugar beet (leaves with tops, roots) was validated at Test Site SGS Polska Sp. z o.o., ul. Cieszyńska 52A, Pszczyna, according to SANTE/2020/12830 Rev. 2, 14 February 2023. Validation criteria and results were summarized in study VAL/17/2024.
The method was validated according to SANTE/2020/12830 Rev. 2, 14 February 2023. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg. The performance of the method during the analytical study complies with SANTE/2020/12830 Rev. 2 criteria (accuracy in the range 70–120%).

Analytical phase:

- Study objective:

The objective of the study is to magnitude of residue of Chlorantraniliprole in sugar beet (Raw Agricultural Commodity) after one application ofCLOROL 200

SC with adjuvant Asystent+.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in sugar beet (leaves with tops, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-85 *Determination of residues of Chlorantraniliprole in plant material using QuEChERS method and LC-MS/MS tandem mass spectrometry*, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC- and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method.

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18°C before analysis. After removal from the freezer the samples were homogenized at Test Facility, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/83/2024), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18°C until beginning of analysis.

- Extraction

10 g of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile was added together with 100 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18°C for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 10 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.6 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	100.0
PK 0.10 mg/kg (10xLOQ)	100.0	-

Extraction of all field samples as well as control and fortified samples was performed on 20.11.2024 (leaves with tops, roots). After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow. Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence. The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 20.11.2024:

Sample Name	Result [mg/kg]	Recovery [%]
beet leaves, sample blank	<LOD	-
beet leaves, PK1 0,010 mg-kg	0.010	101.8
beet leaves, PK1 0,10 mg-kg	0.11	107.2
beet leaves, PK2 0,010 mg-kg	0.010	101.2
beet leaves, PK2 0,10 mg-kg	0.10	102.2
beet leaves, cal 100 ppb'	0.10	-

Sample Name	Result [mg/kg]	Recovery [%]
beet roots, sample blank	<LOD	-
beet roots, PK1 0,010 mg-kg	0.011	105.6
beet roots, PK1 0,10 mg-kg	0.10	101.8
beet roots, PK2 0,010 mg-kg	0.010	99.8
beet roots, PK2 0,10 mg-kg	0.10	101.3
beet roots, cal 100 ppb'	0.10	-

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure.
20.11.2024 (leaves with tops) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 608 minutes (10.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
20.11.2024 (roots) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 570 minutes (9.5 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.3.2.4 Study 12

Comments of zRMS:	The study was conducted according to relevant guidances, GLP requirements and in line with the requested GAP. Study is accepted. The objective of the study was to determine the residue level of chlorantraniliprole in sugar beet in one decline study trial following one applications of the formulated product CLOROL 200 SC. One applications of CLOROL 200 SC was performed at the target dose rate of 20 g of chlorantraniliprole at BBCH 49. The residue concentration detected was <LOD of 0.001 or <LOQ of 0.01 mg/kg mg/kg in sugar beet roots.

Reference:	KCA 6.3
Report	Magnitude of residue of Chlorantraniliprole in sugar beet (Raw Agricultural Commodity) after one application of CLOROL 200 SC with adjuvant Asystent+, one decline curve study trial in Germany - 2024; Wańczyk K., SGS Polska Sp. z o.o., Study numer: 24SGS56
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997; OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021); SANTE/2020/12830 Rev.2, 14 February 2023;
Deviations:	Yes One deviation occurred during field phase. Top with leaves sample in sampling S3 (sample no 8) was smaller than required in the study plan (1,9 instead 2 kg). This deviation has no impact on the study, because the samples volume was enough and representative to do residues analysis.
GLP:	Yes

Acceptability: Yes/No/Supplementary

Materials and methods

- Test Item:

Name		CLOROL 200 SC
Trade name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		chlorantraniliprole
CAS Number		500008-45-7
Formulation Name		SC
Formulation Type		Suspension Concentrate
Main uses		Insecticide
Content of a.s.	nominal	20 % w/v
	analyzed	19,9 % w/v
Density analyzed:		1,0908 g/cm^3
Date of production:		05/04/2023
Certificate of Analysis dated:		17/10/2023
Expiry date		05/04/2025

- Adjuvant

Name	Asystent+
Trade name	Asystent+
Batch No.	P4.2022
Density analyzed	1,03 g/cm^3
Certificate of Analysis dated	10/02/2022
Production date	02/2022
Expiry date	02/2026

- Test System:

Crop	Sugar beet (*Beta vulgaris* L., 1753)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex Alimentarius: VR 0596
RACs harvested	Leaves with tops; roots

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed with adjuvant Asystent + and water. The target dose rate of test item is 0,1 l/ha, equivalent to 20 g of chlorantraniliprole. Dose rate of adjuvant is 0,1 l/ha. Target water volume is 150-200 l/ha according to Good Agricultural Practice.

- Field Phase:

Decline Curve Study (DCS) was established in Germany. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the
crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.
One typical for insecticide application of CLOROL 200 SC with adjuvant Asystent+ was performed with boom sprayer on the treated plot at the target dose rate of 0,1 l/ha, equivalent to 20 g of Chlorantraniliprole. Spray volume was 150-200 l/ha according to Good Agricultural Practice. The reported dose rate of test item was 0,099 l/ha, adjuvant was 0,099 l/ha (198,3 l/ha of water).
Application was performed at BBCH 49.

Remaining spray mixture after application was measured and the volume applied to the treated
plot was calculated to verify delivery rate. Deviation to the target rate was - 0,8 %.
RAC specimens for analyses were collected:
- S1 (Leaves with tops; Root) – +0/-0 DAA
- S2 (Leaves with tops; Root) – 7(±1) DAA
- S3 Leaves with tops; Root) - 14(±1) DAA
- S4 Leaves with tops; Root) - CH/28(±1) DAA

Table 1 Identification of the field trial

Trial number	Study type	Zone	Country (region)	Trial site	Postal code	GPS coordinates
24SGS56-01	DCS	Central Europe	Germany (Lower Saxony)	Emstek	49685	N 52^0 48' 35.8" E 8^0 11' 23.8"

Table 2 Test system information

Crop	Variety	Sowing date	Row spacing [cm]	Plant spacing [cm]	Crop density [/ha]	Commercial Harvest Date
Sugar beet	Calledia	13/04/2024	50	20	100 000 plants	01/10/2024-31/10/2024

Table 3 Soil characterisation

Soil texture	Organic matter content (%)	pH ($CaCl_2$)
Silt loam	1,9	6,2

Table 4 Source of trial weather data

Air temperature and precipitation			
Current year		Historical data – past 5 years	
Source of data	Distance to field site (km)	Source of data	Distance to field site (km)
Emstek [49685]	3,05	Breme [28199]	47,45

Table 5 Temperature data

Month	Current year		Historical data – past 5 years	
	Average minimum air temperature (°C)	Average maximum air temperature (°C)	Average minimum air temperature (°C)	Average maximum air temperature (°C)
September	11,7	21,5	4,7	19,7
October	7,4	15,8	4,6	15,2

Table 6 Rainfall data

Month	Rainfall (mm)	
	Current year	Historical data (average past 5 years)
September	119,7	52,9
October	60,8	73,8

Table 7 Experimental design

Plot ID	Plot width [m]	Plot length [m]	Plot area [m²]	Slope [%]	Distance between plots [m]
U, T	3	20	60	0	20

Table 8 Application equipment data

Trial number	Plot ID	Application Number	Sprayer Configuration	Nozzle Brand	Number of Nozzles	Nozzle Spacing [cm]
24SGS56-01	T	A1	Boom Sprayer	Lechler IDK 120-02	6	50

Table 9 Application data

Date	Time	BBCH	Actual rate of test item (l/ha)	Actual rate a.i. (g /ha)	Actual rate adjuvant (l/ha)	Deviation (%)	Actual spray volume (l/ha)	Treated area (m^2)	Spray mixture (g)	Test item (g)	Adjuvant (g)	Spray mixture remaining (g)	Spray mixture applied (g)
02/09/2024	10:45	49	0,099	19,9	0,099	-0,8	198,3	60	2000	1,091	1,030	810	1190

Table 10 Environmental conditions at application

Application number	Foliage moisture	Soil moisture	Soil temperature at 10 depth (°C)	Air temperature (°C)	Relative humidity (%)	Cloud cover (%)	Wind speed (m/s)	Wind direction (origin)	Rainfall within 3 hours
A1	Dry	Moist	18,8	24,1	42	0	2,8	SW	0

Table 11 Cultivation practices

Date	Operation type	Equipment
08/04/2024	Deep work	Mold board plough
10/04/2024	Superficial work	Rotary harrow

Table 12 Cultivation practices – Fertiliser

Date applied	Product	Fertilizer composition				Amount (/ha)
		% N	% P_2O_5	% K_2O	% Other	
08.04.2024	Dig manure	1	0,3	0,9	-	30 000 L

Results:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	+0/-0 DAA	24SGS56-01 1	sugar beet (leaves with tops)	DPL/86/2024/01U	<LOD
2		24SGS56-01 2	sugar beet (roots)	DPL/86/2024/02U	<LOD
3		24SGS56-01 3	sugar beet (leaves with tops)	DPL/86/2024/03T	0.44*
4		24SGS56-01 4	sugar beet (roots)	DPL/86/2024/04T	<LOQ
5	7(±1) DAA	24SGS56-01 5	sugar beet (leaves with tops)	DPL/86/2024/05T	0.23*
6		24SGS56-01 6	sugar beet (roots)	DPL/86/2024/06T	<LOQ
7	14(±1) DAA	24SGS56-01 7	sugar beet (leaves with tops)	DPL/86/2024/07T	0.14
8		24SGS56-01 8	sugar beet (roots)	DPL/86/2024/08T	<LOQ
9	CH/ 28(±1)DAA	24SGS56-01 9	sugar beet (leaves with tops)	DPL/86/2024/09U	<LOD
10		24SGS56-01 10	sugar beet (roots)	DPL/86/2024/10U	<LOD
11		24SGS56-01 11	sugar beet (leaves with tops)	DPL/86/2024/11T	0.092
12		24SGS56-01 12	sugar beet (roots)	DPL/86/2024/12T	<LOD

DAA – days after application; CH – commercial harvest
*diluted samples
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Conclusions
This study was fully performed as anticipated, in accordance with the study plan and the amendment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s).
The method for determination of chlorantraniliprole in sugar beet (leaves with tops, roots) was validated at Test Site SGS Polska Sp. z o.o., ul. Cieszyńska 52A, Pszczyna, according to SANTE/2020/12830 Rev. 2, 14 February 2023. Validation criteria and results were summarized in study VAL/17/2024.
The method was validated according to SANTE/2020/12830 Rev. 2, 14 February 2023. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg. The performance of the method during the analytical study complies with SANTE/2020/12830 Rev. 2 criteria (accuracy in the range 70–120%).
Analytical phase:

- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in sugar beet RAC (leaves with tops, roots), following one application of CLOROL 200 SC with adjuvant Asystent+.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in sugar beet (leaves with tops, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-85 *Determination of residues of Chlorantraniliprole in plant material using QuEChERS method and LC-MS/MS tandem mass spectrometry*, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC- and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method.

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18°C before analysis. After removal from the freezer the samples were homogenized at Test Facility, using a knife grinder. The homogenized samples were divided into few portions: one portion was used as test sample in this study (DPL/86/2024), other portions were prepared as archival samples and the rest of the homogenized material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The homogenized specimens were further stored at ≤ -18°C until beginning of analysis.

- Extraction

10 g of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile was added together with 100 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18°C for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 10 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.6 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	100.0
PK 0.10 mg/kg (10xLOQ)	100.0	-

Extraction of all field samples as well as control and fortified samples was performed on 20.11.2024 (leaves with tops, roots) and 21.11.2024 (leaves with tops, diluted samples). After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same

time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow. Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence. The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 20.11.2024:

Sample Name	Result [mg/kg]	Recovery [%]
beet leaves, sample blank	<LOD	-
beet leaves, PK1 0,010 mg-kg	0.010	101.8
beet leaves, PK1 0,10 mg-kg	0.11	107.2
beet leaves, PK2 0,010 mg-kg	0.010	101.2
beet leaves, PK2 0,10 mg-kg	0.10	102.2
beet leaves, cal 100 ppb'	0.10	-

Sample Name	Result [mg/kg]	Recovery [%]
beet roots, sample blank	<LOD	-
beet roots, PK1 0,010 mg-kg	0.011	105.6
beet roots, PK1 0,10 mg-kg	0.10	101.8
beet roots, PK2 0,010 mg-kg	0.010	99.8
beet roots, PK2 0,10 mg-kg	0.10	101.3
beet roots, cal 100 ppb'	0.10	-

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of treated samples 21.11.2024:

Sample Name	Result [mg/kg]	Recovery [%]
beet leaves, sample blank	<LOD	-
beet leaves, PK1 0,010 mg-kg	0.010	104.7
beet leaves, PK1 0,10 mg-kg	0.10	101.5
beet leaves, PK2 0,010 mg-kg	0.010	102.2
beet leaves, PK2 0,10 mg-kg	0.10	99.9
beet leaves, cal 100 ppb'	0.11	-

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure.
20.11.2024 (leaves with tops) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 608 minutes (10.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
20.11.2024 (roots) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 570 minutes (9.5 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
21.11.2024 (leaves with tops, diluted samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 399 minutes (6.7 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
Extract stability is not considered to be an issue, since working standard that were used for quantification
were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.4 Magnitude of residues in livestock

Not relevant.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

Not relevant.

A 2.1.6 Other/Special Studies

A 2.1.6.1 Magnitude of residues in honey

A 2.1.6.1.1.1 Study 13

Comments of zRMS:	The study was conducted according to relevant guidances and GLP requirements. Study is accepted. The objective of the study was to determine the chlorantraniliprole residues following two foliar applications of CLOROL 200 SC on phacelia under semi-field conditions. The applications of CLOROL 200 SC was performed at the target dose rate of 40 g of chlorantraniliprole at BBCH 59-65. The residue concentration detected was <LOD or LOQ of 0.002/0.01 mg/kg in honey.

Reference: KCA 6.3

Report	Determination of Chlorantraniliprole residues in honey following two foliar applications of CLOROL 200 SC on Phacelia under semi-field conditions in Poland - 2024; Grzeczak P., SGS Polska Sp. z o.o., Study number: 24SGS46
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997, OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 adopted 14 June 2021), SANTE/11956/2016 rev. 9,14 September 2018, SANTE/2020/12830, Rev. 2, 14 February 2023;
Deviations:	No
GLP:	Yes
Acceptability:	YES

Materials and methods

- Test item:

Trade Name		CLOROL 200 SC
Name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		Chlorantraniliprole
CAS Number		500008-45-7
Formulation Name		SC
Formulation Type		Suspension concentrate
Main uses		Insecticide
Content of a.s.	nominal	200 g/L
	analysed	199,35 g/L
Certificate of analysis dated		17/10/2023
Actual density		1,0908 g/cm^3
Expiry date		04.2025

- Test system:

Crop	Phacelia (*Phacelia tanacetifolia* Benth)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex Alimentarius: -
RACs harvested	Honey

- Application equipment:

The application equipment consisted of boom sprayer.

The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed only with water. No adjuvant was added to the spray mixture. The target dose rate of the test item per application was 0,2 L/ha, equivalent to 40 g a. s. /ha. Target water volume 200-300 l/ha according to Good Agricultural Practice.

- Field Phase:

One harvest study (HS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.
Two typical for insecticide applications of CLOROL 200 SC were performed with boom sprayer on the treated plot at the target dose rate of 0,2 L/ha, equivalent to 40 g chlorantraniliprole. Spray volume was 300 L/ha according to Good Agricultural Practice. The reported dose rate of test item was:
• A1: 0,198 L/ha (296,8 L/ha water), at BBCH stage 59-60
• A2: 0,195 L/ha (292,1 L/ha water), at BBCH stage 62-65
Remaining spray mixture after applications were measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was:
A1 - 1,0 %
A2 - 2,5 %
RAC specimens for analyses were collected:
• S1 (mature honey) - 11 DALA

- Results:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	Honey cell-closure or at the end of flowering	24SGS46-01 1	honey	DPL/51/2024/01U	< LOD
2		24SGS46-01 2	honey	DPL/51/2024/02T	< LOQ

Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

- Conclusion:

This study was fully performed as anticipated and in accordance with the study plan. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s).
The health of the colonies was assessed prior to introduction to the tunnels and at the end of the trial just before the honey collection. The following parameters were assessed:
- strength of the colony (number of frames covered with bees)
- presence of healthy queen (i.e. presence of eggs or presence of queen cells)
- Visual assessment – percentage of frames containing pollen, nectar and brood (eggs, larvae and capped cells).

Results of assessments are presented in Table 16 – Health effect on honey bees. During trials periods there was no bee mortality (e.g. dead bees, health problems) and applications did not show any impact to the bees colony.

The analytical method for determining the residues of chlorantraniliprole in honey meets the criteria of SANTE/2020/12830, Rev. 2 guidelines in terms of precision, accuracy and uncertainty.

Analytical phase:

- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in honey following two applications of CLOROL 200 SC.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in honey were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-68 *Determination of residues of chlorantraniliprole in honey using QuEChERS method and LC-MS/MS tandem mass spectrometry*, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC- and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method .

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18 oC before analysis. The samples were divided into few portions: one portion was used as test sample in this study (DPL/51/2024), other portions were prepared as archival samples and the rest of the material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The specimens were further stored at ≤ -18 oC until beginning of analysis.

- Extraction

5 g of the sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile and 10 ml of deionized water was added together with 50 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogen citrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18 oC for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.3 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples as well as control and fortified samples was performed on 01.07.2024. After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence.

The following results for matrix blank and fortified samples were obtained during analysis of untreated

and treated samples 01.07.2024:

Sample Name	Result [mg/kg]	Recovery [%]
honey, sample blank	<LOD	-
honey, PK1 0,010 mg-kg	0.010	103.9
honey, PK1 0,10 mg-kg	0.11	105.1
honey, PK2 0,010 mg-kg	0.0095	95.5
honey, PK2 0,10 mg-kg	0.097	97.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure.
01.07.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 456 minutes (7.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.6.1.1.2 Study 14

Comments of zRMS:	The study was conducted according to relevant guidances and GLP requirements. Study is accepted. The objective of the study was to determine the chlorantraniliprole residues following two foliar applications of CLOROL 200 SC on phacelia under semi-field conditions. The applications of CLOROL 200 SC was performed at the target dose rate of 40 g of chlorantraniliprole at BBCH 52-65. The residue concentration detected was <LOD or LOQ of 0.002/0.01 mg/kg in honey.

Reference:	KCA 6.3
Report	Determination of Chlorantraniliprole residues in honey following two foliar applications of CLOROL 200 SC on Phacelia under semi-field conditions in Spain- 2024; Grzeczak P., SGS Polska Sp. z o.o., Study number: 24SGS44
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997, OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 adopted 14 June 2021), SANTE/11956/2016 rev. 9,14 September 2018, SANTE/2020/12830, Rev. 2, 14 February 2023;
Deviations:	Yes Honey sample inspection was not reported within 14 days – no impact to the study.
GLP:	Yes
Acceptability:	YES

Materials and methods

- Test item:

Trade Name		CLOROL 200 SC
Name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		Chlorantraniliprole
CAS Number		500008-45-7
Formulation Name		SC
Formulation Type		Suspension concentrate
Main uses		Insecticide
Content of a.s.	nominal	200 g/L
	analysed	199,35 g/L
Certificate of analysis dated		17/10/2023
Actual density		1,0908 g/cm^3
Expiry date		04.2025

- Test system:

Crop	Phacelia (*Phacelia tanacetifolia* Benth)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex Alimentarius: -
RACs harvested	Honey

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed only with water. No adjuvant was added to the spray mixture. The target dose rate of the test item per application was 0,2 L/ha, equivalent to 40 g a. s. /ha. Target water volume 200-300 l/ha according to Good Agricultural Practice.

- Field Phase:

One harvest study (HS) was established in Spain. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.
Two typical for insecticide applications of CLOROL 200 SC were performed with boom sprayer on the treated plot at the target dose rate of 0,2 L/ha, equivalent to 40 g chlorantraniliprole. Spray volume was 300 L/ha according to Good Agricultural Practice. The reported dose rate of test item was:
• A1: 0,202 L/ha (303,4 L/ha water), at BBCH stage 52
• A2: 0,204 L/ha (306,0 L/ha water), at BBCH stage 65
Remaining spray mixture after applications were measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was +1,0 % (A1), +2,0 (A2).
RAC specimens for analyses were collected:
• S1 (mature honey) - 15 DALA

- Results:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	Honey cell-closure or at the end of flowering	24SGS44-01 1	honey	DPL/49/2024/01U	< LOD
2		24SGS44-01 2	honey	DPL/49/2024/02T	< LOQ

Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

- Conclusion:

This study was not fully performed as anticipated, in accordance with the study plan, as one deviation occurred:
Deviation no 1 – Honey sample inspection was not reported within 14 days – no impact to the study.

The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s).
The health of the colonies was assessed prior to introduction to the tunnels and at the end of the trial just before the honey collection. The following parameters were assessed:
- strength of the colony (number of frames covered with bees)
- presence of healthy queen (i.e. presence of eggs or presence of queen cells)
- Visual assessment – percentage of frames containing pollen, nectar and brood (eggs, larvae and capped cells).

During trials periods there was no bee mortality (e.g. dead bees, health problems) and applications did not show any impact to the bees colony.

The analytical method for determining the residues of chlorantraniliprole in honey meets the criteria of SANTE/2020/12830, Rev. 2 guidelines in terms of precision, accuracy and uncertainty.

Analytical phase:
- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in honey following two applications of CLOROL 200 SC.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in honey were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-68 *Determination of residues of chlorantraniliprole in honey using QuEChERS method and LC-MS/MS tandem mass spectrometry*, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC- and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE.
Modular QuEChERS-method .

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18 oC before analysis. The samples were divided into few portions: one portion was used as test sample in this study (DPL/49/2024), other portions were prepared as archival samples and the rest of the material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The specimens were further stored at ≤ -18 oC until beginning of analysis.

- Extraction

5 g of the sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile and 10 ml of deionized water was added together with 50 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogen citrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18 oC for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.3 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples as well as control and fortified samples was performed on 05.07.2024. After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence.

The following results for matrix blank and fortified samples were obtained during analysis of untreated

and treated samples 05.07.2024:

Sample Name	Result [mg/kg]	Recovery [%]
honey, sample blank	<LOD	-
honey, PK1 0,010 mg-kg	0.011	107.5
honey, PK1 0,10 mg-kg	0.10	104.7
honey, PK2 0,010 mg-kg	0.010	101.9
honey, PK2 0,10 mg-kg	0.10	103.0

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure.
05.07.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 342 minutes (5.7 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.6.1.1.3 Study 15

Comments of zRMS:	The study was conducted according to relevant guidances and GLP requirements. Study is accepted. The objective of the study was to determine the chlorantraniliprole residues following two foliar applications of CLOROL 200 SC on phacelia under semi-field conditions. The applications of CLOROL 200 SC was performed at the target dose rate of 40 g of chlorantraniliprole at BBCH 55-62. The residue concentration detected was <LOD of 0.002 mg/kg in honey.

Reference:	KCA 6.3
Report	Determination of Chlorantraniliprole residues in honey following two foliar applications of CLOROL 200 SC on Phacelia under semi-field conditions in Poland - 2024; Grzeczak P., SGS Polska Sp. z o.o., Study numer: 24SGS45
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997, OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 adopted 14 June 2021), SANTE/11956/2016 rev. 9,14 September 2018, SANTE/2020/12830, Rev. 2, 14 February 2023;
Deviations:	No
GLP:	Yes
Acceptability:	YES

Materials and methods

- Test item:

Trade Name		CLOROL 200 SC
Name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		Chlorantraniliprole
CAS Number		500008-45-7
Formulation Name		SC
Formulation Type		Suspension concentrate
Main uses		Insecticide
Content of a.s.	nominal	200 g/L
	analysed	199,35 g/L
Certificate of analysis dated		17/10/2023
Actual density		1,0908 g/cm^3
Expiry date		04.2025

- Test system:

Crop	Phacelia (*Phacelia tanacetifolia* Benth)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex Alimentarius: -
RACs harvested	Honey

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed only with water. No adjuvant was added to the spray mixture. The target dose rate of the test item per application was 0,2 L/ha, equivalent to 40 g a. s. /ha. Target water volume 200-300 l/ha according to Good Agricultural Practice.

- Field Phase:

One harvest study (HS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.
Two typical for insecticide applications of CLOROL 200 SC were performed with boom sprayer on the treated plot at the target dose rate of 0,2 L/ha, equivalent to 40 g chlorantraniliprole. Spray volume was 300 L/ha according to Good Agricultural Practice. The reported dose rate of test item was:
• A1: 0,198 L/ha (297,2 L/ha water), at BBCH stage 55-59
• A2: 0,199 L/ha (298,1 L/ha water), at BBCH stage 62-65
Remaining spray mixture after applications were measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was:
A1 - 1,0 %
A2 - 0,5 %
RAC specimens for analyses were collected:
• S1 (mature honey) - 14 DALA

- Results:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	Honey cell-closure or at the end of flowering	24SGS45-01 1	honey	DPL/50/2024/01U	< LOD
2		24SGS45-01 2	honey	DPL/50/2024/02T	< LOD

Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

- Conclusion:

This study was fully performed as anticipated and in accordance with the study plan. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s). The health of the colonies was assessed prior to introduction to the tunnels and at the end of the trial just before the honey collection. The following parameters were assessed:
- strength of the colony (number of frames covered with bees)
- presence of healthy queen (i.e. presence of eggs or presence of queen cells)
- Visual assessment – percentage of frames containing pollen, nectar and brood (eggs, larvae and capped cells).

Results of assessments are presented in Table 16 – Health effect on honey bees. During trials periods there was no bee mortality (e.g. dead bees, health problems) and applications did not show any impact to the bees colony. The analytical method for determining the residues of chlorantraniliprole in honey meets the criteria of SANTE/2020/12830, Rev. 2 guidelines in terms of precision, accuracy and uncertainty.

Analytical phase:

- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in honey following two applications of CLOROL 200 SC.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in honey were performed according to the multi-residue QuEChERS method.

Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-68 *Determination of residues of chlorantraniliprole in honey using QuEChERS method and LC-MS/MS tandem mass spectrometry*, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC- and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method .

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18 oC before analysis. The samples were divided into few portions: one portion was used as test sample in this study (DPL/50/2024), other portions were prepared as archival samples and the rest of the material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The specimens were further stored at ≤ -18 oC until beginning of analysis.

- Extraction

5 g of the sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile and 10 ml of deionized water was added together with 50 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogen citrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18 oC for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.3 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples as well as control and fortified samples was performed on 05.07.2024. After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence.

The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 01.07.2024:

Sample Name	Result [mg/kg]	Recovery [%]
honey, sample blank	<LOD	-
honey, PK1 0,010 mg-kg	0.010	103.9
honey, PK1 0,10 mg-kg	0.11	105.1
honey, PK2 0,010 mg-kg	0.0095	95.5
honey, PK2 0,10 mg-kg	0.097	97.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure.
01.07.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 456 minutes (7.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day..

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.1.6.1.1.4 Study 16

Comments of zRMS:	The study was conducted according to relevant guidances and GLP requirements. Study is accepted. The objective of the study was to determine the chlorantraniliprole residues following two foliar applications of CLOROL 200 SC on phacelia under semi-field conditions. The applications of CLOROL 200 SC was performed at the target dose rate of 40 g of chlorantraniliprole at BBCH 59-65. The residue concentration detected was <LOD or LOQ of 0.002/0.01 mg/kg in honey.

Reference:	KCA 6.3
Report	Determination of Chlorantraniliprole residues in honey following two foliar applications of CLOROL 200 SC on Phacelia under semi-field conditions in Poland - 2024; Grzeczak P., SGS Polska Sp. z o.o., Study numer: 24SGS47
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997, OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 adopted 14 June 2021), SANTE/11956/2016 rev. 9,14 September 2018, SANTE/2020/12830, Rev. 2, 14 February 2023;
Deviations:	No
GLP:	Yes
Acceptability:	YES

Materials and methods

- Test item:

Trade Name		CLOROL 200 SC
Name		CLOROL 200 SC
Batch No.		CHR/03/2023
Active substance (a.s.)		Chlorantraniliprole
CAS Number		500008-45-7
Formulation Name		SC
Formulation Type		Suspension concentrate
Main uses		Insecticide
Content of a.s.	nominal	200 g/L
	analysed	199,35 g/L
Certificate of analysis dated		17/10/2023
Actual density		1,0908 g/cm^3
Expiry date		04.2025

- Test system:

Crop	Phacelia (*Phacelia tanacetifolia* Benth)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex Alimentarius: -
RACs harvested	Honey

- Application equipment:

The application equipment consisted of boom sprayer.
The foliar application closely simulated commercial-type treatments.

- Target application of the test item:

CLOROL 200 SC was mixed only with water. No adjuvant was added to the spray mixture. The target dose rate of the test item per application was 0,2 L/ha, equivalent to 40 g a. s. /ha. Target water volume 200-300 l/ha according to Good Agricultural Practice.

- Field Phase:

One harvest study (HS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.
Two typical for insecticide applications of CLOROL 200 SC were performed with boom sprayer on the treated plot at the target dose rate of 0,2 L/ha, equivalent to 40 g chlorantraniliprole. Spray volume was 300 L/ha according to Good Agricultural Practice. The reported dose rate of test item was:
• A1: 0,201 L/ha (301,4 L/ha water), at BBCH stage 59-60
• A2: 0,203 L/ha (304,6 L/ha water), at BBCH stage 62-65
Remaining spray mixture after applications were measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was:
A1 +0,5 %
A2 + 1,5 %
RAC specimens for analyses were collected:
• S1 (mature honey) - 11 DALA

- Results:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	Honey cell-closure or at the end of flowering	24SGS47-01 1	honey	DPL/52/2024/01U	< LOD
2		24SGS47-01 2	honey	DPL/52/2024/02T	< LOQ

Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

- Conclusion:

This study was fully performed as anticipated and in accordance with the study plan. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s).
The health of the colonies was assessed prior to introduction to the tunnels and at the end of the trial just before the honey collection. The following parameters were assessed:
- strength of the colony (number of frames covered with bees)
- presence of healthy queen (i.e. presence of eggs or presence of queen cells)
- Visual assessment – percentage of frames containing pollen, nectar and brood (eggs, larvae and capped cells).

During trials periods there was no bee mortality (e.g. dead bees, health problems) and applications did not show any impact to the bees colony. The analytical method for determining the residues of chlorantraniliprole in honey meets the criteria of SANTE/2020/12830, Rev. 2 guidelines in terms of precision, accuracy and uncertainty.

Analytical phase:

- Study objective:

The objective of the study was the determination of residue levels of chlorantraniliprole in honey following two applications of CLOROL 200 SC.

- Analytical method:

Specimen extraction and determination of residues of chlorantraniliprole in honey were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
ANALYTICAL PROCEDURE DPL-68 *Determination of residues of chlorantraniliprole in honey using QuEChERS method and LC-MS/MS tandem mass spectrometry*, based on:
EN 15662:2018 Foods of plant origin. Multimethod for the determination of pesticide residues using GC- and LC-based analysis following acetonitrile extraction/partitioning and clean-up by dispersive SPE. Modular QuEChERS-method .

- Initial sample preparation and homogenisation:

The field specimens arrived at the Test Site in good conditions, frozen and were stored in a freezer at ≤ -18 oC before analysis. The samples were divided into few portions: one portion was used as test sample in this study (DPL/52/2024), other portions were prepared as archival samples and the rest of the material was kept for use as a reference matrix, e.g. for method validation studies or freezer storage stability studies. The specimens were further stored at ≤ -18 oC until beginning of analysis.

- Extraction

5 g of the sample was weighed into a 50 mL centrifuge tube. 10 mL of acetonitrile and 10 ml of deionized water was added together with 50 µL of internal standard solution (1.4) and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogen citrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 5 min for phase separation and finally subjected to a freezing process at ≤ -18 oC for 1.5 h. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

- Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.3 for information on solution preparation).

Table 2. Preparation of fortification and control samples

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.2 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples as well as control and fortified samples was performed on 05.07.2024. After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

- Blank and fortification samples (qc samples):

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10xLOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10xLOQ per analytical set of respective matrix were analyzed during each of the sequence.

The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 01.07.2024:

Sample Name	Result [mg/kg]	Recovery [%]
honey, sample blank	<LOD	-
honey, PK1 0,010 mg-kg	0.010	103.9
honey, PK1 0,10 mg-kg	0.11	105.1
honey, PK2 0,010 mg-kg	0.0095	95.5
honey, PK2 0,10 mg-kg	0.097	97.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev. 2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70–120% confirms the active substance stability during the analytical procedure.
01.07.2024 - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 456 minutes (7.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

A 2.2 Magnitude of residues in plants ~~But already have been evaluated~~ have been evaluated during inclusion of it on Annex I

and approved in 02.08.2007 and 13 March 2013. Also First registration pf Coragen 200 SC in Poland was in 2011 where those studies were used (Authorization number: R-65/2011).

A 2.2.1.1.1 Cauliflower and broccoli

Report:	Foster, A.C., Cairns, S.D., 2007
OECD IIA data point:	IIA 6.3
Title:	Magnitude and decline of DPX-E2Y45 residues in cauliflower and broccoli (flowering brassicas) following foliar applications of DPX-E2Y45 35WG - northern and southern Europe, 2006
Document No.:	DuPont-18772
Guidelines:	European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC.
GLP:	Yes

Report:	Foster, A.C., Cairns, S.D., 2008
OECD IIA data point:	IIA 6.3
Title:	Magnitude and decline of chlorantraniliprole residues in cauliflower and broccoli (flowering brassicas) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] and DPX-E2Y45 35WG formulated products - Europe, 2007
Document No.:	DuPont-21338
Guidelines:	European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC.
GLP:	Yes

MATERIALS AND METHODS

Charles River Laboratories has conducted field studies with chlorantraniliprole on cauliflower and broccoli (*Brassica oleracea*) for DuPont Crop Protection in the 2006 and 2007 growing seasons. Six magnitude of residue tests were conducted, two in Italy (broccoli, cauliflower), two in Hungary (broccoli, cauliflower), one in Poland (cauliflower) and one in northern France (cauliflower). Four decline tests were conducted, one in Greece (broccoli), one in northern France (broccoli), one in Germany (cauliflower) and one in the UK (broccoli). Four reverse decline tests were conducted, one in Greece (cauliflower), one in Spain (broccoli), one in Germany (broccoli) and one in northern France (cauliflower).

At all MOR and decline test locations, two applications of Chlorantraniliprole 35WG (DPX-E2Y45-206 or DPX-E2Y45-215) were applied as foliar broadcast sprays. In addition, at the four decline test locations, two applications of Chlorantraniliprole 20SC (DPX-E2Y45-239) were applied to separate plots as foliar broadcast sprays. At all tests, applications were made at approximately the targeted rate of 30 g a.s./ha (2006 season) or 35 g a.s./ha (2007 season), for nominal seasonal application rates of 60-70 g a.s./ha. The two applications of formulated product were made at target 7 day (±1) intervals. Spray volumes of approximately 200-800 litres per hectare were employed for the applications. There were no surfactants/additives included in the spray mixture. The study use patterns are summarized in Table 2 and Table 3.

The last application to each plot occurred 1 day (MOR trials and decline trials) before predicted commercial harvest. For the magnitude of residue tests, specimens of cauliflower and broccoli were collected at 1 DALA from the treated and untreated plots. For the decline tests (2007 season), treated specimens were collected from the treated plots immediately before the last application (*e.g.*, *c.a.* -1 h), after the last application (*e.g.*, *c.a.* +2 h) after the product had dried onto the crop, and again at 1 and 3 DALA (BBCH 43-49), all on the day of harvest of the mature plants. Over this narrow time window, both the 1 and 3 DALA samplings represented mature fruit, collected on different days from the same treatment plot. Specimens from the accompanying untreated plots were harvested at 1 DALA. For reverse decline tests (2006 season), specimens at each indicated sampling interval were collected at the normal commercial harvest date. To achieve this, application timing was staggered across individual treatment plots so that the targeted sampling interval would occur on approximately the same date for each plot, coinciding with normal commercial harvest. This constituted a reverse residue decline design. Specimens from the accompanying untreated plots were also collected at normal commercial harvest. The sampling intervals are summarized in Table 4. The targeted PHI under the cauliflower and broccoli GAP is 1 day.

Table 2
Study Use Pattern

		Application		

Test Identification (City, State/Region, Country, Year)	EP[a]	Method/Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] (Days)	Total Rate (g a.s./ha)[d]	Tank Mix Adjuvants	Ref
Test 01 (Olivares, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 28 day DBH	805	30.26	3.76	-	60.52	None	DuPont-18772
		Foliar Broadcast/ 21 day DBH	808	30.26	3.75	7		None	
	35WG	Foliar Broadcast/ 21 day DBH	811	30.26	3.73	-	60.52	None	
		Foliar Broadcast/ 14 day DBH	808	30.26	3.75	7		None	
	35WG	Foliar Broadcast/ 14 day DBH	816	30.62	3.75	-	60.52	None	
		Foliar Broadcast/ 7 day DBH	804	29.90	3.72	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	807	30.26	3.75	-	61.23	None	
		Foliar Broadcast/ 1 day DBH	826	30.97	3.75	6		None	
	35WG	Foliar Broadcast/ 7 day DBH	806	30.26	3.75	-	60.52	None	
		Foliar Broadcast/ 0 day DBH	805	30.26	3.76	7		None	

Table 2
Study Use Pattern (continued)

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] (Days)	Total Rate (g a.s./ha)[d]		
Test 02 (Chalkidona, Thessaloniki, Greece, 2006)	35WG	Foliar Broadcast/ 28 day DBH	796	29.75	3.74	-	60.28	None	DuPont-18772
		Foliar Broadcast/ 20 day DBH	817	30.53	3.74	8		None	
	35WG	Foliar Broadcast/ 20 day DBH	810	30.28	3.74	-	60.93	None	
		Foliar Broadcast/ 14 day DBH	820	30.65	3.74	6		None	
	35WG	Foliar Broadcast/ 14 day DBH	813	30.40	3.74	-	61.18	None	
		Foliar Broadcast/ 7 day DBH	823	30.78	3.74	7		None	
	35WG	Foliar Broadcast/ 8 day DBH	823	30.78	3.74	-	60.88	None	
		Foliar Broadcast/ 1 day DBH	805	30.10	3.74	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	813	30.40	3.74	-	60.53	None	
		Foliar Broadcast/ 0 day DBH	806	30.13	3.74	7		None	

Table 2
Study Use Pattern (continued)

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] (Days)	Total Rate (g a.s./ha)[d]		
Test 03 (Settala, Lombardia, Italy, 2006)	35WG	Foliar Broadcast/ 9 day DBH	814	30.62	3.76	-	61.24	None	DuPont-18772
		Foliar Broadcast/ 1 day DBH	815	30.62	3.76	8		None	
Test 04 (Saint-Omer, Nord Pas de Calais, N. France, 2006)	35WG	Foliar Broadcast/ 28 day DBH	394	29.55	7.50	-	59.45	None	DuPont-18772
		Foliar Broadcast/ 20 day DBH	400	29.90	7.48	8		None	
	35WG	Foliar Broadcast/ 20 day DBH	400	29.90	7.48	-	60.16	None	
		Foliar Broadcast/ 14 day DBH	404	30.26	7.49	6		None	
	35WG	Foliar Broadcast/ 14 day DBH	399	29.90	7.49	-	58.74	None	
		Foliar Broadcast/ 7 day DBH	388	28.84	7.43	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	410	30.62	7.47	-	61.24	None	
		Foliar Broadcast/ 1 day DBH	409	30.62	7.49	6		None	
		Foliar Broadcast/ 7 day DBH	388	28.84	7.43	-		None	

	35WG	Foliar Broadcast/ 0 day DBH	393	29.55	7.52	7	58.39	None	

Table 2
Study Use Pattern (continued)

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] (Days)	Total Rate (g a.s./ha)[d]		
Test 05 (Kaputy, Central Poland, Poland, 2006)	35WG	Foliar Broadcast/ 8 day DBH	822	30.97	3.77	-	61.94	None	DuPont-18772
		Foliar Broadcast/ 1 day DBH	824	30.97	3.76	7		None	
Test 06 (Goch-Kessel, North Rhine – Westphalia, Germany, 2006)	35WG	Foliar Broadcast/ 28 day DBH	800	29.90	3.74	-	59.31	None	DuPont-18772
		Foliar Broadcast/ 21 day DBH	787	29.41	3.74	7		None	
	35WG	Foliar Broadcast/ 21 day DBH	810	30.28	3.74	-	60.50	None	
		Foliar Broadcast/ 14 day DBH	808	30.22	3.74	7		None	
	35WG	Foliar Broadcast/ 14 day DBH	793	29.66	3.74	-	59.94	None	
		Foliar Broadcast/ 7 day DBH	810	30.28	3.74	7		None	
	35WG	Foliar Broadcast/ 8 day DBH	803	30.03	3.74	-	59.69	None	
		Foliar Broadcast/ 1 day DBH	793	29.66	3.74	7		None	

	35WG	Foliar Broadcast/ 7 day DBH	807	30.15	3.74	-	60.05	None	
		Foliar Broadcast/ 0 day DBH	800	29.90	3.74	7		None	

Table 2
Study Use Pattern (continued)

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] (Days)	Total Rate (g a.s./ha)[d]		
Test 07 (Bai-sieux,Nord Pas de Calais, N. France, 2006)	35WG	Foliar Broadcast/ 9 day DBH	395	29.90	7.57	-	60.52	None	DuPont-18772
		Foliar Broadcast/ 1 day DBH	405	30.62	7.56	8		None	
Test 08 (Baracska, Fejér County, Hungary, 2006)	35WG	Foliar Broadcast/ 8 day DBH	207	30.99	15.0	-	63.48	None	DuPont-18772
		Foliar Broadcast/ 1 day DBH	217	32.49	15.0	7		None	

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Liters/hectare
[d] grams active ingredient per hectare
[e] grams active ingredient per hectolitre (or 100 L)
[f] Retreatment Interval

Table 3
Study Use Pattern

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Reference
		Method/Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] (Days)	Total Rate (g a.s./ha) [d]		
Test 01 (Chalkidona, Thessaloniki, Central Macedonia, Greece, 2007)	35WG	Foliar Broadcast/ 9 day DBH	503	35.19	6.99	-	70.21	None	DuPont-21338
					6.99	8			
	20SC	Foliar Broadcast/ 9 day DBH	501	35.26	7.04	-	70.39	None	DuPont-21338
		Foliar Broadcast/ 1 day DBH	499	35.13	7.04	8		None	DuPont-21338
Test 02 (Tortona, Piemonte, Italy, 2007)	35WG	Foliar Broadcast/ 7 day DBH	487	33.92	6.97	-	69.24	None	DuPont-21338
		Foliar Broadcast/ 1 day DBH	505	35.32	6.99	6		None	DuPont-21338
Test 03 (St Omer, Nord-Pas-De-Calais N. France, 2007)	35WG	Foliar Broadcast/ 9 day DBH	491	34.20	6.97	-	69.17	None	DuPont-21338
		Foliar Broadcast/ 1 day DBH	502	34.97	6.97	8		None	DuPont-21338
	20SC	Foliar Broadcast/ 9 day DBH	485	34.10	7.03	-	69.01	None	DuPont-21338
		Foliar Broadcast/ 1 day DBH	496	34.91	7.04	8		None	DuPont-21338

Table 3
Study Use Pattern (continued)

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Reference
		Method/Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] (Days)	Total Rate (g a.s./ha) [d]		
Test 04 (Oderberg, Brandenberg, Germany, 2007)	35WG	Foliar Broadcast/ 8 day DBH	511	35.80	7.00	-	70.10	None	DuPont-21338
		Foliar Broadcast/ 1 day DBH	490	34.30	7.00	7		None	DuPont-21338
	20SC	Foliar Broadcast/ 8 day DBH	522	36.53	7.00	-	72.69	None	DuPont-21338
		Foliar Broadcast/ 1 day DBH	517	36.16	7.00	7		None	DuPont-21338
Test 05 (Clacton-on-Sea, Essex, UK, 2007)	35WG	Foliar Broadcast/ 8 day DBH	508	35.67	7.02	-	70.64	None	DuPont-21338
		Foliar Broadcast/ 1 day DBH	497	34.97	7.04	7		None	DuPont-21338
	20SC	Foliar Broadcast/ 8 day DBH	506	35.52	7.02	-	71.24	None	DuPont-21338
		Foliar Broadcast/ 1 day DBH	509	35.72	7.02	7		None	DuPont-21338

Table 3
Study Use Pattern (continued)

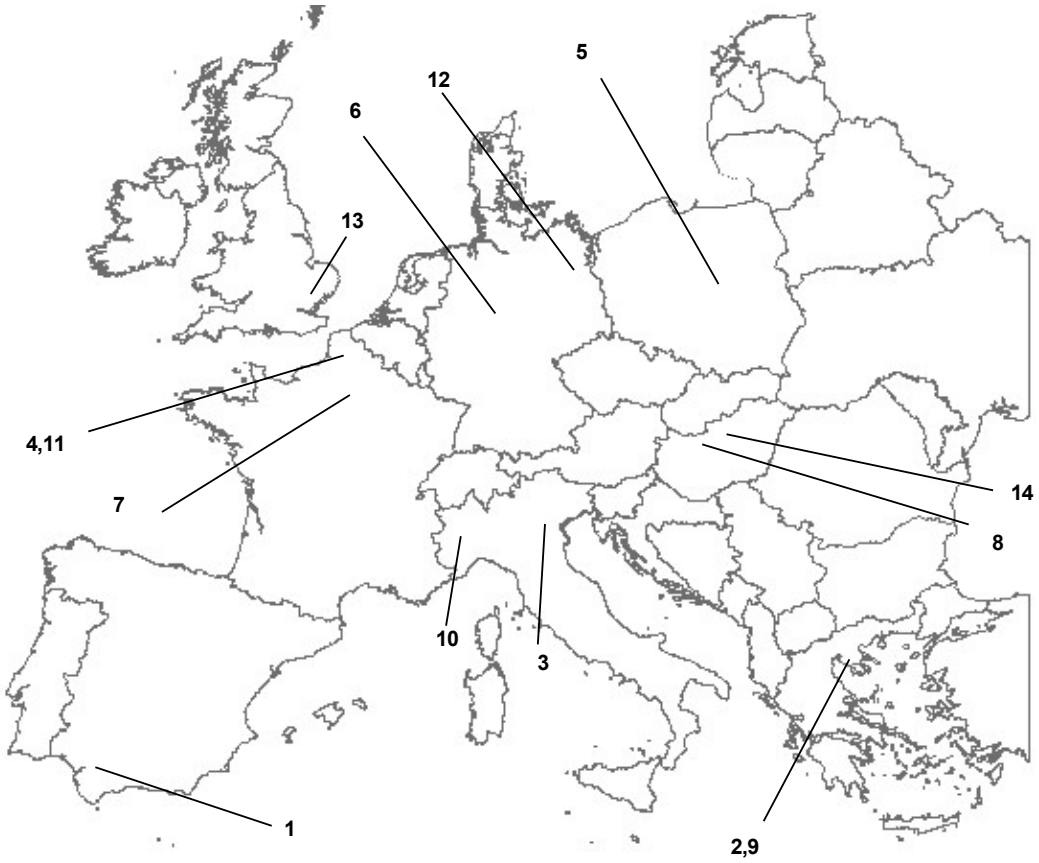
Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Reference
		Method/Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] (Days)	Total Rate (g a.s./ha) [d]		
Test 06 (Velence, Fejér County, Hungary, 2007)	35WG	Foliar Broadcast/ 8 day DBH	517	36.02	6.97	-	71.69	None	DuPont-21338
		Foliar Broadcast/ 1 day DBH	510	35.67	6.99	7		None	DuPont-21338

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Liters/hectare
[d] grams active ingredient per hectare
[e] grams active ingredient per hectolitre (or 100 L)
[f] Retreatment Interval

A total of 6 magnitude of residue tests, 4 decline, and 4 reverse decline tests were conducted in the growing seasons of 2006 and 2007. A summary of these field-grown cauliflower and broccoli studies is given below. Locations of the field-grown cauliflower and broccoli test sites are given in the following figure.

Figure 1

Map: Chlorantraniliprole northern and southern European field-grown cauliflower and broccoli (flowering brassicas) test sites



Map No.	Reference, Test No.	Location
1	DuPont-18772, 1	Olivares, Andalucia, Spain
2	DuPont-18772, 2	Chalkidona, Thessaloniki, Greece
3	DuPont-18772, 3	Settala, Lombardia, Italy
4	DuPont-18772, 4	Saint-Omer, Nord Pas de Calais, France (north)
5	DuPont-18772, 5	Kaputy, Central Poland
6	DuPont-18772, 6	Goch-Kessel, North Rhine-Westphalia, Germany
7	DuPont-18772, 7	Baisieux, Nord Pas de Calais, France (north)
8	DuPont-18772, 8	Baracska, Fejér County, Hungary
9	DuPont-21338, 1	Chalkidona, Thessaloniki, Central Macedonia, Greece
10	DuPont-21338, 2	Tortona, Piemonte, Italy

11	DuPont-21338, 3	St Omer, Nord-Pas-De-Calais, France (north)
12	DuPont-21338, 4	Oderberg, Brandenberg, Germany
13	DuPont-21338, 5	Clacton-on-Sea, Essex, England UK
14	DuPont-21338, 6	Velence, Fejér County, Hungary

A field-grown cauliflower and broccoli residue data summary (in mg/kg) is presented in Table 4 and

Table 5. To generate these data, the following analysis and recovery information pertains.

Analysis method: LC-MS/MS method (DuPont-13295; Chlorantraniliprole DAR, Volume 3, B5) developed as the chlorantraniliprole residue method for determining residues of chlorantraniliprole in/on crops.

Analyte:	Chlorantraniliprole
Extraction:	Analyte extracted from crop matrices with acetonitrile following water presoak.
Clean-up:	SAX (Strong Anion Exchange) and HLB (Hydrophilic Lipophilic Balanced) Solid Phase Extraction (SPE) cartridges
Chromatography:	LC
Detection:	Mass spectrometer detection (MS/MS) in APCI positive mode. Two ion transitions are acquired 284 m/z – 177 m/z and 484 m/z – 453 m/z. The former transition is used for quantification and the second transition for confirmation. In cases where a significant interference is detected in the former transition the latter transition may be used for quantification purposes
LOQ:	0.010 mg/kg

Storage stability: All specimens were analysed within 9 months of sampling. Chlorantraniliprole residues are stable in a variety of crops including predominantly water-, oil-, protein- and, starch-containing commodities as represented by fruits, a fruiting vegetable, a root crop, a non-oily grain, and an oilseed (apple, grape, tomato, leaf lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay, and ginned cottonseed) for at least 24 months when stored frozen at -20 ± 10°C (see Chlorantraniliprole DAR, Volume 3, B7, pages 13-52 (pdf pagination)). Therefore, no degradation is expected to have occurred between harvest and analysis.

Table 4

Residues of chlorantraniliprole in field-grown cauliflower and broccoli (flowering brassicas) from supervised tests

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g a.s./ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg) [c,d]	Reference
Test 01 (Olivares, Andalucia, Spain, 2006)	35WG	Broccoli/ Monada	Broccoli/ Inflorescence	30.26 60.52 61.23 60.52 60.52 60.52	-1 h (0) +2 h (0) 1 7 14 21	0.14 0.32 0.37 0.18 0.052 0.008	DuPont-18772
Test 02 (Chalkidona, Thessaloniki, Greece, 2006)	35WG	Cauliflower/ Siria	Cauliflower/ Inflorescence	30.40 60.53 60.88 61.18 60.93 60.28	-1 h (0) +2 h (0) 1 7 14 20	0.007 0.031 0.012 nd nd nd	DuPont-18772

Test 03 (Settala, Lombardia, Italy, 2006)	35WG	Broccoli/ Celsius	Broccoli/ Inflorescence	61.24	1	0.19	DuPont-18772
Test 04 (Saint-Omer, Nord Pas de Calais, N. France, 2006)	35WG	Cauliflower/ Aviso	Cauliflower/ Inflorescence	28.84 58.39 61.24 58.74 60.16 59.45	-1 h (0) +1 h (0) 1 7 14 20	nd 0.031 0.006 nd nd nd	DuPont-18772
Test 05 (Kaputy Ożarów Mazowiecki, Central Poland, Poland, 2006)	35WG	Cauliflower/ Amerigo	Cauliflower/ Inflorescence	61.94	1	0.004	DuPont-18772
Test 06 (Goch-Kessel, North Rhine-Westphalia, Germany, 2006)	35WG	Broccoli/ Lord	Broccoli/ Inflorescence	30.15 60.05 59.69 59.94 60.50 59.31	-1 h (0) +1 h (0) 1 7 14 21	0.012 0.13 0.12 0.036 0.020 nd	DuPont-18772
Test 07 (Baisieux, Nord Pas de Calais, N. France, 2006)	35WG	Cauliflower/ Nautilus	Cauliflower/ Inflorescence	60.52	1	0.082	DuPont-18772
Test 08 (Baracska, Fejér County, Hungary, 2006)	35WG	Cauliflower/ Beta	Cauliflower/ Inflorescence	63.48	1	0.019	DuPont-18772

[a] EP = End-use Product

[b] DALA = Days after last application (Days between last application and sampling)

[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.

[d] Control specimens were collected and analyzed for the 0 or 1 DALA sampling dates. No detectable residues, nd, were found in all instances.

Table 4

Residues of chlorantraniliprole in field-grown cauliflower and broccoli (flowering brassicas) from supervised tests (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g a.s./ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg) [c,d]	Reference
Test 01 (Chalkidona, Thessaloniki, Central Macedonia, Greece, 2007)	35WG	Broccoli/ Marathon	Heads	70.21	(-1 h) (+2 h) 1 3	0.023 0.060 0.088 0.070	DuPont-21338
	20SC	Broccoli/ Marathon	Heads	70.39	1	0.10	DuPont-21338
Test 02 (Tortona, Piemonte, Italy, 2007)	35WG	Cauliflower/ Fremont	Heads	69.24	1	0.036	DuPont-21338

Test 03 (St Omer, Nord-Pas-De-Calais, France, 2007)	35WG	Broccoli/ Mara-thon	Heads	69.17	(-1 h) (+1 h) 1 3	0.019 0.10 0.097 0.064	DuPont-21338
	20SC	Broccoli/ Mara-thon	Heads	69.01	1	0.10	DuPont-21338
Test 04 (Oder-berg, Branden-berg, Germany, 2007)	35WG	Cauliflower/ Neckarperle	Heads	70.10	(-1 h) (+2 h) 1 3	0.021 0.053 0.045 0.047	DuPont-21338
	20SC	Cauliflower/ Neckarperle	Heads	72.69	1	0.043	DuPont-21338
Test 05 (Clacton-on-Sea, Essex, UK, 2007)	35WG	Broccoli/ Mara-thon	Heads	70.64	(-1 h) (+2 h) 1 3	0.016 0.087 0.12 0.12	DuPont-21338
	20SC	Broccoli/ Mara-thon	Heads	71.24	1	0.14	DuPont-21338
Test 06 (Ve-lence, Fejér County, Hungary, 2007)	35WG	Broccoli/ Calabrese	Heads	71.69	1	0.064	DuPont-21338

[a] EP = End-use Product

[b] DALA = Days after last application (Days between last application and sampling)

[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.

[d] Control specimens were collected and analyzed for the target 1 DALA sampling dates. No detectable residues, nd, were found in all instances.

Table 5

Summary of residue data from field-grown cauliflower and broccoli (flowering brassicas) trials with chlorantraniliprole

Commodity	EP[a]	Total Application Rate (g a.s./ha)	DALA/PHI (days)	Residue Levels in ppm (mg/kg)						
				n[b]	Min.[b]	Max.[b]	HAFT[b]	Median[b] (STMdR)	Mean[b] (STMR)	Std. Dev.[b]
Chlorantraniliprole										
Broccoli/ Cauliflower	35WG	58.39-71.69	0	8	0.010	0.32	---	0.057	0.090	0.10
			1	14	0.004	0.37	---	0.073	0.090	0.097
			3	4	0.047	0.12	---	0.067	0.075	0.031
			7	4	nd	0.18	---	0.020	0.056	0.084
			14	4	nd	0.052	---	0.012	0.020	0.023
			21	4	nd	0.008	---	nd	0.005	0.002
Broccoli/ Cauliflower	20SC	69.01-72.69	1	4	0.043	0.14	---	0.10	0.096	0.040

[a] EP = End-use Product

[b] N = number of individual specimens,
Min = minimum individual specimen residue,
Max = maximum individual specimen residue,

HAFT = Highest Average residue from one Field Test; (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set).
Median = median of individual specimen residues.
Mean = mean of individual specimen residues.
Std Dev = standard deviation of mean

Recovery data: Average recovery data for fortifications run concurrently with the treated specimens are given below to demonstrate the validity of the analytical method.

Table 6
Summary of concurrent recoveries of chlorantraniliprole from cauliflower and broccoli – DuPont-18772 (2006 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (RSD) (% ± %)
Chlorantraniliprole				
Broccoli	0.010	2	82, 76	79
	0.10	2	105, 99	102
	0.50	2	99, 94	97
Overall	-	6	-	92 ± 11 (12)
Cauliflower	0.010	2	89, 77	83
	0.10	2	84, 85	84
Overall	-	4	-	84 ± 5 (6)

Statistics were calculated using non-rounded recovery values

Table 7

Summary of concurrent recoveries of chlorantraniliprole from cauliflower and broccoli – DuPont-21338 (2007 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (CV) (% ± % (%))
Concurrent Fortifications – Chlorantraniliprole				
Cauliflower	0.010	2	90, 106	98
Heads	0.10	2	84, 86	85
Overall	-	4	-	92 ± 10 (11)
Broccoli Heads	0.010	3	93, 95, 107	99 ± 7 (8)
	0.10	3	82, 90, 115[a]	96 ± 17 (18)
	0.20	2	106, 101	104
Overall	-	8	-	99 ± 11 (11)

a Out recovery acceptance criteria but included in calculations

RESULTS AND DISCUSSION

The residue studies presented herein were carried out in eight different EU countries and provide data relevant to conditions in the field-grown cauliflower and broccoli-growing regions of northern and southern Europe.

All of the analytical work associated with the studies was performed at Charles River Laboratories, Tranent, EH33 2NE, Scotland in the spring of 2007 and the winter of 2007-8.

In the northern and southern European regions, residues in field-grown cauliflower and broccoli were less than or equal to 0.37 mg/kg at 1 DALA, the target PHI, or longer sampling intervals, in the fourteen residue tests conducted in 2006 and 2007 in which Chlorantraniliprole 35WG was applied at 83-102% of GAP rate of application. Across all 2006 and 2007 tests and formulations, broccoli residues were less than or equal to

0.37 mg/kg, whereas cauliflower residues were less than or equal to 0.082 mg/kg.

In four side-by-side tests conducted in 2007, residues in cauliflower and broccoli were less than or equal to 0.12 and 0.14 mg/kg at 1 DALA following applications of Chlorantraniliprole 35WG or Chlorantraniliprole 20SC, respectively. The residue levels from cauliflower and broccoli treated with Chlorantraniliprole 35WG and Chlorantraniliprole 20SC formulations, were comparable according to the criteria defined in EU 7525/VI/1995 Rev. 7 (2001) App. D, for the four side-by-side tests conducted in 2006. Therefore, the data generated following application of Chlorantraniliprole 35WG will be used in conjunction with the data generated following application of Chlorantraniliprole 20SC for further residue population comparisons.

Dissipation half-lives for chlorantraniliprole in cauliflower and broccoli from four reverse decline residue trials conducted in 2006 were 4 (broccoli), 3 (cauliflower), 1 (cauliflower), and 5 (broccoli) days for DuPont-18772, Tests 1, 2, 4, and 6, respectively. The calculated half-lives for chlorantraniliprole in cauliflower and broccoli from four decline residue trials conducted in 2007 were 4 (broccoli) and 22 (cauliflower) days for two tests (DuPont-21338, Tests 3 and 4), whereas broccoli residues

showed no discernable decline for two tests (DuPont-21338, Test 1 and Test 5), over the studied 3-day period.

The study data show an overall consistent residue profile when chlorantraniliprole was applied in accordance with GAP.

Recovery values for fresh control fortification run concurrently with treated specimens in all the tests were within 76-115% (n = 22) for cauliflower and broccoli. Approximately 80% or more of the recoveries were within 70-110% and the relative standard deviations were less than 20% for all tests. Therefore, the analytical methods used performed well for the determination of chlorantraniliprole in treated crops.

CONCLUSION EU FIELD-GROWN CAULIFLOWER AND BROCCOLI

Overall consistent residue behaviour of chlorantraniliprole on field-grown cauliflower and broccoli was found for two seasons of study in northern and southern Europe, for application and sampling conducted according to GAP. Residues in field-grown cauliflower and broccoli were less than or equal to 0.37 mg/kg at 1 DALA, the target PHI, or longer sampling intervals, in the fourteen residue tests conducted in which Chlorantraniliprole 35WG or Chlorantraniliprole 20SC was applied. The residue data show that residues do not consistently decline in cauliflower and broccoli with increasing DALA. At six of eight decline trials, dissipation half-lives of 4, 3, 1, 5, 4 and 22 days were calculated. There were no declines of residues at the remaining two tests, over the studied 3-day period.

A 2.2.1.1.2 Cabbage

Report:	Foster, A.C., Cairns, S.D., 2007
OECD IIA data point:	IIA 6.3
Title:	Magnitude and decline of DPX-E2Y45 residues in cabbage (head brassicas) following foliar applications of DPX-E2Y45 35WG - northern and southern Europe, 2006
Document No.:	DuPont-18770
Guidelines:	European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC.
GLP:	Yes

Report:	Foster, A.C., Cairns, S.D., 2008
OECD IIA data point:	IIA 6.3
Title:	Magnitude and decline of chlorantraniliprole residues in cabbage (head brassicas) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] and DPX E2Y45 35WG formulated products - Europe, 2007
Document No.:	DuPont-21337
Guidelines:	European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC.
GLP:	Yes

A 2.2.2 MATERIALS AND METHODS

The field program was conducted in 2006 and 2007 at one location in Spain, two locations in Greece, four locations in northern France, one location in Poland, one location in Hungary, two locations in Germany, one location in the UK, and two locations in Italy. Six magnitude of residue tests, five reverse decline, and three decline cabbage tests were conducted

In 2006, chlorantraniliprole (DPX-E2Y45-206, 35WG formulation) was applied twice at the target rates of 30 g a.s./ha to field cabbages for a seasonal application rate of 60 g a.s./ha. In 2007, two applications of Chlorantraniliprole 35WG (DPX-E2Y45-215) or Chlorantraniliprole 20SC [DPX-E2Y45-239; 200 g a.s./L (w/v); 18.5% (w/w)] were applied as foliar broadcast sprays. At all tests, applications were made at approximately the targeted rate of 35 g a.s./ha, for a nominal seasonal application rate of 70 g a.s./ha.

The applications of Chlorantraniliprole 35WG were made at 6-8 day intervals with the last application occurring prior to normal harvest according to the use patterns described in Table 8 and sampling intervals described in Table 9. Spray volumes of approximately 200-800 liters per hectare were employed for the applications. There were no surfactants/additives included in the spray mixture. For the magnitude of residue and decline tests, the last application was made 1 day before the predicted commercial harvest. For the magnitude of residue tests, specimens of cabbage were collected at 1 DALA from the treated and untreated plots. For the decline tests, treated specimens were collected from the treated plot immediately before the last application (*e.g.*, *c.a.* -1 h), after the last application (*e.g.*, *c.a.* +1 h to +3 h) after the product had dried onto the crop, and again at 1 and 3 DALA (BBCH 48-49). Over this narrow time window, both the 1 and 3 DALA samplings represented mature commodities, collected on different days from the same treatment plot. Specimen collections at -0, +0, and 3 DALA only occurred in those plots treated with the water dispersible granule formulation in the decline tests. Specimens from the accompanying untreated plots were also harvested on day of harvest. For the residue decline tests, specimens at each indicated sampling interval were collected at the normal commercial harvest date. To achieve this, application timing was staggered across individual treatment plots so that the targeted sampling interval would occur on approximately the same date for each plot, coinciding with normal commercial harvest. This constituted a reverse residue decline design. The targeted PHI under GAP is 1 day.

Table 8
Study Use Pattern

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] Days	Total Rate (g a.s./ha)[d]		
Test 01 (Villalba del Alcor, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 7 day DBH	779	29.19	3.75	-	59.09	None	DuPont-18770
		Foliar Broadcast/ 1 day DBH	800	29.90	3.74	6		None	
Test 02 (Eringhem, Nord Pas-de-Calais, N. France, 2006)	35WG	Foliar Broadcast/ 27 day DBH	400	30.26	7.57	-	60.88	None	DuPont-18770
		Foliar Broadcast/ 21 day DBH	404	30.62	7.58	6		None	
	35WG	Foliar Broadcast/ 21 day DBH	410	30.97	7.55	-	62.30	None	
		Foliar Broadcast/ 14 day DBH	415	31.33	7.55	7		None	
	35WG	Foliar Broadcast/ 14 day DBH	410	30.97	7.55	-	61.23	None	
		Foliar Broadcast/ 7 day DBH	399	30.26	7.58	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	404	30.62	7.58	-	60.88	None	
		Foliar Broadcast/ 1 day DBH	399	30.26	7.58	6		None	
	35WG	Foliar Broadcast/ 7 day DBH	404	30.62	7.58	-	60.17	None	
		Foliar Broadcast/ 0 day DBH	393	29.55	7.52	7		None	
Test 03 (Tortona, Piemonte, Italy, 2006)	35WG	Foliar Broadcast/ 28 day DBH	794	29.90	3.77	-	58.74	None	DuPont-18770
		Foliar Broadcast/ 21 day DBH	763	28.84	3.78	7		None	
	35WG	Foliar Broadcast/ 21 day DBH	822	30.97	3.77	-	62.65	None	
		Foliar Broadcast/ 14 day DBH	835	31.68	3.79	7		None	
	35WG	Foliar Broadcast/ 14 day DBH	798	30.26	3.79	-	60.52	None	
		Foliar Broadcast/ 7 day DBH	803	30.26	3.77	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	808	30.62	3.79	-	60.17	None	
		Foliar Broadcast/ 1 day DBH	785	29.55	3.76	6		None	
	35WG	Foliar Broadcast/ 7 day DBH	773	29.19	3.78	-	59.45	None	
		Foliar Broadcast/ 0 day DBH	800	30.26	3.78	7		None	

Table 8
Study Use Pattern (continued)

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] Days	Total Rate (g a.s./ha)[d]		
Test 04 (Poncey Les Athée, Bourgogne N. France, 2006)	35WG	Foliar Broadcast/ 28 day DBH	811	30.26	3.73	-	60.88	None	DuPont-18770
		Foliar Broadcast/ 22 day DBH	814	30.62	3.76	6		None	
	35WG	Foliar Broadcast/ 22 day DBH	780	29.19	3.74	-	60.52	None	
		Foliar Broadcast/ 14 day DBH	833	31.33	3.76	8		None	
	35WG	Foliar Broadcast/ 14 day DBH	796	29.90	3.76	-	59.09	None	
		Foliar Broadcast/ 7 day DBH	774	29.19	3.77	7		None	
	35WG	Foliar Broadcast/ 8 day DBH	791	29.55	3.74	-	59.45	None	
		Foliar Broadcast/ 1 day DBH	798	29.90	3.75	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	800	29.90	3.74	-	59.80	None	
		Foliar Broadcast/ 0 day DBH	798	29.90	3.75	7		None	
Test 05 (Falenty Nowe,Central Poland Mazovian Region, Poland, 2006)	35WG	Foliar Broadcast/ 28 day DBH	779	29.19	3.75	-	59.81	None	DuPont-18770
		Foliar Broadcast/ 21 day DBH	813	30.62	3.77	7		None	
	35WG	Foliar Broadcast/ 21 day DBH	796	29.90	3.76	-	59.45	None	
		Foliar Broadcast/ 14 day DBH	789	29.55	3.75	7		None	
	35WG	Foliar Broadcast/ 14 day DBH	787	29.55	3.75	-	58.74	None	
		Foliar Broadcast/ 7 day DBH	782	29.19	3.73	7		None	
	35WG	Foliar Broadcast/ 9 day DBH	771	28.84	3.74	-	58.74	None	
		Foliar Broadcast/ 1 day DBH	796	29.90	3.76	8		None	
	35WG	Foliar Broadcast/ 7 day DBH	827	30.97	3.74	-	61.23	None	
		Foliar Broadcast/ 0 day DBH	808	30.26	3.75	7		None	

Table 8
Study Use Pattern (continued)

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] Days	Total Rate (g a.s./ha)[d]		
Test 06 (Chalkidona, Thessaloniki, Greece, 2006)	35WG	Foliar Broadcast/ 28 day DBH	813	30.69	3.77	-	61.38	None	DuPont-18770
		Foliar Broadcast/ 20 day DBH	813	30.69	3.77	8		None	
	35WG	Foliar Broadcast/ 20 day DBH	820	30.94	3.77	-	61.38	None	
		Foliar Broadcast/ 14 day DBH	807	30.44	3.77	6		None	
	35WG	Foliar Broadcast/ 14 day DBH	813	30.69	3.77	-	61.00	None	
		Foliar Broadcast/ 7 day DBH	803	30.31	3.77	7		None	
	35WG	Foliar Broadcast/ 8 day DBH	810	30.57	3.77	-	60.48	None	
		Foliar Broadcast/ 1 day DBH	793	29.91	3.77	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	797	30.06	3.77	-	60.35	None	
		Foliar Broadcast/ 0 day DBH	803	30.29	3.77	7		None	
Test 07 (Goch-Kessel, North Rhine - Westphalia, Germany, 2006)	35WG	Foliar Broadcast/ 8 day DBH	627	31.53	5.03	-	62.39	None	DuPont-18770
		Foliar Broadcast/ 1 day DBH	613	30.86	5.03	7		None	
Test 08 (Seregélyes, Fejér County, Hungary, 2006)	35WG	Foliar Broadcast/ 8 day DBH	213	32.00	15.00	-	63.54	None	DuPont-18770
		Foliar Broadcast/ 1 day DBH	210	31.54	15.02	7		None	

Table 8
Study Use Pattern (continued)

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] Days	Total Rate (g a.s./ha)[d]		
Test 01 (Eringhem, Nord, North	35WG	Foliar Broadcast/ 9 day DBH	480.00	33.69	7.02	-	68.40	None	DuPont-21337
		Foliar Broadcast/ 1 day DBH	494.00	34.71	7.03	8		None	
		Foliar Broadcast/ 9 day DBH	485.00	33.85	6.98	-		None	DuPont-

France, 2007)	20SC	Foliar Broadcast/ 1 day DBH	497.00	34.62	6.97	8	68.47	None	21337
Test 02 (Ortwig, Brandenburg, Germany, 2007)	35WG	Foliar Broadcast/ 8 day DBH	483.47	33.84	7.00	-	68.43	None	DuPont-21337
		Foliar Broadcast/ 1 day DBH	494.13	34.59	7.00	7		None	
	20SC	Foliar Broadcast/ 8 day DBH	490.13	34.30	7.00	-	69.35	None	DuPont-21337
		Foliar Broadcast/ 1 day DBH	500.80	35.05	7.00	7		None	
Test 03 (San Donato Milanese, Lombardia, Italy, 2007)	35WG	Foliar Broadcast/ 8 day DBH	513.00	36.13	7.04	-	70.84	None	DuPont-21337
		Foliar Broadcast/ 1 day DBH	493.00	34.17	7.04	7		None	
	20SC	Foliar Broadcast/ 8 day DBH	484.00	33.92	7.01	-	69.24	None	DuPont-21337
		Foliar Broadcast/ 1 day DBH	507.00	35.32	6.97	7		None	
Test 04 (Nea Magnesia, Thessaloniki, Central Macedonia, Greece, 2007)	35WG	Foliar Broadcast/ 8 day DBH	501.67	35.03	6.98	-	70.17	None	DuPont-21337
		Foliar Broadcast/ 1 day DBH	503.33	35.14	6.98	7		None	
	20SC	Foliar Broadcast/ 8 day DBH	500.56	35.01	6.99	-	70.18	None	DuPont-21337
		Foliar Broadcast/ 1 day DBH	502.78	35.17	7.00	7		None	
Test 05 (North Berwick, East Lothian, UK, 2007)	20SC	Foliar Broadcast/ 8 day DBH	482.00	33.70	6.99	-	67.40	None	DuPont-21337
		Foliar Broadcast/ 1 day DBH	484.00	33.70	6.96	7		None	
	35WG	Foliar Broadcast/ 8 day DBH	509.00	35.67	7.01	-	72.04	None	DuPont-21337
		Foliar Broadcast/ 1 day DBH	519.00	36.37	7.01	7		None	

Table 8
Study Use Pattern (continued)

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] Days	Total Rate (g a.s./ha)[d]		
Test 06 (Aubers, Nord, North France, 2007)	20SC	Foliar Broadcast/ 7 day DBH	514.00	35.93	6.99	-	71.86	None	DuPont-21337
		Foliar Broadcast/ 1 day DBH	514.00	35.93	6.99	6		None	
	35WG	Foliar Broadcast/ 7 day DBH	519.00	36.30	6.99	-	72.60	None	DuPont-21337
		Foliar Broadcast/ 1 day DBH	519.00	36.30	6.99	6		None	

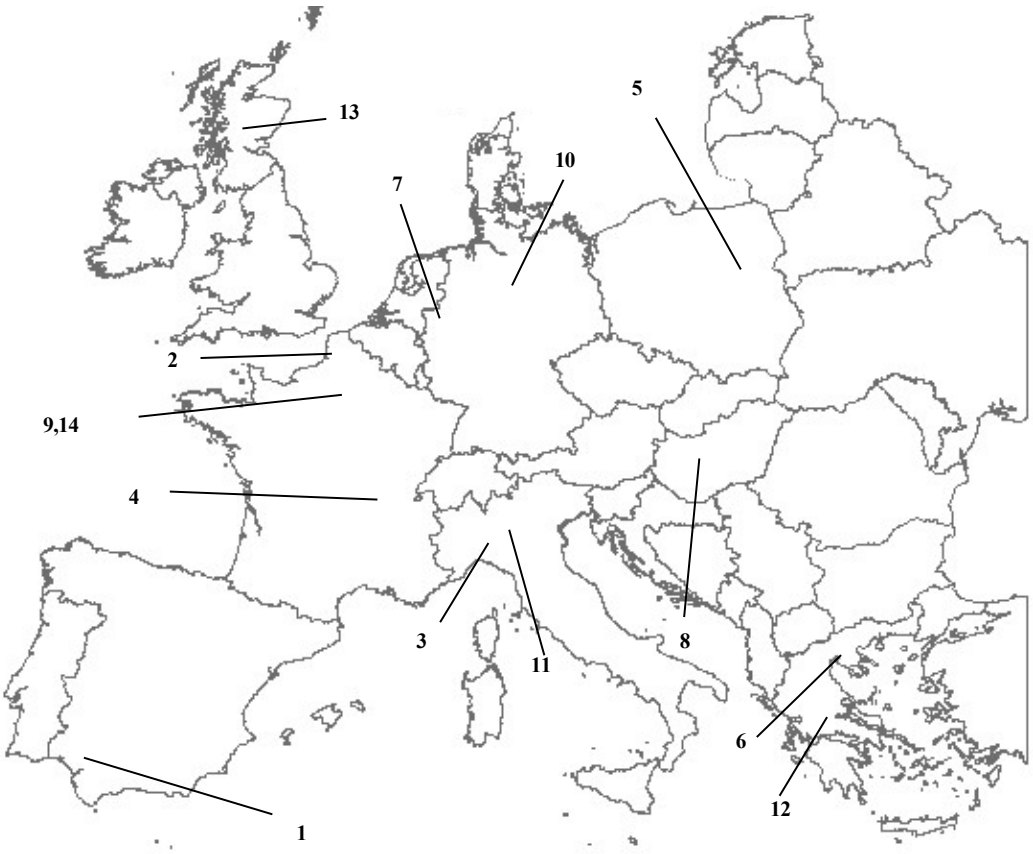
[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Liters/hectare
[d] grams active ingredient per hectare
[e] g active ingredient/hL (gram active ingredient per hectoliter or 100 L)

f Retreatment Interval

A total of 6 magnitude of residue, 3 decline, and 5 reverse decline tests were conducted in the growing seasons of 2006 and 2007. A summary of these field cabbages studies is given below. Locations of the field cabbages test sites are given in the following figure.

Figure 2

Map: Chlorantraniliprole northern and southern European field cabbages (head brassicas) test sites



Map No.	Reference, Test No.	Location
1	DuPont-18770, 1	Villalba del Alcor, Andalucia, Spain
2	DuPont-18770, 2	Eringhem, Nord Pas-de-Calais, Northern France
3	DuPont-18770, 3	Tortona, Piemonte, Italy
4	DuPont-18770, 4	Poncey les Athée, Bourgogne, Northern France
5	DuPont-18770, 5	Falenty Nowe, Central Poland Mazovian Region
6	DuPont-18770, 6	Chalkidona, Thessaloniki, Greece
7	DuPont-18770, 7	Goch-Kessel, North Rhine – Westphalia, Germany
8	DuPont-18770, 8	Seregélyes, Fejér County, Hungary
9	DuPont-21337, 1	Eringhem, Nord, France (North)
10	DuPont-21337, 2	Ortwig, Brandenburg, Germany

11	DuPont-21337, 3	San Donato Milanese, Lombardia, Italy
12	DuPont-21337, 4	Nea Magnesia, Thessaloniki, Central Macedonia, Greece
13	DuPont-21337, 5	North Berwick, East Lothian, UK
14	DuPont-21337, 6	Aubers, Nord, France (North)

A field cabbages residue data summary (in mg/kg) is presented in Table 9 and

Table 10. To generate these data, the following analysis and recovery information

pertains.

Analysis method: LC-MS/MS method (DuPont-13295; Chlorantraniliprole DAR, Volume 3, B5) developed as the chlorantraniliprole residue method for determining residues of chlorantraniliprole in/on crops.

Analyte:	Chlorantraniliprole
Extraction:	Analyte extracted from crop matrices with acetonitrile following water presoak.
Clean-up:	SAX (Strong Anion Exchange) and HLB (Hydrophilic Lipophilic Balanced) Solid Phase Extraction (SPE) cartridges
Chromatography:	LC
Detection:	Mass spectrometer detection (MS/MS) in APCI positive mode. Two ion transitions are acquired 284 m/z – 177 m/z and 484 m/z – 453 m/z. The former transition is used for quantification and the second transition for confirmation. In cases where a significant interference is detected in the former transition the latter transition may be used for quantification purposes
LOQ:	0.010 mg/kg

Storage stability: All specimens were analysed within 9 months of sampling. Chlorantraniliprole residues are stable in a variety of crops including predominantly water-, oil-, protein- and, starch-containing commodities as represented by fruits, a fruiting vegetable, a root crop, a non-oily grain, and an oilseed (apple, grape, tomato, leaf lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay, and ginned cottonseed) for at least 24 months when stored frozen at -20 ± 10°C (see Chlorantraniliprole DAR, Volume 3, B7, pages 13-52 (pdf pagination)). Therefore, no degradation is expected to have occurred between harvest and analysis.

Table 9
Residues of chlorantraniliprole in field cabbages (head brassicas) from supervised tests

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g a.s./ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c,d]	Ref
Test 01 (Villalba del Alcor, Andalucia, Spain, 2006)	35WG	Cabbage/ Bronco	Cabbage Heads	59.09	1	0.012	DuPont-18770
Test 02 (Eringhem, Nord Pas-de-Calais, N. France, 2006)	35WG	Cabbage/ Brutus	Cabbage Heads	30.62 60.17 60.88 61.23 62.30	-1 h +2 h 1 7 14	nd 0.013 0.009 nd nd	DuPont-18770

				60.88	21	nd	
Test 03 (Tortona, Piemonte, Italy, 2006)	35WG	Cabbage/ Famosa	Cabbage Heads	29.19 59.45 60.17 60.52 62.65 58.74	-1 h +1 h 1 7 14 21	0.020 0.034 0.10 0.023 nd nd	DuPont-18770
Test 04 (Poncey les Athée, Bourgogne, N. France, 2006)	35WG	Cabbage/ Zerlina	Cabbage Heads	29.90 59.80 59.45 59.09 60.52 60.88	-1 h +2 h 1 7 14 22	nd nd nd nd nd nd	DuPont-18770
Test 05 (Falenty Nowe, Central Poland Mazovian Region, Poland, 2006)	35WG	Cabbage/ Milstone	Cabbage Heads	30.97 61.23 58.74 58.74 59.45 59.81	-1 h +1 h 1 7 14 21	0.019 0.022 0.007 nd 0.007 0.009	DuPont-18770
Test 06 (Chalkidona, Thessaloniki, Greece, 2006)	35WG	Cabbage/ Magnisias	Cabbage Heads	30.06 60.35 60.48 61.00 61.38 61.38	-1 h +2 h 1 7 14 20	nd nd nd nd nd nd	DuPont-18770
Test 07 (Goch-Kessel, North Rhine - Westphalia, Germany, 2006)	35WG	Cabbage/ Buskaro	Cabbage Heads	31.53 30.86	1	nd	DuPont-18770

Table 9
Residues of chlorantraniliprole in field cabbages (head brassicas) from supervised tests (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g a.s./ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c,d]	Ref
Test 08 (Seregélyes, Fejér County, Hungary, 2006)	35WG	Cabbage/ Júniusi óriás	Cabbage Heads	63.54	1	0.009	DuPont-18770
Test 01 (Eringhem, Nord, North France, 2007)	35WG	Cabbage/ Shelton	Heads	68.47	(-1 h) (+1 h) 1 3	nd 0.029 0.009 nd	DuPont-21337
	20SC	Cabbage/ Shelton	Heads	68.40	1	0.008	DuPont-21337

Test 02 (Ortwig, Brandenburg, Germany, 2007)	35WG	Cabbage/ Cassandra	Heads	69.35	(-1 h) (+3 h) 1 3	nd 0.012 nd 0.006	DuPont-21337
	20SC	Cabbage/ Cassandra	Heads	68.43	1	0.009	DuPont-21337
Test 03 (San Donato Milanese, Lombardia, Italy, 2007)	35WG	Cabbage/ Castello	Heads	69.24	(-1 h) (+2 h) 1 3	nd 0.014 0.009 0.007	DuPont-21337
	20SC	Cabbage/ Castello	Heads	70.84	1	0.015	DuPont-21337
Test 04 (Nea Magnesia, Thessaloniki, Central Macedonia Greece, 2007)	35WG	Cabbage/ Grandslam	Heads	70.18	1	0.011	DuPont-21337
	20SC	Cabbage/ Grandslam	Heads	70.17	1	0.009	DuPont-21337
Test 05 (North Berwick, East Lothian, UK, 2007)	35WG	Cabbage/ Destiny	Heads	72.04	1	0.095	DuPont-21337
	20SC	Cabbage/ Destiny	Heads	67.40	1	0.053	DuPont-21337
Test 06 (Aubers, Nord, North France, 2007)	35WG	Cabbage/Count	Heads	72.60	1	0.012	DuPont-21337
	20SC	Cabbage/Count	Heads	71.86	1	0.012	DuPont-21337

[a] EP = End-use Product

[b] DALA = Days after last application (Days between last application and sampling)

[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.

[d] Control specimens were collected and analyzed. No detectable residues, nd, were found in all instances.

Table 10

Summary of residue data from field cabbage (head brassicas) trials with chlorantraniliprole

Commodity	EP[a]	Total Application Rate (g ai/ha)	DALA/ PHI (days)	Residue Levels in ppm (mg/kg)						
				n[b]	Min.[b]	Max.[b]	HAFT[b]	Median[b] (STMdR)	Mean[b] (STMR)	Std. Dev.[b]
Chlorantraniliprole										
Head cabbage	35WG	29.19-36.13	-0[c]	8	nd	0.022	0.022	0.004	0.008	0.008
		58.74-71.86	0	8	0.004	0.034	0.034	0.014	0.016	0.011
			1	14	0.004	0.10	0.10	0.009	0.021	0.033
			3	3	nd	0.007	0.007	0.006	0.005	0.002
			7	5	0.004	0.023	0.023	0.004	0.008	0.008
			14	5	0.004	0.007	0.007	0.004	0.005	0.001
			21	5	0.004	0.009	0.009	0.004	0.005	0.002
Head cabbage	20SC	68.47-72.60	1	6	0.008	0.053	0.053	0.011	0.018	0.018

[a] EP = End-use Product

[b] N = number of individual specimens,
Min = minimum individual specimen residue,
Max = maximum individual specimen residue,
HAFT = Highest Average residue from one Field Test; (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set).

Median = median of individual specimen residues,
Mean = mean of individual specimen residues,
Std Dev = standard deviation of mean
[c] Shortly before the last application

Recovery data: Average recovery data for fortifications run concurrently with the treated specimens are given below to demonstrate the validity of the analytical method.

Table 11

Summary of concurrent recoveries of chlorantraniliprole from cabbage (DuPont-18770)

Matrix	Fortification Level in ppm (mg/kg)	Sample Size (n)	Recoveries (%)	Mean ± std. dev. (% ± %)
Chlorantraniliprole				
Cabbage	0.010	3	93, 91, 85	90 ± 4 (5)
Cabbage	0.10	3	105, 110, 91	102 ± 10 (10)
Cabbage	0.30	2	94, 101	97
Overall	-	8	-	96 ± 8 (9)

Statistics were calculated using non-rounded recovery values

Table 12
Summary of concurrent recoveries of chlorantraniliprole from cabbage (DuPont-21337)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (CV) (% ± % (%))
Concurrent Fortifications – Chlorantraniliprole				
Cabbage Heads	0.010 0.10	2 2	112, 93 97, 102	103 100
Overall	-	4	-	101 ± 8 (8)

RESULTS AND DISCUSSION

The residue studies presented herein were carried out in eight different EU countries and provide data relevant to conditions in the field cabbages-growing regions of northern and southern Europe.

All of the analytical work associated with the studies was performed at Charles River Laboratories, Tranent, EH33 2NE, Scotland in the winter of 2006, the spring of 2007, and March 2008.

In the northern and southern European regions, residues in field cabbages were less than or equal to 0.10 mg/kg at 1 DALA, the target PHI, or longer sampling intervals, in the fourteen residue tests conducted in 2006 and 2007 in which Chlorantraniliprole 35WG or Chlorantraniliprole 20SC was applied at 84-103% of GAP rate of application.

The calculated half-lives for chlorantraniliprole in field cabbages were approximately 2 (based on two sampling times showing detectable residues), 4, 30, approximately 1 (based on two sampling times showing detectable residues), 4, and 3 days for DuPont-18770 Tests 2, 3, and 5, and DuPont-21337 Tests 1, 2, and 3, respectively. Residues of chlorantraniliprole in cabbage were not detected (<0.004 mg/kg) in DuPont-18770 Test 4 and Test 6, for any sampling interval.

The study data show an overall consistent residue profile when chlorantraniliprole was applied in accordance with GAP.

Recovery values for fresh control fortification run concurrently with treated specimens in all the tests were within 85-112% (n = 12) for field cabbages. Approximately 75% or more of the recoveries were within 70-110% and the relative standard deviations were less than 20% for all fortification levels. Therefore, the analytical methods used performed well for the determination of chlorantraniliprole in treated crops.

CONCLUSION – EU FIELD-GROWN CABBAGE TRIALS

Overall consistent residue behaviour of chlorantraniliprole on field cabbages was found for two seasons of study in Europe, for application and sampling conducted according to GAP. The residue data show that residues decline in field cabbages with increasing DALA with dissipation half-lives of 1-30 days. Residues were less than or equal to 0.10 mg/kg at 1 DALA, the target PHI, or longer sampling intervals, for field cabbages.

A 2.2.2.1.1 Carrots

Report:	Cairns, S., Hoskins, M., Foster, A. 2011
OECD IIA data point:	IIA 6.3
Title:	Magnitude and decline of chlorantraniliprole residues in carrots following foliar applications of Chlorantraniliprole 35WG - Europe 2009 and 2010
Document No.:	DuPont-27575
Guidelines:	European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC.
GLP:	Yes

A 2.2.2.2 MATERIALS AND METHODS

A field program was conducted containing 8 Magnitude of Residue (MOR) tests and 10 Decline tests (DEC) in order to evaluate the residual behaviour of chlorantraniliprole in carrots following 2 foliar applications of Chlorantraniliprole 35WG. This summary contains field and analytical data for Europe in the 2009 (Test Nos. 1–10) and 2010 growing seasons (Test Nos. 11–18). For the 2009 growing season, 2 MOR and 3 DEC tests were performed in northern Europe (North France, Germany, UK and Czech Republic); 2 MOR and 3 DEC tests were conducted in southern Europe (South France, Italy, Spain and Greece). For the 2010 growing season, 2 MOR and 2 DEC tests were performed in northern Europe

(North France, Germany, UK and Czech Republic); 2 MOR and 2 DEC tests were conducted in southern Europe (Italy, Greece, South France and South Spain).

At all test sites, with the exception of Test 1, the applications were made at approximately the targeted rate of

40.25 g a.s./ha (4.0 or 8.0 g a.s./hL) for a nominal seasonal application rate of approximately 80.5 g a.s./ha. Test 1 received a seasonal application of 64.90 g a.s./ha.

Two applications of Chlorantraniliprole 35WG (DPX-E2Y45-259) were made per treated plot. The first application was made at a target 31 ± 3 days before the predicted commercial harvest date. The second application was made at a target 21 ± 2 days before the predicted commercial harvest date. Target spray volumes of 500 L/ha (France only) or 800-1000 L/ha were employed for the applications. There were no surfactants/additives included in the spray mixture. The use patterns are presented in Table 13.

For the MOR tests, carrot root specimens were collected at *ca.* 21 ± 2 days after last application from both the treated and untreated plots. For the normal decline tests, treated carrot root specimens were collected immediately before the last application (*e.g. ca.* –1 h), again once the last application had dried onto the crop (*e.g. ca.* +2 h), and at target 7 ± 1, 14 ± 1, 21 ± 2 and 28 ± 3 days after the last application. The sampling intervals are presented in

Table 14.

Table 13
Study use pattern – 2009 and 2010 growing seasons

Test Identification (City, State/Region, Country, Year)	EP[a]	Method/ Timing[b]	Vol (L/ha)	g a.s./ha	g a.s./hL	RTI[c] Days	Total Rate (g a.s./ha)	Tank Mix Adjuvants
Test 01 Saucats Gironde, South France, 2009	35WG	Foliar Spray 31 DBH	800	33.4	4.18	10		None
		Foliar Spray 21 DBH	800	31.5	3.94			
Test 02 Saint Connec, Côtes-D' Armor, North France, 2009	35WG	Foliar Spray 31 DBH	478	38.7	8.10	10		None
		Foliar Spray 21 DBH	489	39.6	8.10			
Test 03 Moustoir Remungol, Morbihan, North France, 2009	35WG	Foliar Spray 31 DBH	494	40.0	8.10	10		None
		Foliar Spray 21 DBH	468	37.9	8.10			
Test 04 Bosco Mesola, Emilia Romagna Italy, 2009	35WG	Foliar Spray 31 DBH	1039	41.89	4.03	10	82.02	None
		Foliar Spray 21 DBH	990	40.13	4.05			
Test 05 Castelnuovo Scrivia, Piemonte Italy, 2009	35WG	Foliar Spray 29 DBH	1025	41.54	4.05	9	82.37	None
		Foliar Spray 20 DBH	1010	40.83	4.04			

Test 06 Conil de la Frontera, Andalucia, Spain, 2009	35WG	Foliar Spray 28 DBH	999	40.48	4.05	7		None
		Foliar Spray 21 DBH	1010	40.83	4.04			
Test 07 Chalkidona, Thessaloniki, Central Macedonia, Greece, 2009	35WG	Foliar Spray 31 DBH	1001	40.53	4.05	10		None
		Foliar Spray 21 DBH	1011	40.93	4.05			
Test 08 Cargill, Perthshire, UK, 2009	35WG	Foliar Spray 29 DBH	1001	40.48	4.04	9		None
		Foliar Spray 20 DBH	990	40.13	4.05			
Test 09 Motterwitz, Saxony, Germany, 2009	35WG	Foliar Spray 30 DBH	1038	41.76	4.02	9		None
		Foliar Spray 21 DBH	982	39.50	4.02			

Table 13
Study use pattern – 2009 and 2010 growing seasons (continued)

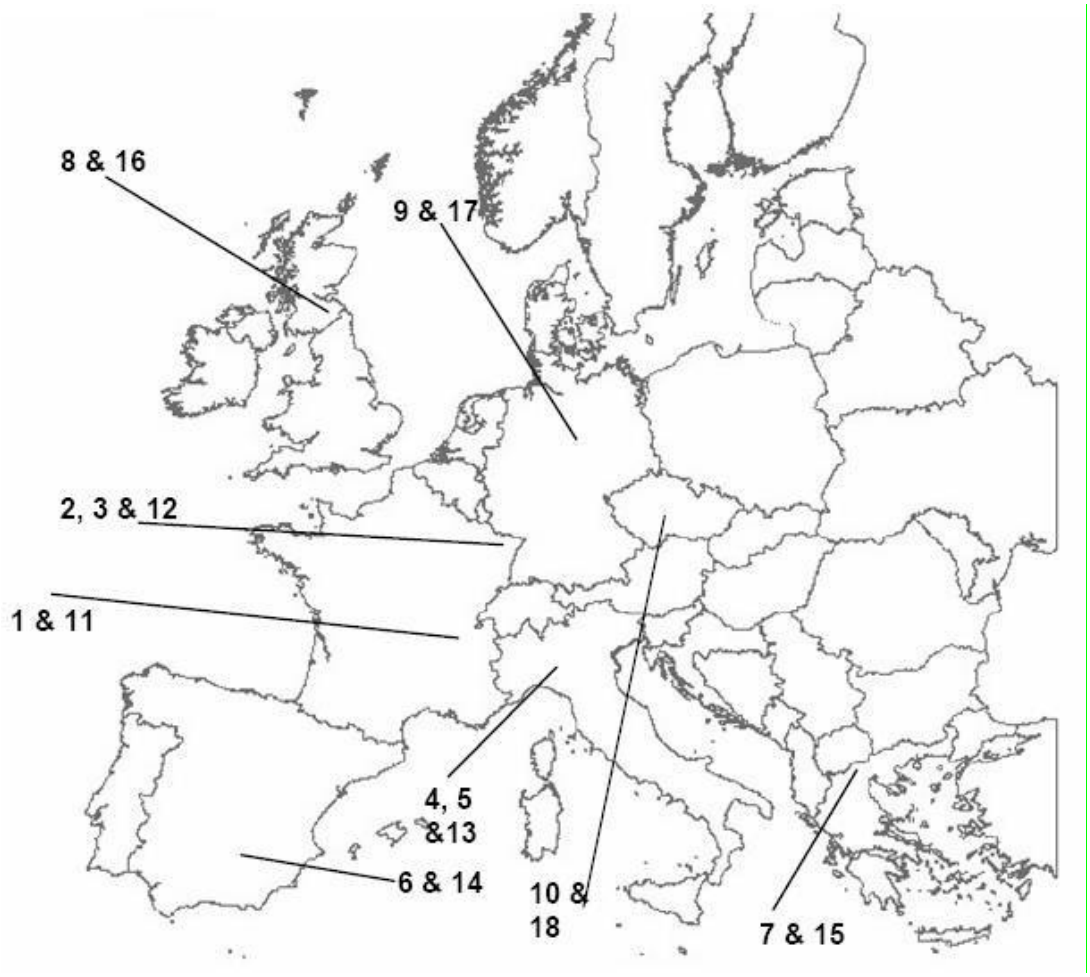
Test Identification (City, State/Region, Country, Year)	EP[a]	Meth-od/ Tim-ing[b]	Vol (L/ha)	g a.s./ha	g a.s./hL	RTI[c] Days	Total Rate (g a.s./ha)	Tank Mix Adjuvants
Test 10 Ostrožská Nová Ves, Zlínský kraj, Czech Republic, 2009	35WG	Foliar Spray 32 DBH	1043	42.02	4.03	11		None
		Foliar Spray 21 DBH	1025	41.30	4.03			
Test 11 Blagon Gironde, France, 2010	35WG	Foliar Spray 31 DBH	502	40.4	8.05	10		None
		Foliar Spray 21 DBH	506	40.7	8.05			
Test 12 Ploerdut, Morbihan, France, 2010	35WG	Foliar Spray 32 DBH	506	40.6	8.03	11		None
		Foliar Spray 21 DBH	511	41.1	8.04			
Test 13 Bosco Mesola, Emilia Romagna, Italy, 2010	35WG	Foliar Spray 27 DBH	996	40.54	4.07	8	80.00	None
		Foliar Spray 19 DBH	965	39.46	4.09			
Test 14 Arcos de la Frontera, Andalucia, Spain, 2010	35WG	Foliar Spray 31 DBH	998	40.18	4.03	10	80.36	None
		Foliar Spray 21 DBH	997	40.18	4.03			
Test 15 Nea Chalkidona, Thessaloniki, Central Macedonia, Greece, 2010	35WG	Foliar Spray 31 DBH	1001	40.75	4.07	10		None
		Foliar Spray 21 DBH	993	40.43	4.07			
Test 16 Se-		Foliar Spray 31 DBH	1032	41.63	4.03			

ton, East Lothian, UK, 2010	35WG	Foliar Spray 22 DBH	1008	40.54	4.02	9		None
Test 17 Motterwitz, Saxony, Germany, 2010	35WG	Foliar Spray 31 DBH	963	38.75	4.02	10		None
		Foliar Spray 21 DBH	1000	40.22	4.02			
Test 18 Kunovi-ce, Zlínský kraj, Czech Republic, 2010	35WG	Foliar Spray 30 DBH	1032	41.53	4.02	10		None
		Foliar Spray 20 DBH	968	38.97	4.03			

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Retreatment Interval

A total of 8 magnitude of residue and 10 normal decline residue trials (9 in the northern EU, 9 in the southern EU) were conducted in the growing seasons of 2009 and 2010. A summary of these carrot studies is given below. Locations of the carrot trial sites are given in Figure 3.

Figure 3
Map: Chlorantraniliprole EU carrot trial sites



Test No.	Country	Location, Region
1	South France	Saucats, Gironde
2	North France	Saint Connec, Côtes-D'Armor
3	North France	Moustoir Remungol, Morbihan
4	Italy	Bosco Mesola, Emilia Romagna
5	Italy	Castelnuovo Scrivia, Piemonte
6	Spain	Conil de la Frontera, Andalucia
7	Greece	Nea Chalkidona, Thessaloniki, Central Macedonia
8	UK North	Cargill, Perthshire
9	Germany	Motterwitz, Saxony
10	Czech Republic	Ostrožská Nová Ves, Zlínský kraj
11	South France	Blagon Gironde
12	North France	Ploerdut, Morbihan
13	Italy	Bosco Mesola, Emilia Romagna
14	Spain	Arcos de La Frontera, Andalucia
15	Greece	Nea Chalkidona, Thessaloniki, Central Macedonia
16	UK North	Seton, East Lothian
17	Germany	Motterwitz, Saxony
18	Czech Republic	Kunovice, Zlinsky kraj,

A carrot residue data summary (in mg/kg) is presented in Table 14 and Table

15. To generate these data, the following analysis information pertains.

Analysis method: LC-MS/MS method (DuPont-13295; Chlorantraniliprole DAR, Volume 3, B5) developed as the chlorantraniliprole residue method for determining residues of chlorantraniliprole in/on crops.

Analyte:	Chlorantraniliprole
Extraction:	Analyte extracted from crop matrices with acetonitrile following water pre-soak.
Clean-up:	SAX (Strong Anion Exchange) and HLB (Hydrophilic Lipophilic Balanced) Solid Phase Extraction (SPE) cartridges
Chromatography:	LC
Detection:	Mass spectrometer detection (MS/MS) in APCI positive ion mode. Two ion transitions are acquired 284 m/z → 177 m/z and 484 m/z → 453 m/z. The former transition is used for quantification and the second transition for confirmation. In cases where a significant interference is detected in the former transition the latter transition may be used for quantification purposes
LOQ:	0.010 mg/kg

Storage stability: All samples were analysed within 9 months of sampling. Chlorantraniliprole residues are stable in a variety of crops including predominantly water-, oil-, protein-, and starch-containing commodities as represented by fruits, a fruiting vegetable, a root crop, a non-oily grain, and an oilseed (apple, grape, tomato, leaf lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay, and ginned cotton seed) for at least 24 months when stored frozen at -20 ± 10°C (see Chlorantraniliprole DAR, Volume 3, B7, pages 13-52 (pdf pagination)). Therefore, no degradation is expected to have occurred between harvest and analysis.

Table 14

Residues of chlorantraniliprole in carrots from 2009 and 2010 EU supervised trials

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g a.s./ha)	DALA[b]/ PHI (days)	Residue[c,d] (mg/kg)
Test 01 Saucats Gironde, South France, 2009	35WG	Carrot/ Dordogne	Carrot Roots	64.90	-0 +0 7 14 21 28	ND ND ND 0.008 ND ND
Test 02 Saint Connec, Côtes-D'Armor, North France, 2009	35WG	Carrot/ Kingston	Carrot Roots	78.30	21	ND
Test 03 Moustoir Remungol, Morbihan, North France, 2009	35WG	Carrot/Mac Kabro	Carrot Roots	77.90	-0 +0 7 14 21 28	ND ND ND ND ND ND
Test 04 Bosco Mesola, Emilia Romagna Italy, 2009	35WG	Carrot/ Dordogne	Carrot Roots	82.02	21	0.025
Test 05 Castelnuovo Scrivia, Piemonte Italy, 2009	35WG	Carrot/ Dordogne	Carrot Roots	82.37	-0 +0 7 14 20 27	0.004 0.010 0.096 0.006 0.036 0.030
Test 06 Conil de la Frontera, Andalucia, Spain, 2009	35WG	Carrot/Nevis	Carrot Roots	81.31	-0 +0 7 14 21 28	ND ND 0.009 0.040 0.004 ND

[a] EP = End-use Product

[b] DALA = Days after last application (Days between last application and sampling)

[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg).

[d] Control specimens were collected and analyzed for the target harvest sampling date and at 0 DALA for the decline trials. No detectable residues, nd, were found in all instances.

Table 14

Residues of chlorantraniliprole in carrots from 2009 and 2010 EU supervised trials (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g a.s./ha)	DALA[b]/ PHI (days)	Residue[c,d] (mg/kg)
Test 07 Nea Chalkidona, Thessaloniki, Central Macedonia, Greece, 2009	35WG	Carrot/Tempo F1	Carrot Roots	81.46	21	0.030
Test 08 Cargill, Perthshire, UK, 2009	35WG	Carrot/Romance	Carrot Roots	80.61	-0 +0 7 14 21 28	0.012 0.008 0.016 0.013 0.009 0.027
Test 09 Mottewitz, Saxony, Germany, 2009	35WG	Carrot/ Nantaise 2	Carrot Roots	81.26	-0 +0 7 14 21 28	0.020 0.010 0.022 0.024 0.021 0.015
Test 10 Ostrožská Nová Ves, Zlínský kraj, Czech Republic, 2009	35WG	Carrot/ Kamaran F1	Carrot Roots	83.32	21	0.014
Test 11 Blagon Gironde, south France, 2010	35WG	Carrot/ Dordogne	Carrot Roots	81.10	-0 +0 7 14 21 28	ND ND 0.005 ND 0.005 ND
Test 12 Ploerdut, Morbihan, north France, 2010	35WG	Carrot/Kiev	Carrot Roots	81.70	21	0.010

[a] EP = End-use Product

[b] DALA = Days after last application (Days between last application and sampling)

[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg).

[d] Control specimens were collected and analyzed for the target harvest sampling date. A residue was detected in the +0 day control for Test 09 of 0.007 mg/kg. No other detectable residues, nd, were found.

Table 14

Residues of chlorantraniliprole in carrots from 2009 and 2010 EU supervised trials (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/Variety	Commodity or Matrix	Total Rate (g a.s./ha)	DALA[b]/ PHI (days)	Residue[c,d] (mg/kg)
Test 13 Bosco Mesola, Emilia Romagna Italy, 2010	35WG	Carrot/Napoli	Carrot Roots	80.00	19	0.005
Test 14 Arcos de la Frontera, Andalucia, Spain, 2010	35WG	Carrot/Namur	Carrot Roots	80.36	-0 +0 7 14 21 28	ND ND ND ND ND ND
Test 15 Nea Chalkidona, Thessaloniki, Central Macedonia, Greece, 2010	35WG	Carrot/Tempo F1	Carrot Roots	81.18	21	ND
Test 16 Seton, East Lothian, UK, 2010	35WG	Carrot/Nairobi	Carrot Roots	82.17	-0 +0 8 15 22 29	ND ND ND ND ND ND
Test 17 Mottewitz, Saxony, Germany, 2010	35WG	Carrot/ Nantaise 2	Carrot Roots	78.97	21	ND
Test 18 Kunovice, Zlínský kraj, Czech Republic, 2010	35WG	Carrot/ Kamaran F1	Carrot Roots	80.50	-0 +0 7 14 20 27	ND ND ND ND ND ND

[a] EP = End-use Product

[b] DALA = Days after last application (Days between last application and sampling)

[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg).

[d] Control specimens were collected and analyzed for the target harvest sampling date and at 0 DALA for the decline trials. No detectable residues, nd, were found in all instances.

Table 15

Summary of residue data from carrot field tests with chlorantraniliprole

Commodity	EP[a]	Total Application Rate (g a.s./ha)	DALA/ PHI (days)	Residue Levels in ppm (mg/kg)						
				N[b]	Min.[b]	Max.[b]	HAFT[b]	Median[b] (STMdR)	Mean[b] (STMR)	Std. Dev.[b]
Chlorantraniliprole										
Carrot Roots (2009-2010)	35WG	33.40–41.76	-0[c]	10	ND	0.020	0.020	ND	0.005	0.006
		64.90–83.32	0[d]	10	ND	0.010	0.010	ND	0.004	0.004
			7-8	10	ND	0.096	0.096	0.004	0.016	0.029
			14-15	10	ND	0.040	0.040	0.004	0.010	0.013
			19-22	18	ND	0.036	0.036	0.005	0.010	0.011
			27-29	10	ND	0.030	0.030	ND	0.009	0.011

[a] EP = End-use Product

[b] N = number of individual specimens,
Min = minimum individual specimen residue,
Max = maximum individual specimen residue,
HAFT = Highest Average residue from one Field Test; (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set),
Median = median of individual specimen residues,
Mean = mean of individual specimen residues,
Std Dev = standard deviation of mean

[c] Shortly before the last application

[d] Shortly after the last application

[e] Where a result of ND was generated ½ the LOD value was used for the purposes of calculations (0.002 mg/kg)

Recovery data: Recovery data for fortifications run concurrently with the treated samples are given below to demonstrate the validity of the analytical method.

Table 16
Summary of concurrent recoveries of chlorantraniliprole from carrot roots – DuPont-27575 (2009-2010 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev (rsd) % ± % (rsd%)
Concurrent Fortifications – Chlorantraniliprole				
Carrot Roots	0.010	11	66, 79, 91, 83, 84, 87, 100, 124, 92, 89, 91	90 ± 14 (16)
	0.10	11	76, 66, 69, 80, 76, 84, 106, 83, 82, 89, 84	81 ± 11 (13)
Overall	-	22	-	85 ± 13 (15)

RESULTS AND DISCUSSION

The residue trials presented herein were carried out in seven different EU countries in the 2009 and 2010 growing seasons and provide data relevant to conditions in the carrot-growing regions of the northern and southern EU.

All of the analytical work associated with the studies was performed at Charles River Laboratories, Tranent, EH33 2NE, Scotland. The analytical work was carried out during two different time periods: first time for the Season 2009 residue trials, in the November 2009 to February 2010 period and in the November to December of 2010 period for the 2010 residue trials.

In southern Europe, residues in carrots were less than or equal to 0.036 mg/kg at 21 DALA, the target PHI, or longer sampling intervals, in the 9 residue tests conducted in 2009 and 2010 in which Chlorantraniliprole 35WG was applied at 81-102% of GAP rate of application per season.

In northern Europe, residues in carrots were less than or equal to 0.027 mg/kg at 21 DALA, the target PHI, or longer sampling intervals, in the 9 residue tests conducted in 2009 and 2010 in which Chlorantraniliprole 35WG was applied at 97-104% of GAP rate of application per season.

Recovery values for fresh control fortifications run concurrently with treated samples in all the trials were within 66–124 % (mean = 85 ± 13% rsd (15%)) (n = 22) for carrot roots. Most of the recoveries were within 70–110% and the relative standard deviations were less than 20% for all trials. Therefore, the analytical methods used performed well for the determination of chlorantraniliprole in treated crops.

CONCLUSION – EU TRIALS

Overall consistent residue behaviour of chlorantraniliprole on carrots was found for two seasons of study in the northern and southern EU for application and sampling conducted supportive of GAP.

In southern Europe, residues in carrots were less than or equal to 0.036 mg/kg at 21 DALA, the target PHI, or longer sampling intervals, in the 9 residue tests conducted in 2009 and 2010 in which Chlorantraniliprole 35WG was applied at 81-102% of GAP rate of application per season.

In northern Europe, residues in carrots were less than or equal to 0.027 mg/kg at 21 DALA, the target PHI, or longer sampling intervals, in the 9 residue tests conducted in 2009 and 2010 in which Chlorantraniliprole 35WG was applied at 97-104% of GAP rate of application per season.

The average half-life for chlorantraniliprole in carrot roots could not be calculated. In the decline tests, residues of chlorantraniliprole were not detected or were detected at low levels which did not consistently decline during the test period.

A 2.2.2.2.1 Maize/Sweet corn

Report:	Foster, A.C., Cairns, S.D., 2007
OECD IIA data point:	IIA 6.3
Title:	Magnitude and decline of DPX-E2Y45 residues in maize following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - northern and southern Europe, 2006
Document No.:	DuPont-20120
Guidelines:	European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC.
GLP:	Yes

Report:	Foster, A.C., Cairns, S.D., 2008
OECD IIA data point:	IIA 6.3
Title:	Magnitude and decline of chlorantraniliprole residues in maize following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] and DPX-E2Y45 35WG formulated products - Europe, 2007
Document No.:	DuPont-21629
Guidelines:	European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC.
GLP:	Yes

MATERIALS AND METHODS

The field program was conducted in 2006 and 2007 at four locations in Germany, three locations in Spain, two locations each in northern France, southern France, Greece, Hungary, and Italy, and at one location in Poland.

Eight magnitude of residue (MOR) and six decline maize tests were conducted. In 2006, Chlorantraniliprole 20SC (DPX-E2Y45-205; 200 g a.s./L (w/v); 18.5% (w/w)) was applied twice at the target rate of 31g a.s./ha to maize, for a seasonal application rate of 62 g a.s./ha. In 2007, Chlorantraniliprole 35WG (DPX-E2Y45-215) or Chlorantraniliprole 20SC (DPX-E2Y45-239; 200 g a.s./L (w/v); 18.5% (w/w)) were applied at approximately the targeted rate of 31 g a.s./ha, for a seasonal application rate of 62 g a.s./ha. The first application was made at approximately BBCH 55 and the second at 7 days prior to harvest of the green plant destined for silage, where harvest of the green plant was targeted to occur at approximately BBCH 83-85, the dough stage. Spray volumes of approximately 250-525 liters per hectare were employed for the applications. There were no surfactants/additives included in the spray mixture.

Applications were made according to the use patterns described in Table 17 and sampling intervals described in Table 18 and Table 19. The targeted PHI under GAP is 7 days for maize whole green plant (with extrapolation to sweet corn), whereas harvest of mature grain is defined according to growth stage (BBCH 89). For the magnitude of residue tests, the following specimens of maize were collected at 7 DALA from the treated and untreated plots:

1) whole green plant and 2) cobs plus kernels with outer leaves removed (for extrapolation to sweet corn). At BBCH 89 (40-50 DALA), the treated and untreated plots were sampled again (mature grain only). For the normal decline tests, treated specimens of whole green plant with increasing maturity were collected immediately before the last application (*e.g., ca.* -1 h), once the product had dried onto the crop (*e.g., ca.* +2 h), and at 3 DALA, 7 DALA, 14 DALA from the treated plots. At BBCH 89 (21-34 DALA), treated mature grain specimens were sampled. Maize specimens from the accompanying untreated plots were collected at +0 DALA, 7 DALA and mature grain on the day of harvest.

Table 17 Study Use Pattern

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] Days	Total Rate g a.s./ha[d]		
Test 01 (Antequera, Andalucia, Spain, 2006)	20SC	Foliar Broadcast/ BBCH 55	502	31.10	6.20	-	62.41	NA	DuPont-20120
		Foliar Broadcast/ 7 day DBH	505	31.31	6.20	50		NA	

Test 02 (Douai, Nord Pas De Calais, France, 2006)	20SC	Foliar Broadcast/ BBCH 55	252	31.31	12.42	-	61.57	NA	DuPont-20120
		Foliar Broadcast/ 7 day DBH	244	30.26	12.40	86		NA	
Test 03 (Corteolona, Lombardia, Italy, 2006)	20SC	Foliar Broadcast/ BBCH 55	514	31.72	6.17	-	63.44	NA	DuPont-20120
		Foliar Broadcast/ 7 day DBH silage	511	31.72	6.21	40		NA	
Test 04 (Saint Trivier sur Moignans, Rhône-Alpes, France, 2006)	20SC	Foliar Broadcast/ BBCH 55	496	30.68	6.19	-	61.99	NA	DuPont-20120
		Foliar Broadcast/ 7 day DBH	506	31.31	6.19	50		NA	
Test 05 (Rozbity Kamień, PL 08-310 Central Poland, Poland, 2006)	20SC	Foliar Broadcast/ BBCH 55	514	31.93	6.21	-	62.82	NA	DuPont-20120
		Foliar Broadcast/ 7 day DBH	499	30.89	6.19	56		NA	
Test 06 (Nea Malgara, Thessaloniki, Greece, 2006)	20SC	Foliar Broadcast/ BBCH 55	521.98	32.32	6.19	-	63.66	NA	DuPont-20120
		Foliar Broadcast/ 7 day DBH	506.17	31.34	6.19	39		NA	

Test 07 (Goch-Nierswalde, North Rhine Westphalia, Germany, 2006)	20SC	Foliar Broad-cast/ BBCH 55	478	29.58	6.19	-	60.88	NA	DuPont-20120
		Foliar Broad-cast/ 7 day DBH	506	31.30	6.19	52		NA	

Table 17
Study Use Pattern (continued)

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] Days	Total Rate g a.s./ha[d]		
Test 08 (Kápolnásnyek, County Fejér, Hungary, 2006)	20SC	Foliar Broadcast/ BBCH 55	518.75	32.04	6.18	-	62.62	NA	DuPont-20120
		Foliar Broad-cast/ 7 day DBH	496.25	30.58	6.16	15		NA	
Test 09 (Termens, Lleida, Spain, 2006)	20SC	Foliar Broad-cast/ BBCH 55	521	32.35	6.21	-	62.82	NA	DuPont-20120
		Foliar Broad-cast/ 7 day DBH	492	30.47	6.19	47		NA	
Test 10 (Motterwitz,	20SC	Foliar Broad-cast/ BBCH 55	520	32.30	6.21	-	62.10	NA	DuPont-20120

Saxony, Germa-ny, 2006)		Foliar Broad-cast/ 7 day DBH	480	29.80	6.21	43		NA	
Test 01 (Charnay-lès-Macon, 71960, Bourgogne, France, 2007)	20SC	Foliar Broadcast/ BBCH 55	509	31.46	6.18	--	61.70	None	DuPont-21629
		Foliar Broad-cast/ 34 day DBH	489	30.24	6.18	50		None	
Test 2 (Graf-fignana, 26813, Lombardia, Italy, 2007)	20SC	Foliar Broad-cast/ BBCH 55-59	506	31.46	6.22	--	61.70	None	DuPont-21629
		Foliar Broad-cast/ 40 day DBH	486	30.24	6.22	35		None	
	35WG	Foliar Broad-cast/ BBCH 55-59	500	30.77	6.15	--	62.24	None	DuPont-21629
		Foliar Broad-cast/ 40 day DBH	507	31.47	6.21	35		None	
Test 3 (Saint Martin le		Foliar Broad-cast/ BBCH 55	510	31.66	6.21	--		None	

Châtel, 01310, Rhône-Alpes, France, 2007)	20SC	Foliar Broad-cast/ 30 day DBH	497	30.85	6.21	48	62.51	None	DuPont-21629

Table 17
Study Use Pattern (continued)

Test Identification (City, State/Region, Country,/Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] Days	Total Rate g a.s./ha[d]		
Test 4 (Altreetz, 16259, Brandenburg, Germany 2007)	20SC	Foliar Broad-cast/ BBCH 55	522	32.40	6.21	--	63.56	None	DuPont-21629
		Foliar Broad-cast/ 44 day DBH	502	31.16	6.21	44		None	
	35WG	Foliar Broad-cast/ BBCH 55	520	32.34	6.22	--	64.27	None	DuPont-21629
		Foliar Broad-cast/ 44 day DBH	513	31.93	6.22	44		None	

Test 5 (Imathia, GR-59032, Central Macedonia, Greece, 2007)	20SC	Foliar Broadcast/ BBCH 55	498	31.01	6.22	--	61.80	None	DuPont-21629
		Foliar Broadcast/ 21 day DBH	495	30.79	6.22	39		None	
Test 6 (Goch-Nierswalde, D-47574, North Rhine Westphalia, Germany, 2007)	20SC	Foliar Broadcast/ BBCH 55	509	31.61	6.21	--	61.97	None	DuPont-21629
		Foliar Broadcast/ 33 day DBH	489	30.36	6.21	74		None	
Test 07 (Kápolnásnyék, H-275, Fejér County, Hungary, 2007)	20SC	Foliar Broadcast/ BBCH 55	409	31.70	7.75	-	63.74	None	DuPont-21629
		Foliar Broadcast/ 50 day DBH	413	32.04	7.75	24		None	
	35WG	Foliar Broadcast/ BBCH 55	404	31.43	7.77	-	62.86	None	DuPont-21629
		Foliar Broadcast/ 50 day DBH	404	31.43	7.77	24		None	

Table 17
Study Use Pattern (continued)

		Application		

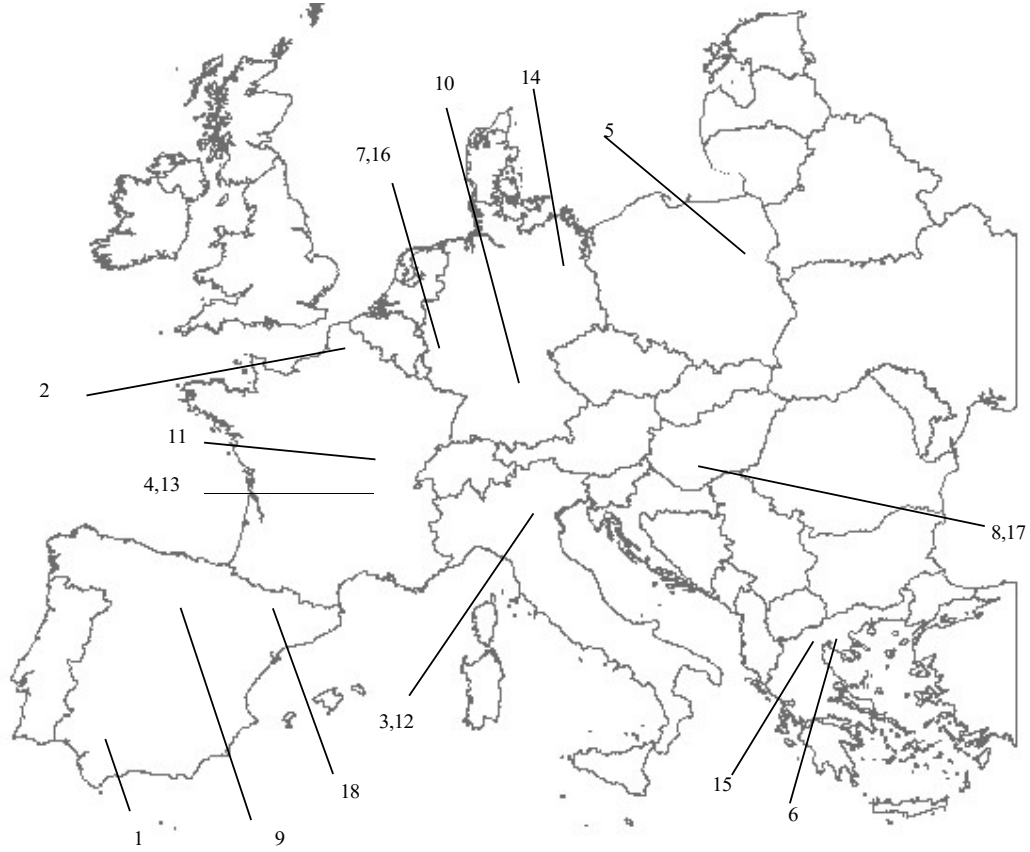
Test Identification (City, State/Region, Country,/Year)	EP[a]	Method/ Timing[b]	Vol[c] (L/ha)	g a.s./ha[d]	g a.s./hL[e]	RTI[f] Days	Total Rate g a.s./ha[d]	Tank Mix Adjuvants	Ref
Test 08 (Térmens, 25670, Catalunya, Spain, Catalunya, Spain, 2007)	20SC	Foliar Broadcast/ BBCH 55	490	30.45	6.21	-	61.91	None	DuPont-21629
		Foliar Broadcast/ 47 day DBH	504	31.46	6.24	47		None	
	35WG	Foliar Broadcast/ BBCH 55	491	30.42	6.20	-	61.19	None	DuPont-21629
		Foliar Broadcast/ 47 day DBH	500	30.77	6.15	47		None	

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Liters/hectare
[d] grams active substance per hectare
[e] g active substance/hL (gram active substance per hectoliter or 100 L)
[f] Retreatment Interval NA = Not applicable

A total of 8 magnitude of residue tests and 10 decline tests were conducted in the growing seasons of 2006 and 2007. A summary of these maize studies is given below. Locations of the maize test sites are given in the figure below.

Figure 4

Map: Chlorantraniliprole northern and southern European maize test sites



Map No.	Reference, Test No.	Location
1	DuPont-20120, 1	Antequera, Andalucia, Spain
2	DuPont-20120, 2	Douai, Nord Pas de Calais, North France
3	DuPont-20120, 3	Corteolona, Lombardia, Italy
4	DuPont-20120, 4	Saint Trivier sur Moignans, Rhône-Alpes, South France
5	DuPont-20120, 5	Rozbity Kamień, Central Poland

6	DuPont-20120, 6	Nea Malgara, Thessaloniki, Greece
7	DuPont-20120, 7	Goch-Nierswalde, North Rhine Westphalia, Germany
8	DuPont-20120, 8	Kápolnásnyek, County Fejér, Hungary
9	DuPont-20120, 9	Térmens, Lleida, Spain
10	DuPont-20120, 10	Motterwitz, Saxony, Germany
11	DuPont-21629, 1	Charnay-lès-Macon, Bourgogne, France (North)
12	DuPont-21629, 2	Graffignana, Lombardia, Italy
13	DuPont-21629, 3	Saint Martin le Châtel, Rhône-Alpes, France (South)
14	DuPont-21629, 4	Altreetz, Brandenburg, Germany
15	DuPont-21629, 5	Imathia, Central Macedonia, Greece
16	DuPont-21629, 6	Goch-Nierswalde, North Rhine Westphalia, Germany
17	DuPont-21629, 7	Kápolnásnyék, Fejér County, Hungary
18	DuPont-21629, 8	Térmens, Catalunya, Spain

A maize residue data summary (in mg/kg) is presented in Table 18, Table 19, and Table 20. To generate these data, the following analysis

and recovery information pertains.

Analysis method: LC-MS/MS method (DuPont-13295; Chlorantraniliprole DAR, Volume 3, B5) developed as the chlorantraniliprole residue method for determining residues of chlorantraniliprole in/on crops.

Analyte:	Chlorantraniliprole
Extraction:	Analyte extracted from crop matrices with acetonitrile following water presoak.
Clean-up:	SAX (Strong Anion Exchange) and HLB (Hydrophilic Lipophilic Balanced) Solid Phase Extraction (SPE) cartridges
Chromatography:	LC
Detection:	Mass spectrometer detection (MS/MS) in APCI positive mode. Two ion transitions are acquired 284 m/z – 177 m/z and 484 m/z – 453 m/z. The former transition is used for quantification and the second transition for confirmation. In cases where a significant interference is detected in the former transition the latter transition may be used for quantification purposes
LOQ:	0.010 mg/kg

Storage stability: All specimens were analysed within 9 months of sampling.

Table 18

Residues of chlorantraniliprole in maize from supervised tests – 2006 season

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate g a.s./ha	DALA[b]/ PHI (days)	Residue ppm (mg/kg) [c,d]			Ref
						Whole Green Plant	Mature Grain	Cobs and Kernels	
Test 01 (Antequera, Andalucia, Spain, 2006)	20SC	Maize/ Zaragoza	Whole Green Plant Grains	62.41	7 36	0.24 NA	NA nd	NA NA	DuPont-20120
Test 02 (Douai, Nord Pas De Calais, France, 2006)	20SC	Maize/ Cosmos	Whole Green Plant/Cobs/ Kernels/ Grains	61.57	-0 +0 3 7 14 61	nd 0.60 0.58 0.090 0.21 NA	NA NA NA NA NA nd	NA NA NA nd NA NA	DuPont-20120
Test 03 (Corteolona, Lombardia, Italy, 2006)	20SC	Maize/ Eleonora	Whole Green Plant/Cobs/ Kernels/ Grains	63.44	-0 +0 3 7 14 30	0.12 0.36 0.33 0.35 0.31 NA	NA NA NA NA NA nd	NA NA NA nd NA NA	DuPont-20120
Test 04 (Saint Trivier sur Moignans, Rhône-Alpes, France, 2006)	20SC	Maize/ DKC 5011	Whole Green Plant/Cobs/ Kernels/ Grains	61.99	-0 +0 3 7 14 39	0.23 0.55 1.1 0.93 0.27 NA	NA NA NA NA NA nd	NA NA NA nd NA NA	DuPont-20120

Test 05 (Rozbity Kamień, PL 09-180, Central Po-land, Poland, 2006)	20SC	Maize/ Delito	Whole Green Plant Grains	62.82	7 23	0.29 NA	NA nd	NA NA	DuPont-20120
Test 06 (Nea malgara, Thessaloniki, Greece, 2006)	20SC	Maize/ Z98	Whole Green Plant/Cobs/ Kernels/ Grains	63.66	-0 +0 3 7 14 20	0.53 0.79 0.047 0.47 0.56 NA	NA NA NA NA NA nd	NA NA NA nd NA NA	DuPont-20120

[a] EP = End-use Product

[b] DALA = Days after last application (Days between last application and sampling)

[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; ≤0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.

[d] Control specimens were collected and analyzed for the target 0 DALA (Tests 1-5) and 14 DALA (Tests 1-2) sampling dates. No detectable residues, nd, were found in all instances.

NA Not Applicable

Table 18

Residues of chlorantraniliprole in maize from supervised tests – 2006 season (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate g a.s./ha	DALA[b]/ PHI (days)	Residue ppm (mg/kg) [c,d]			Ref
						Whole Green Plant	Mature Grain	Cobs and Kernels	
Test 07 (Goch-Nierswalde, North Rhine Westphalia, Germany, 2006)	20SC	Maize/ Gavott	Whole Green Plant/ Cobs/ Kernels/ Grains	60.88	-0 +0 3 7 14 45	0.073 0.44 1.0 1.3 0.77 NA	NA NA NA NA NA nd	NA NA NA nd NA NA	DuPont-20120

Test 08 (Kápolnásnyek, County Fejér, Hungary, 2006)	20SC	Maize/ DK 440	Whole Green Plant/Grains	62.62	7 62	0.55 NA	NA nd	NA NA	DuPont-20120
Test 09 (Térmens, Lleida, Spain, 2006)	20SC	Maize/ DKC 6575	Whole Green Plant/Grains	62.82	7 51	0.66 NA	NA nd	NA NA	DuPont-20120
Test 10 (Motterwitz, Saxony, Germany, 2006)	20SC	Maize/ Monumental	Whole Green Plant/Cobs/ Kernels/ Grains	62.10	-0 +0 3 7 14 35	0.034 0.59 0.35 0.36 0.35 NA	NA NA NA NA NA nd	NA NA NA nd NA NA	DuPont-20120

[a] EP = End-use Product

[b] DALA = Days after last application (Days between last application and sampling)

[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.

[d] Control specimens were collected and analyzed at relevant PHIs. No detectable residues, nd, were found in all instances, except for DuPont-20120 Test 8 whole green plant where residues of 0.005 mg/kg were found.

NA Not Applicable

Table 19
Residues of chlorantraniliprole in maize (cereals) from supervised tests – 2007 Season

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g a.s./ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c]	Ref.

Test 01 (Charnay-lès-Macon, Bourgogne, France, 2007)	20SC	Maize/ Pana-ma	Whole Green Plant Whole Green Plant Whole Green Plant Whole Green Plant Whole Plant Mature Grain	61.70 (SC)	-0 +0 3 7 14 34	0.076 0.55 0.45 0.69 0.35 nd	DuPont-21629
Test 02 (Graffignana, Lombardia, Italy, 2007)	20SC	Maize/ Kubric	Whole Green Plant Cobs + Kernels Mature Grain	61.70 (SC)	7 7 40	1.7 nd nd	DuPont-21629
	35WG		Whole Green Plant Cobs + Kernels Mature Grain	62.24 (WG)	7 7 40	1.6 nd nd	
Test 03 (Saint Martin le Châtel, Rhône-Alpes, France 2007)	20SC	Maize/ Lemoro	Whole Green Plant Whole Green Plant Whole Green Plant Whole Green Plant Whole Plant Mature Grain	62.51 (SC)	-0 +0 3 7 14 30	0.15 0.99 0.58 1.0 0.55 nd	DuPont-21629
Test 04 (Al-treetz, Bran-denburg, Germany, 2007)	20SC	Maize/ DKC 2960	Whole Green Plant Cobs + Kernels Ma-ture Grain	63.56 (SC)	7 7 44	0.34 nd nd	DuPont-21629
	35WG		Whole Green Plant Cobs + Kernels Mature Grain	64.27 (WG)	7 7 44	0.55 nd nd	
Test 05 (Ima-thia, Central Macedonia, Greece, 2007)	20SC	Maize/ Z-98	Whole Green Plant Whole Green Plant Whole Green Plant Whole Green Plant Whole Plant Mature Grain	61.80 (SC)	-0 +0 3 7 14 21	0.17 0.27 0.11 0.066 0.33 nd	DuPont-21629
Test 06 (Goch-Nierswalde, North Rhine Westphalia, Germany, 2007)	20SC	Maize/ Darlin	Whole Green Plant Whole Green Plant Whole Green Plant Whole Green Plant Whole Plant Ma-ture Grain	61.97 (SC)	-0 +0 3 7 14 33	0.51 2.5 1.7 0.99 1.2 nd	DuPont-21629

Test 07 (Kápolnásnyék, Fejér County, Hungary, 2007)	20SC	Maize/ DK 440	Whole Green Plant Cobs + Kernels Mature Grain	63.74 (SC)	7 7 50	0.92 nd nd	DuPont-21629
	35WG		Whole Green Plant Cobs + Kernels Mature Grain	62.86 (WG)	7 7 50	1.6 nd nd	

Table 19
Residues of chlorantraniliprole in maize (cereals) from supervised tests – 2007 Season (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g a.s./ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c]	Ref.
Test 08 (Térmens, Catalunya, Spain, 2007)	20SC	Maize/ DKC5784YG	Whole Green Plant Cobs + Kernels Mature Grain	61.91 (SC)	7 7 47	0.74 nd nd	DuPont-21629
	35WG		Whole Green Plant Cobs + Kernels Mature Grain	61.19 (WG)	7 7 47	0.69 nd nd	

[a] EP = End-use Product

[b] DALA = Days after last application (Days between last application and sampling)

[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.

Control specimens were collected and analyzed at relevant PHIs. No detectable residues, nd, were found in all instances, except for DuPont-21629 Test 4 whole green plant where residues of 0.008 mg/kg were found.

Table 20

Summary of residue data from maize tests with chlorantraniliprole

Commodity	EP[a]	Total Application Rate (g a.s./ha)	DALA/ PHI (days)	Residue Levels in ppm (mg/kg)						
				n[b]	Min.[b]	Max.[b]	HAFT[b]	Median[b] (STMdR)	Mean[b] (STMR)	Std. Dev.[b]

Chlorantraniliprole										
Maize cobs + kernels (for extrapolation to sweet corn)	20SC	60.88-63.74	7	10	nd	nd	nd	nd	nd	---
	35WG	61.19-64.27	7	4	nd	nd	nd	nd	nd	---
Maize mature grain	20SC	60.88-63.74	20-62	18	nd	nd	nd	nd	nd	---
	35WG	61.19-64.27	40-50	4	nd	nd	nd	nd	nd	---
Maize whole plant	20SC	29.58-32.32	-0[c]	10	nd	0.53	0.53	0.10	0.18	0.19
		60.88-63.74	0	10	0.27	2.5	2.5	0.57	0.76	0.64
			3	10	0.047	1.7	1.7	0.52	0.62	0.51
			7	18	0.066	1.7	1.7	0.61	0.65	0.43
			14	10	0.21	1.2	1.2	0.35	0.49	0.30
Maize whole plant	35WG	61.19-64.27	7	4	0.55	1.6	1.6	1.1	1.1	0.57

[a] EP = End-use Product

[b] N = number of individual specimens,
Min = minimum individual specimen residue, Max = maximum individual specimen residue,
HAFT = Highest Average residue from one Field Test; (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set),
Median = median of individual specimen residues, Mean = mean of individual specimen residues,
Std Dev = standard deviation of mean

[c] Shortly before the last application

Recovery data: Average recovery data for fortifications run concurrently with the treated specimens are given below to demonstrate the validity of the analytical method.

Table 21

Summary of concurrent recoveries of chlorantraniliprole from maize - DuPont-21020 (2006 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev (rsd) % ± % (%)
Chlorantraniliprole				

Maize Whole Green Plants	0.010 0.10 2.0	5 5 2	95, 107, 103, 86, 80 89, 91, 85, 72, 61[a] 87, 86	94 ± 11 (12) 80 ± 13 (16) 87
Overall	NA	12	NA	87 ± 12 (14)
Mature Grain	0.010 0.10	2 2	99, 109 102, 92	104 97
Overall	NA	4	NA	101 ± 7 (7)
Cobs and Kernels	0.010 0.10	2 2	87, 95 95, 87	91 91
Overall	NA	4	NA	91 ± 5 (5)

Statistics were calculated using non-rounded recovery values

[a] Recovery value outside of acceptance criteria (accepted range 70-110%) but included in calculations

Table 22

Summary of concurrent recoveries of chlorantraniliprole from maize – DuPont-21629 (2007 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (CV) (% ± % (%))
Chlorantraniliprole				
Maize (Whole Green Plants and Whole Plants)	0.010 0.10 3.0	3 3 2	104, 108, 107 92, 78, 65[a] 75, 76	106 ± 2 (2) 78 ± 14 (18) 75
Overall	-	8	-	88 ± 17 (19)
Maize (Cobs and Kernels)	0.010 0.10	2 2	86, 83 78, 74	84 76
Overall	-	4	-	80 ± 5 (6)
Maize (Mature Grain)	0.010 0.10	2 2	88, 92 88, 103	90 95

Overall	-	4	-	93 ± 7 (8)

[a] Outside the range of 70%-110%, but included in calculations

RESULTS AND DISCUSSION

The residue studies presented herein were carried out in seven different EU countries and provide data relevant to conditions in the maize-growing regions of northern and southern Europe.

All of the analytical work associated with the studies was performed at Charles River Laboratories, Tranent, EH33 2NE, Scotland in the spring of 2007 and in early 2008 (January to April).

In northern and southern Europe, residues in whole green maize plants were less than or equal to 1.7 mg/kg at 7 DALA, the target PHI, or longer sampling intervals, in the eighteen residue tests conducted in which Chlorantraniliprole 20SC or Chlorantraniliprole 35WG was applied at 97-106% of GAP rate of application. In addition, residues in maize cobs plus kernels with outer leaves removed (for extrapolation to sweet corn) were not detected (<0.004 mg/kg) at 7 DALA, the target PHI, in the ten residue tests conducted in which Chlorantraniliprole 20SC or Chlorantraniliprole 35WG was applied at 97-106% of GAP rate of application. Residues were also not detected (<0.004 mg/kg) at BBCH 89 (20-62 DALA) in mature maize grain in the 18 residue tests in which Chlorantraniliprole 20SC or Chlorantraniliprole 35WG was applied at 97-106% of GAP rate of application.

The calculated half-lives for chlorantraniliprole in maize whole green plant were 7, 79, 10, 25, 27, 25 and

14 days for DuPont-20120 Tests 2, 3, 4, and 10 and DuPont-21629 Tests 1, 3 and 6, respectively. For three of the tests (DuPont-20120 Tests 6 and 7 and DuPont-21629 Test 5), residues in whole green plant did not show a discernible decline.

All sets of data show an overall consistent residue profile when chlorantraniliprole was applied in accordance with GAP.

Recovery values for fresh control fortification run concurrently with treated specimens in all the tests were within 61-109% (n = 36) for maize whole green plants, cobs plus kernels, and mature grain. Approximately 90% or more of the recoveries were within 70–110% and the relative standard deviations were <20% for all fortification levels. Therefore, the analytical methods used performed well for the determination of chlorantraniliprole in treated crops.

CONCLUSION – EU MAIZE/SWEET CORN TESTS

Overall consistent residue behaviour of chlorantraniliprole on maize was found for two seasons of study in northern and southern Europe, for application and sampling conducted according to GAP. The residue data show that residues decline in maize with increasing DALA with dissipation half-lives of 7-79 days. Residues were less than or equal to 1.7 mg/kg at target PHI 7 DALA, or longer sampling intervals, for maize whole green plant. No residues were detected in cobs plus kernels with husks removed (for extrapolation to sweet corn) or in mature grain (BBCH 89).

A 2.2.2.2.2 Pome Fruit

Report: Foster, A.C., Cairns, S.D. (2005); Decline of DPX-E2Y45 residues in apple fruit (pome fruit) following foliar applications of DPX-E2Y45 35WG or DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - Europe, 2004

DuPont Report No.: DuPont-14141

Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Inveresk Research, Tranent, Scotland, UK

Testing Facility Report/Project No.: 685368

GLP: Yes

Certifying Authority: Department of Health (UK)

Report: Foster, A.C., Cairns, S.D. (2007a); Magnitude and decline of DPX-E2Y45 residues in apples and pears (pome fruit) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - Northern and Southern Europe, 2005

DuPont Report No.: DuPont-16577, Revision No. 1

Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK

Testing Facility Report/Project No.: 687543

GLP: Yes

Certifying Authority: Department of Health (UK)

Report: Foster, A.C., Cairns, S.D. (2007b); Magnitude and decline of DPX-E2Y45 residues in apples and pears (pome fruit) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - northern and southern Europe, 2006

DuPont Report No.: DuPont-18752

Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK

Testing Facility Report No.: 689650

GLP: Yes

Certifying Authority: Department of Health (UK)

MATERIALS AND METHODS

The first field program was conducted in 2004 with two normal declines at one location each in Spain and France. At each trial site, two treated plots were established and DPX-E2Y45-179 (20SC formulation) or DPX-E2Y45-178 (35WG formulation) was applied twice by foliar application at targeted application rates of 35-47.5 g ai/ha (3.5-7 g ai/hL) at application 1 (A1), and 42-52.5 g ai/ha (3.5-7 g ai/hL) at application 2 (A2), for a seasonal application rate of 77-100 g ai/ha (64-83% maximum EU recommended rate of 120 g ai/ha/season). The first application (A1) occurred 35 days before the predicted commercial harvest date. The second application (A2) occurred 14-15 days after A1 and therefore, 20-21 days before the predicted commercial harvest date according to the use patterns described in Table 53 and sampling intervals described in Table 55. No surfactants or adjuvants were added to the applications.

Additional field programs were conducted in 2005 and 2006. Twelve magnitude of residue trials were conducted - one each in Germany, Belgium, Hungary, Poland, and Italy; two each in Greece and north France, and three in south France. In addition, six reverse decline trials were conducted, two in The Netherlands, one in north France, two in Spain, and one in south France. Ten trials were conducted in apples and eight trials were conducted in pears. At fourteen of eighteen trial locations, DPX-E2Y45-205 (20SC formulation) was applied twice as a foliar broadcast spray at a target application rate of 4.0 g ai/hL (40-60 g ai/ha). Spray volumes and rates per application were varied according to the orchard dimensions and/or northern or southern EU region of study. At the remaining four trial locations (2 each in 2005 and 2006), low spray volumes (400 L/ha) were employed at application rates of 40.0 g ai/ha (10.0 g ai/hL) in 2005 and 50.0 g ai/ha (12.5 g ai/hL) in 2006 for each of the two applications.

The two applications of Chlorantraniliprole 20SC were made at 14-day (±1) intervals with the last application occurring approximately 0-90 days before the predicted commercial harvest, according to the use patterns described in Table 53 and Table 54 and sampling intervals described in Table 55 and Table 56. No surfactants or adjuvants were added to the applications.

The targeted PHI under GAP is 14 days. The target application rates for the 2005 and 2006 seasons correspond to 100% EU recommended spray concentration (4 g ai/hL) for standard volume spray applications (67-100% maximum EU recommended ground rate of 120 g ai/ha/season dependent upon tree size, spacing, and cultural practice). The target application rates for the 2005 and 2006 seasons' low-volume applications are 125% and 156%, respectively, EU recommended minimum application rate of 32 g ai/ha/application (64 g ai/ha/season).

Table 53
Study Use Pattern for 2004 and 2005 growing seasons

		Application		

Trial Identification (City, State/Region, Country, Year)	EP[a]	Method/Timing	Vol, GPA[b] (L/ha)	Rate (lb ai/A) (g ai/ha)[c]	Rate[d] (g ai/hL)	RTI[e] (days)	Total Rate (lb ai/A) (g ai/ha)[c]	Tank Mix Adjuvants	Reference
Trial 01 El Palau d'Anglesola, Catalunya, Spain, 2004	20SC	Foliar/ 14 DBFH[f]	107 (1002)	0.033 (36.79)	3.67	--	0.072 (81.14)	None	DuPont-14141
	20SC	Foliar/ 0 DBFH	129 (1207)	0.040 (44.35)	3.67	14		None	
Trial 01 El Palau d'Anglesola, Catalunya, Spain, 2004	35WG	Foliar/ 14 DBFH	107 (1002)	0.032 (35.82)	3.57	--	0.070 (78.80)	None	DuPont-14141
	35WG	Foliar/ 0 DBFH	129 (1204)	0.038 (42.98)	3.56	14		None	
Trial 02 St Sylvestre Cappel, Norde-Pas-de-Calais, N. France, 2004	20SC	Foliar/ 15 DBFH	72 (672)	0.044 (49.40)	7.35	--	0.093 (104.05)	None	DuPont-14141
	20SC	Foliar/ 0 DBFH	80 (745)	0.049 (54.65)	7.34	15		None	
Trial 02 St Sylvestre Cappel, Norde-Pas-de-Calais N. France, 2004	35WG	Foliar/ 15 DBFH	73 (683)	0.044 (49.07)	7.18	--	0.091 (101.73)	None	DuPont-14141
	35WG	Foliar/ 0 DBFH	79 (737)	0.047 (52.66)	7.15	15		None	

Table 53

Study Use Pattern for 2004 and 2005 growing seasons (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Reference
		Method/Timing	Vol, GPA[b] (L/ha)	Rate (lb ai/A) (g ai/ha)[c]	Rate[d] (g ai/hL)	RTI[e] (days)	Total Rate (lb ai/A) (g ai/ha)[c]		
Test 01 Kalkar, North Rhine-Westphalia, Germany, 2005	20SC	Foliar Broadcast/ 28 DBH	111.6 (1043)	0.037 (41.80)	4.01	--	0.073 (81.88)	None	DuPont-16577
		Foliar Broadcast/ 14 DBH	107.0 (1000)	0.036 (40.07)	4.01	14		None	
Test 02 Groesbeek, Limburg, Netherlands, 2005	20SC	Foliar Broadcast/ 104 DBH	111.3 (1040)	0.037 (41.67)	4.01	--	0.073 (82.10)	None	DuPont-16577
		Foliar Broadcast/ 90 DBH	108.0 (1009)	0.036 (40.43)	4.01	14		None	
	20SC	Foliar Broadcast/ 71 DBH	111.7 (1044)	0.037 (41.85)	4.01	--	0.073 (81.63)	None	
		Foliar Broadcast/ 56 DBH	106.2 (993)	0.036 (39.77)	4.01	15		None	
	20SC	Foliar Broadcast/ 42 DBH	106.6 (996)	0.036 (39.89)	4.01	--	0.072 (80.85)	None	
		Foliar Broadcast/ 28 DBH	109.3 (1022)	0.037 (40.96)	4.01	14		None	
	20SC	Foliar Broadcast/ 29 DBH	107.7 (1007)	0.036 (40.37)	4.01	--	0.072 (80.73)	None	
		Foliar Broadcast/ 14 DBH	107.7 (1007)	0.036 (40.37)	4.01	15		None	
	20SC	Foliar Broadcast/ 21 DBH	108.4 (1013)	0.036 (40.61)	4.01	--	0.074 (82.63)	None	
		Foliar Broadcast/ 7 DBH	112.2 (1049)	0.038 (42.03)	4.01	14		None	
	20SC	Foliar Broadcast/ 14 DBH	108.9 (1018)	0.036 (40.78)	4.01	--	0.072 (80.68)	None	
		Foliar Broadcast/ 0 DBH	106.6 (996)	0.036 (39.89)	4.01	14		None	

Table 53
Study Use Pattern for 2004 and 2005 growing seasons (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Reference
		Method/Timing	Vol, GPA[b] (L/ha)	Rate (lb ai/A) (g ai/ha)[c]	Rate[d] (g ai/hL)	RTI[e] (days)	Total Rate (lb ai/A) (g ai/ha)[c]		
Test 03 Groesbeek, Limburg, Netherlands, 2005	20SC	Foliar Broadcast/ 104 DBH	109.2 (1021)	0.037 (40.91)	4.01	--	0.072 (80.14)	None	DuPont-16577
		Foliar Broadcast/ 90 DBH	104.7 (979)	0.035 (39.24)	4.01	14		None	
	20SC	Foliar Broadcast/ 71 DBH	105.4 (985)	0.035 (39.49)	4.01	--	0.071 (79.06)	None	
		Foliar Broadcast/ 56 DBH	105.7 (988)	0.035 (39.57)	4.01	15		None	
	20SC	Foliar Broadcast/ 42 DBH	108.8 (1017)	0.036 (40.74)	4.01	--	0.071 (79.47)	None	
		Foliar Broadcast/ 28 DBH	103.5 (967)	0.035 (38.74)	4.01	14		None	
	20SC	Foliar Broadcast/ 29 DBH	105.2 (983)	0.035 (39.40)	4.01	--	0.070 (78.05)	None	
		Foliar Broadcast/ 14 DBH	103.2 (965)	0.035 (38.65)	4.01	15		None	
	20SC	Foliar Broadcast/ 21 DBH	104.3 (975)	0.035 (39.07)	4.01	--	0.071 (79.31)	None	
		Foliar Broadcast/ 7 DBH	107.4 (1004)	0.036 (40.24)	4.01	14		None	
	20SC	Foliar Broadcast/ 14 DBH	106.1 (992)	0.035 (39.74)	4.01	--	0.071 (78.48)	None	
		Foliar Broadcast/ 0 DBH	103.5 (967)	0.036 (38.74)	4.01	14		None	

Table 53
Study Use Pattern for 2004 and 2005 growing seasons (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Reference
		Method/Timing	Vol, GPA[b] (L/ha)	Rate (lb ai/A) (g ai/ha)[c]	Rate[d] (g ai/hL)	RTI[e] (days)	Total Rate (lb ai/A) (g ai/ha)[c]		
Test 04 Godewaersvelde, Norde-Pas-de-Calais, France (north), 2005	20SC	Foliar Broadcast/ 28 DBH	104.7 (979)	0.035 (39.24)	4.01	--	0.070 (78.68)	None	DuPont-16577
		Foliar Broadcast/ 14 DBH	105.4 (985)	0.035 (39.44)	4.00	14		None	
Test 05 Herlies, Norde-Pas-de-Calais, France (north), 2005	20SC	Foliar Broadcast/ 97 DBH	44.4 (415)	0.037 (41.53)	10.00	--	0.073 (81.81)	None	DuPont-16577
		Foliar Broadcast/ 84 DBH	43.0 (402)	0.036 (40.28)	10.02	13		None	
	20SC	Foliar Broadcast/ 70 DBH	42.4 (396)	0.035 (39.65)	10.03	--	0.070 (78.89)	None	
		Foliar Broadcast/ 56 DBH	41.9 (392)	0.035 (39.24)	10.01	14		None	
	20SC	Foliar Broadcast/ 42 DBH	43.3 (405)	0.036 (40.49)	10.00	--	0.072 (80.98)	None	
		Foliar Broadcast/ 27 DBH	43.2 (404)	0.036 (40.49)	10.02	15		None	
	20SC	Foliar Broadcast/ 27 DBH	43.5 (407)	0.036 (40.70)	10.00	--	0.073 (81.81)	None	
		Foliar Broadcast/ 14 DBH	43.9 (410)	0.037 (41.11)	10.03	13		None	
	20SC	Foliar Broadcast/ 20 DBH	43.8 (409)	0.037 (40.91)	10.00	--	0.072 (80.35)	None	
		Foliar Broadcast/ 7 DBH	42.0 (393)	0.035 (39.44)	10.04	13		None	
	20SC	Foliar Broadcast/ 15 DBH	43.2 (404)	0.036 (40.49)	10.02	--	0.072 (80.14)	None	
		Foliar Broadcast/ 0 DBH	42.3 (395)	0.035 (39.65)	10.04	15		None	

Table 53
Study Use Pattern for 2004 and 2005 growing seasons (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Reference
		Method/Timing	Vol, GPA[b] (L/ha)	Rate (lb ai/A) (g ai/ha)[c]	Rate[d] (g ai/hL)	RTI[e] (days)	Total Rate (lb ai/A) (g ai/ha)[c]		
Test 06 Almenar, Catalunya Spain, 2005	20SC	Foliar Broadcast/ 104 DBH	160.9 (1504)	0.054 (60.31)	4.01	--	0.11 (120.42)	None	DuPont-16577
		Foliar Broadcast/ 90 DBH	160.2 (1497)	0.054 (60.11)	4.02	14		None	
	20SC	Foliar Broadcast/ 70 DBH	161.1 (1506)	0.054 (60.31)	4.00	--	0.11 (121.04)	None	
		Foliar Broadcast/ 56 DBH	161.8 (1512)	0.054 (60.73)	4.02	14		None	
	20SC	Foliar Broadcast/ 42 DBH	161.0 (1505)	0.054 (60.31)	4.01	--	0.11 (120.62)	None	
		Foliar Broadcast/ 28 DBH	161.1 (1506)	0.054 (60.31)	4.00	14		None	
	20SC	Foliar Broadcast/ 28 DBH	159.3 (1489)	0.053 (59.69)	4.01	--	0.11 (120.21)	None	
		Foliar Broadcast/ 14 DBH	161.4 (1509)	0.054 (60.52)	4.01	14		None	
	20SC	Foliar Broadcast/ 21 DBH	160.9 (1504)	0.054 (60.31)	4.01	--	0.11 (121.04)	None	
		Foliar Broadcast/ 7 DBH	162.1 (1515)	0.054 (60.73)	4.01	14		None	
	20SC	Foliar Broadcast/ 14 DBH	162.0 (1514)	0.054 (60.73)	4.01	--	0.11 (121.04)	None	
		Foliar Broadcast/ 0 DBH	160.6 (1501)	0.054 (60.31)	4.02	14		None	

Table 53
Study Use Pattern for 2004 and 2005 growing seasons (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Reference
		Method/Timing	Vol, GPA[b] (L/ha)	Rate (lb ai/A) (g ai/ha)[c]	Rate[d] (g ai/hL)	RTI[e] (days)	Total Rate (lb ai/A) (g ai/ha)[c]		
Test 07 Platani, Pella, Central Macedonia, Greece, 2005	20SC	Foliar Broadcast/ 28 DBH	161.4 (1509)	0.054 (60.52)	4.01	--	0.11 (121.80)	None	DuPont-16577
		Foliar Broadcast/ 14 DBH	163.5 (1528)	0.055 (61.28)	4.01	14		None	
Test 08 El Palau d'Aglesola, Catalunya, Spain, 2005	20SC	Foliar Broadcast/ 104 DBH	161.6 (1510)	0.054 (60.52)	4.01	--	0.11 (120.63)	None	DuPont-16577
		Foliar Broadcast/ 90 DBH	160.4 (1499)	0.054 (60.11)	4.01	14		None	
	20SC	Foliar Broadcast/ 70 DBH	161.7 (1511)	0.054 (60.52)	4.01	--	0.11 (120.63)	None	
		Foliar Broadcast/ 57 DBH	160.1 (1496)	0.054 (60.11)	4.02	13		None	
	20SC	Foliar Broadcast/ 42 DBH	161.4 (1509)	0.054 (60.52)	4.01	--	0.11 (121.25)	None	
		Foliar Broadcast/ 28 DBH	162.0 (1514)	0.054 (60.73)	4.01	14		None	
	20SC	Foliar Broadcast/ 28 DBH	161.4 (1509)	0.054 (60.52)	4.01	--	0.11 (121.04)	None	
		Foliar Broadcast/ 14 DBH	161.2 (1507)	0.054 (60.52)	4.02	14		None	
	20SC	Foliar Broadcast/ 22 DBH	160.8 (1503)	0.054 (60.31)	4.01	--	0.11 (120.83)	None	
		Foliar Broadcast/ 7 DBH	161.2 (1507)	0.054 (60.52)	4.02	15		None	
	20SC	Foliar Broadcast/ 14 DBH	160.6 (1501)	0.054 (60.31)	4.02	--	0.11 (120.00)	None	
		Foliar Broadcast/ 0 DBH	159.2 (1488)	0.053 (59.69)	4.01	14		None	

Table 53

Study Use Pattern for 2004 and 2005 growing seasons (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Reference
		Method/Timing	Vol, GPA[b] (L/ha)	Rate (lb ai/A) (g ai/ha)[c]	Rate[d] (g ai/hL)	RTI[e] (days)	Total Rate (lb ai/A) (g ai/ha)[c]		
Test 09 La Motte-Servolex, Rhône-Alpes, France (south), 2005	20SC	Foliar Broadcast/ 105 DBH	104.8 (980)	0.035 (39.24)	4.00	--	0.072 (80.15)	None	DuPont-16577
		Foliar Broadcast/ 90 DBH	109.6 (1024)	0.037 (40.91)	4.00	14		None	
	20SC	Foliar Broadcast/ 70 DBH	108.9 (1018)	0.036 (40.70)	4.00	--	0.072 (81.19)	None	
		Foliar Broadcast/ 55 DBH	108.4 (1013)	0.036 (40.49)	4.00	15		None	
	20SC	Foliar Broadcast/ 42 DBH	107.3 (1003)	0.036 (40.07)	4.00	--	0.072 (80.56)	None	
		Foliar Broadcast/ 27 DBH	108.4 (1013)	0.036 (40.49)	4.00	15		None	
	20SC	Foliar Broadcast/ 27 DBH	109.9 (1027)	0.037 (41.11)	4.00	--	0.072 (80.76)	None	
		Foliar Broadcast/ 14 DBH	106.0 (991)	0.035 (39.65)	4.00	13		None	
	20SC	Foliar Broadcast/ 21 DBH	108.6 (1015)	0.036 (40.70)	4.01	--	0.072 (80.35)	None	
		Foliar Broadcast/ 7 DBH	106.2 (993)	0.035 (39.65)	3.99	14		None	
	20SC	Foliar Broadcast/ 14 DBH	108.9 (1018)	0.036 (40.70)	4.00	--	0.072 (80.98)	None	
		Foliar Broadcast/ 0 DBH	107.8 (1008)	0.036 (40.28)	4.00	14		None	

Table 53
Study Use Pattern for 2004 and 2005 growing seasons (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Reference
		Method/Timing	Vol, GPA[b] (L/ha)	Rate (lb ai/A) (g ai/ha)[c]	Rate[d] (g ai/hL)	RTI[e] (days)	Total Rate (lb ai/A) (g ai/ha)[c]		
Test 10 Châteauneuf sur Isíre, Rhône-Alpes, France (south), 2005	20SC	Foliar Broadcast/ 28 DBH	43.7 (408)	0.036 (40.70)	10.0	--	0.073 (82.02)	None	DuPont-16577
		Foliar Broadcast/ 14 DBH	44.2 (413)	0.037 (41.32)	10.0	14		None	

[a] EP = End-use Product
[b] Gallons (US) per acre (Litres/hectare)
[c] lb active ingredient per acre (grams active ingredient per hectare)
[d] g active substance/hL (gram active substance per hectolitre or 100 L)
[e] Retreatment Interval
[f] DBFH = Days before first harvest; DBH = Days before harvest

Table 54
Study Use Pattern for 2006 growing season

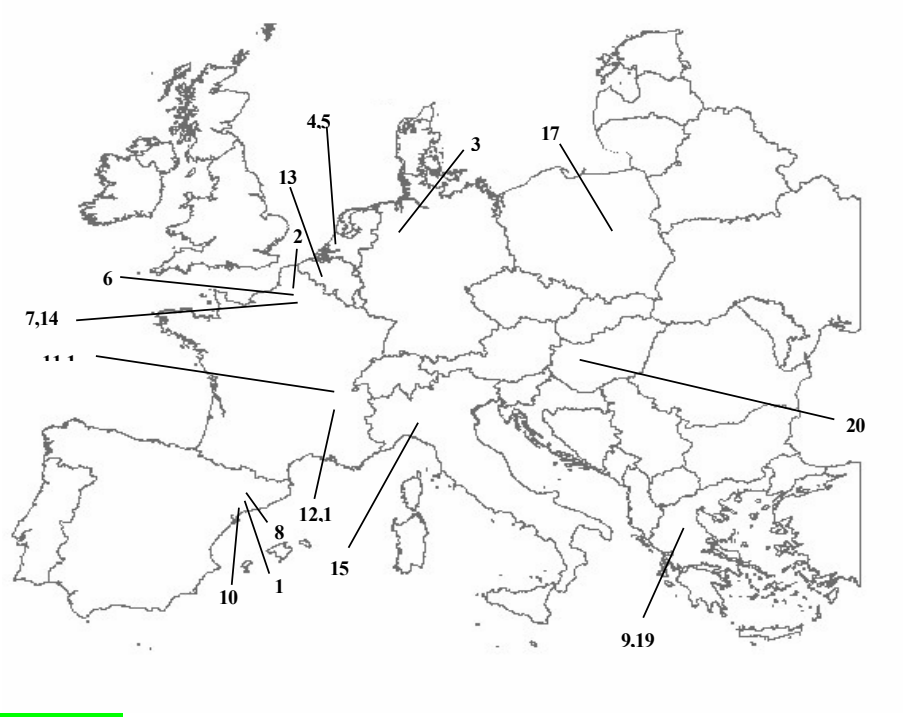
Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Ad-juvants	Ref
		Method/Timing[b]	Vol (L/ha)	(g ai/ha)	(g ai/hL)	RTI[c] Days	Total Rate (g ai/ha)		
Test 01 (Molembaix, Hainant, Belgium, 2006)	20SC	Foliar Broadcast/ 28 day DBH	1012	40.49	4.00	-	80.77	None	DuPont-18752
		Foliar Broadcast/ 14 day DBH	1007	40.28	4.00	14		None	
Test 02 (Herlies Nord Pas de		Foliar Broadcast/ 27 day DBH	407	50.92	12.51	-		None	

Calais, France (north), 2006)	20SC	Foliar Broadcast/ 13 day DBH	398	49.67	12.48	13	100.59	None	DuPont-18752
Test 03 (Casalnoceto, Piemonte, Italy, 2006)	20SC	Foliar Broadcast/ 28 day DBH	1500	60.11	4.01	-	120.42	None	DuPont-18752
		Foliar Broadcast/ 14 day DBH	1505	60.31	4.01	14		None	
Test 04 (Loire/Rhône, Rhône-Alpes, France (south), 2006)	20SC	Foliar Broadcast/ 28 day DBH	994	39.86	4.01	-	79.93	None	DuPont-18752
		Foliar Broadcast/ 14 day DBH	1002	40.07	4.00	14		None	
Test 05 (Osieczek, Mazovian Region Poland, 2006)	20SC	Foliar Broadcast/ 28 day DBH	1097	43.83	4.00	-	88.07	None	DuPont-18752
		Foliar Broadcast/ 14 day DBH	1104	44.24	4.01	14		None	
Test 06 (Dommartin, Rhône-Alpes, France (south), 2006)	20SC	Foliar Broadcast/ 28 day DBH	403	50.30	12.48	-	99.76	None	DuPont-18752
		Foliar Broadcast/ 14 day DBH	396	49.46	12.49	14		None	

Table 54
Study Use Pattern for 2006 growing season (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol (L/ha)	(g ai/ha)	(g ai/hL)	RTI[c] Days	Total Rate (g ai/ha)		
Test 07 (Platani, Pella, Central Macedonia, Greece, 2006)	20SC	Foliar Broadcast/ 29 day DBH	1550	62.11	4.01	-	122.56	None	DuPont-18752
		Foliar Broadcast/ 15 day DBH	1509	60.45	4.01	14		None	
Test 08 (Mor, Fejér County, Hungary, 2006)	20SC	Foliar Broadcast/ 28 day DBH	1297	51.97	4.01	-	102.1	None	DuPont-18752
		Foliar Broadcast/ 14 day DBH	1278	50.13	3.92	14		None	

[a] EP = End-use Product
[b] DBH = Days before harvest



[c] Retreatment Interval

A total of two normal decline trials (one in northern EU and one in southern EU) each containing two treated plots were conducted in the growing season of 2004, 4 magnitude of residue trials (2 in the northern EU and 2 in the southern EU) and 6 reverse decline trials (3 in the northern EU and 3 in the southern EU) were conducted in the growing season of 2005, and 8 magnitude of residue trials (4 in the northern EU and 4 in the southern EU) were conducted in the growing season of 2006. A summary of these apple and pear studies is given below. Locations of the EU pome trial sites are given in Figure 7.

Figure 7

Map: Chlorantraniliprole EU apple and pear (pome fruit) trial sites

Map No.	Reference, Trial No.	Location
1	DuPont-14141, 1	El Palau d'Anglesola, Catalunya, Spain
2	DuPont-14141, 2	St Sylvestre Cappel, Norde-Pas-de-Calais, France (North)
3	DuPont-16577, 1	Kalkar, North Rhine-Westphalia, Germany
4	DuPont-16577, 2	Groesbeek, Limburg, The Netherlands
5	DuPont-16577, 3	Groesbeek, Limburg, The Netherlands
6	DuPont-16577, 4	Godewaersvelde, Norde-Pas-de-Calais, France (North)
7	DuPont-16577, 5	Herlies, Norde-Pas-de-Calais, France (North)
8	DuPont-16577, 6	Almenar, Catalunya, Spain
9	DuPont-16577, 7	Platani, Pella, Central Macedonia, Greece
10	DuPont-16577, 8	Palau d'Anglesola, Catalunya, Spain
11	DuPont-16577, 9	Motte-Servolex, Rhône-Alpes, France (South)
12	DuPont-16577, 10	Châteamneuf sur Isíre, Rhône-Alpes, France (South)
13	DuPont-18752, 1	Molembaix, Hainant, Belgium
14	DuPont-18752, 2	Herlies, Nord Pas de Calais, France (North)
15	DuPont-18752, 3	Casalnoceto, Piemonte, Italy
16	DuPont-18752, 4	Loire/Rhône, Rhône-Alpes, France (South)
17	DuPont-18752, 5	Osieczek, Mazowian Region, Poland
18	DuPont-18752, 6	Dommartin, Rhône-Alpes, France (South)
19	DuPont-18752, 7	Platani, Pella, Central Macedonia, Greece
20	DuPont-18752, 8	Mor, Fejér County, Hungary

An apple and pear residue data summary (in mg/kg) is presented in Table 55, Table 56, and Table 57. To generate these data, the following analysis information pertains.

Analysis method: LC-MS/MS method (DuPont-13295) developed as the chlorantraniliprole residue method for determining residues of chlorantraniliprole in/on crops.

Analyte: Chlorantraniliprole

Extraction: Analyte extracted from crop matrices with acetonitrile following water pre-soak.

Clean-up: SAX (Strong Anion Exchange) and HLB (Hydrophilic Lipophilic Balanced) Solid Phase Extraction (SPE) cartridges

Chromatography: LC

Detection: Mass spectrometer detection (MS/MS) in APCI positive ion mode. Two ion transitions are acquired 284 m/z → 177 m/z and 484 m/z → 453 m/z. The former transition is used for quantification and the second transition for confirmation. In cases where a significant interference is detected in the former transition the latter transition may be used for quantification purposes

LOQ 0.010 mg/kg

Storage stability: All samples were analysed within 6 months of sampling. Chlorantraniliprole residues are stable in a variety of crops including predominantly water-, oil-, protein-, and starch-containing commodities as represented by fruits, a fruiting vegetable, a root crop, a non-oily grain, and an oilseed (apple, grape, tomato, leaf lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay, and ginned cotton seed) for at least 24 months when stored frozen at -20 ± 10°C (see Point IIA 6.1.1 of this document). Therefore, no degradation is expected to have occurred between harvest and analysis.

Table 55
Residues of chlorantraniliprole in apple and pear (pome) fruit from 2004 and 2005 EU supervised trials

Trial Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate lb ai/A (g ai/ha)	DALA[b] / PHI (days)	Residue (mg/kg)[c]	Ref
Trial 01 El Palau d'Anglesola, Catalunya, Spain, 2004	20SC	Apple/ Golden Delicious	Apple Fruit	0.072 (81.14)	-1 h +3 h 7 14 21 28 35	0.049 0.077 0.097 0.077 0.048 0.062 0.061	DuPont-14141
Trial 01 El Palau d'Anglesola, Catalunya, Spain, 2004	35WG	Apple/ Golden Delicious	Apple Fruit	0.070 (78.80)	-1 h +3 h 7 14 21 28	0.024 0.059 0.043 0.055 0.035 0.026	DuPont-14141

					35	0.025	
Trial 02 St Sylvestre Cappel, Norde-Pas-de-Calais N. France, 2004	20SC	Apple/ Jonagold	Apple Fruit	0.093 (104.05)	-1 h +2 h 7 14 21 28 35	0.033 0.086 0.11 0.091 0.081 0.11 0.072	DuPont-14141
Trial 02 St Sylvestre Cappel, Norde-Pas-de-Calais N. France, 2004	35WG	Apple/ Jonagold	Apple Fruit	0.091 (101.73)	-1 h +2 h 7 14 21 28 35	0.068 0.14 0.068 0.071 0.048 0.076 0.070	DuPont-14141

Table 55
Residues of chlorantraniliprole in apple and pear (pome) fruit from 2004 and 2005 EU supervised trials (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate lb ai/A (g ai/ha)	DALA[b] / PHI (days)	Residue (mg/kg)[c]	Ref
Test 01 Kalkar, North Rhine-Westphalia, Germany, 2005	20SC	Apple / Elstar	Whole Fruit	0.073 (81.88)	(+2 h) 14	0.036 0.054	DuPont-16577
Test 02 Groesbeek, Limburg, The Netherlands, 2005	20SC	Apple / Elstar	Whole Fruit	0.072 (80.68)	(-1 h) (+2 h)	0.034 0.036	DuPont-16577
				0.074 (82.63)	7	0.066	
				0.072 (80.73)	14	0.069	
				0.072 (80.85)	28	0.052	
				0.073 (81.63)	56	0.016	

				0.073 (82.10)	90	0.004	
Test 03 Groesbeek, Limburg, The Netherlands, 2005	20SC	Pear / Doyenné du Cornice	Whole Fruit	0.070 (78.48)	(-1 h) (+2 h)	0.036 0.087	DuPont-16577
				0.071 (79.31)	7	0.085	
				0.070 (78.05)	14	0.082	
				0.071 (79.47)	28	0.064	
				0.071 (79.06)	56	0.021	
				0.072 (80.14)	90	0.014	
Test 04 Godewaersvelde, Norde-Pas-de-Calais, France (north), 2005	20SC	Pear / Conference	Whole Fruit	0.070 (78.68)	(+2 h) 14	0.073 0.046	DuPont-16577
Test 05 Herlies, Norde-Pas-de-Calais, France (north), 2005	20SC	Jonagold (apple)	Whole Fruit	0.072 (80.14)	(-1 h) (+4 h)	0.051 0.081	DuPont-16577
				0.072 (80.35)	7	0.090	
				0.073 (81.81)	14	0.068	
				0.072 (80.98)	27	0.027	
				0.070 (78.89)	56	0.020	
				0.073 (81.81)	84	nd	

Table 55
Residues of chlorantraniliprole in apple and pear (pome) fruit from 2004 and 2005 EU supervised trials (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate lb ai/A (g ai/ha)	DALA[b] / PHI (days)	Residue (mg/kg)[c]	Ref

Test 06 Almenar, Catalunya Spain (north), 2005	20SC	Golden Delicious (apple)	Whole Fruit	0.11 (121.04)	(-1 h) (+2 h)	0.062 0.12	DuPont-16577
				0.11 (121.04)	7	0.13	
				0.11 (120.21)	14	0.051	
				0.11 (120.62)	28	0.066	
				0.11 (121.04)	56	0.054	
				0.11 (120.42)	90	0.028	
Test 07 Platani, Pella, Central Macedonia, Greece, 2005	20SC	Granny Smith (Apple)	Whole Fruit	0.11 (121.80)	(+2 h) 14	0.073 0.024	DuPont-16577
Test 08 El Palau d'Aglesola, Catalunya, Spain (north), 2005	20SC	Blanca de Aranjuez (Pear)	Whole Fruit	0.11 (120.0)	(-1 h) (+2 h)	0.022 0.033	DuPont-16577
				0.11 (120.83)	7	0.064	
				0.11 (121.04)	14	0.034	
				0.11 (121.25)	28	nd	
				0.11 (120.63)	57	0.024	
				0.11 (120.63)	90	0.016	
Test 09 La Motte-Servolex, Rhône-Alpes, France (south), 2005	20SC	Duchesse de Bered (pear)	Whole Fruit	0.072 (81.98)	(-1 h) (+1 h)	0.022 0.028	DuPont-16577
				0.072 (80.35)	7	0.047	
				0.072 (80.76)	14	0.053	
				0.072 (80.56)	27	0.030	
				0.072 (81.19)	55	0.014	

				0.072 (80.15)	90	0.008	
Test 10 Châteamneuf sur Isíre, Rhône-Alpes, France (south), 2005	20SC	Pink Lady (apple)	Whole Fruit	0.073 (82.02)	(+2 h) 14	0.088 <u>0.039</u>	DuPont-16577

[a] EP = End-use Product (20SC is the end-use product specified in the EU GAP table).
[b] DALA = Days after last application (Days between last application and sampling)
[c] The designation "nd" is used for treated samples/specimens for which no peak was observed or residue was <LOD (below the limit of detection; 0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.
For each decline trial, the highest residue value for any sample collected at the target PHI or later is underlined.

Table 56

Residues of chlorantraniliprole in apples and pears (pome fruit) from 2006 supervised trials

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg) [c,d]	Ref
Test 01 (Molembaix, Hainant, Belgium, 2006)	20SC	Apple / Golden	Whole Fruit	80.77	0 (+1 h)	0.036	DuPont-18752
					14	<u>0.13</u>	
Test 02 (Herlies Nord Pas de Calais, France (north), 2006)	20SC	Pear / Doyenne du Cornice	Whole Fruit	100.59	0 (+1 h)	0.18	DuPont-18752
					14	<u>0.090</u>	
Test 03 (Casalnoceto, Piemonte, Italy, 2006)	20SC	Apple / Golden	Whole Fruit	120.42	0 (+1 h)	0.059	DuPont-18752
					14	<u>0.048</u>	
Test 04 (Loire/Rhône,		Pear /			0 (+1 h)	0.19	DuPont-

Rhône-Alpes, France (south), 2006)		Beurre Hardy			14	0.096	18752
Test 05 (Osieczek, Mazovian Region Poland, 2006)	20SC	Apple / Idared	Whole Fruit	88.07	0 (+2 h) 14	0.009 0.010	DuPont-18752
Test 06 (Dommartin, Rhône-Alpes, France (south), 2006)	20SC	Pear / Louise Bonne	Whole Fruit	99.76	0 (+3 h) 14	0.084 0.024	DuPont-18752
Test 07 (Plat-ani, Pella, Central Macedonia, Greece, 2006)	20SC	Apple / Granny Smith	Whole Fruit	122.56	0 (+2 h) 14	0.048 0.022	DuPont-18752
Test 08 (Mor, Fejér County, Hungary, 2006)	20SC	Pear / Basc Kobak	Whole Fruit	102.1	0 (+2 h) 14	0.085 nd	DuPont-18752

[a] EP = End-use Product

[b] DALA = Days after last application (Days between last application and sampling)

[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.

[d] Control specimens were collected and analyzed for the target 14 DALA sampling dates (Tests 1–8 inclusive). With the exception of Test 3 (0.021 mg/kg) no detectable residues, nd, were found in all instances.

Table 57

Summary of residue data from EU apple and pear (pome) field trials with chlorantraniliprole

Commodity	EP[a]	Total Application Rate (g ai/ha)	PHI (days)	Residue levels in ppm (mg/kg)						
				N[b]	Min.[b]	Max.[b]	HAFT[b]	Median[b] (STMdR)	Mean[b] (STMR)	Std. Dev.[b]
Chlorantraniliprole										

Apple and Pear Fruit	20SC	78.05-122.56	-0[c]	8	0.022	0.062	0.062	0.035	0.039	0.014
			0	20	0.009	0.19	0.19	0.075	0.076	0.047
			7	8	0.047	0.13	0.13	0.088	0.086	0.027
			14	20	<0.004	0.13	0.13	0.052	0.056	0.032
			21	2	0.048	0.081	0.081	0.065	0.065	0.023
			27-28	6	<0.004	0.066	0.066	0.041	0.040	0.024
			35	2	0.061	0.072	0.072	0.067	0.067	0.008
			55-57	6	0.014	0.054	0.054	0.020	0.025	0.015
			84-90	6	<0.004	0.028	0.028	0.009	0.012	0.010
Apple Fruit	35WG	78.80-101.73	-0[c]	2	0.024	0.068	0.068	0.046	0.046	0.031
			0	2	0.059	0.14	0.14	0.100	0.100	0.057
			7	2	0.043	0.068	0.068	0.056	0.056	0.018
			14	2	0.055	0.071	0.071	0.063	0.063	0.011
			21	2	0.048	0.048	0.048	0.048	0.048	0.000
			28	2	0.062	0.076	0.076	0.069	0.069	0.010
			35	2	0.061	0.070	0.070	0.066	0.066	0.006

[a] EP = End-use Product

[b] N = number of individual specimens,

Min = minimum individual specimen residue, Max = maximum individual specimen residue,

HAFT = Highest Average residue from one Field Test; (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set),

Median = median of individual specimen residues, Mean = mean of individual specimen residues,

Std Dev = standard deviation of mean

[c] Shortly before the last application

Recovery data: Recovery data for fortifications run concurrently with the treated samples are given below to demonstrate the validity of the analytical method.

Table 58

Summary of concurrent recoveries of chlorantraniliprole from apple and pear (pome) fruit

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (rsd) (% ± % (%))
Concurrent Fortifications – Chlorantraniliprole– DuPont-14141 (2004 season)				
Apple fruit	0.010 0.10	3 4	87, 104, 108, (138[a]) 101, 96, 84, 90	96 ± 9 (9)
Concurrent Fortifications – Chlorantraniliprole – DuPont-16577 (2005 season)				
Apple/Pear Fruit	0.010	12	98, 107, 86, 85, 110, 91, 85, 85, 110, 108, 96, 91	96 ± 10 (11)
	0.10	12	101, 94, 90, 85, 74, 76, 74, 79, 99, 93, 88, 87	87 ± 9.4 (11)
	0.30	2	97, 99	98
			Overall (DuPont-16577)	92 ± 11 (12)
Concurrent Fortifications – Chlorantraniliprole – DuPont-18752 (2006 season)				
Apple Fruit	0.010	4	106, 90, 78, 75	87 ± 14 (16)
	0.10	4	114, 101, 91, 86	98 ± 12 (12)
	0.20	2	93, 92	93
			Overall Apple (DuPont-18752)	93 ± 12 (13)
Pear Fruit	0.010	2	86, 98	92 ± 8.3 (9.0)
	0.10	2	96, 97	96 ± 0.6 (0.6)
	0.20	2	96, 93	94 ± 2.2 (2.3)
			Overall Pear (DuPont-18752)	94 ± 4 (4)

[a] Outlying data point removed from further calculations.

RESULTS AND DISCUSSION

The residue studies presented herein were carried out in nine different EU countries in the 2004, 2005, and 2006 growing seasons and provide data relevant to conditions in the apple and pear-growing regions of the northern and southern EU.

All of the analytical work associated with the studies was performed at Charles River Laboratories, Tranent, EH33 2NE, Scotland. The analytical work was carried out during three different time periods: first time for the season 2004 residue trials, in the winter of 2005-6 for the season 2005 residue trials, and in the winter of 2006-7 for the season 2006 residue trials.

Chlorantraniliprole 20SC formulation: In the EU region, residues in pome fruit were less than or equal to

0.13 mg/kg at 14 DALA, the target PHI, or later sampling intervals, in the twenty trials conducted in 2004, 2005, and 2006 in which Chlorantraniliprole 20SC was applied. Dissipation half-lives for chlorantraniliprole in pome fruit from 2 normal decline residue trials conducted in 2004 and 6 reverse decline residue trials conducted in 2005 in which Chlorantraniliprole 20SC was applied were 57, 165, 23, 30, 21, 48, 71, and 29 days for

DuPont-14141, trials 1 and 2, DuPont-16577, trials 2, 3, 5, 6, 8, and 9, respectively.

Chlorantraniliprole 35WG formulation: In the EU region, residues in apple fruit were less than or equal to

0.071 mg/kg at 14 DALA, the target PHI, or later sampling intervals, in the 2 normal decline residue trials conducted in 2004 in which Chlorantraniliprole 35WG was applied. Dissipation half-lives for chlorantraniliprole in apple fruit following application of Chlorantraniliprole 35WG were 27 and 47 days for DuPont-14141, trials 1 and 2, respectively.

The residue levels from apples treated with Chlorantraniliprole 35WG and Chlorantraniliprole 20SC formulations, were comparable according to the criteria defined in EU 7525/VI/1995 Rev. 7 (2001) App. D, for DuPont-14141, trials 1 and 2 conducted in northern and southern EU (see Point IIA 6.3.2.5 of this document). Therefore, the data generated following application of Chlorantraniliprole 35WG will be used in conjunction with the data generated following application of Chlorantraniliprole 20SC for further residue population comparisons.

The study use patterns for all 2004, 2005, and 2006 trials corresponded to 65-104% maximum EU recommended ground rate of 2 applications at 60 g ai/ha (120 g ai/ha/season) dependent upon tree size, spacing, and cultural practice. The low-volume application rates corresponded to 123-159% the EU minimum recommended rate of 32 g ai/ha/appl (64 g ai/ha/season) for low-volume applications. All trials resulted in similar chlorantraniliprole residues on pome fruit, therefore data generated from all field trials will be considered as part of the EU pome fruit residue population for further residue population comparison. All trials show an overall consistent residue profile when chlorantraniliprole is applied in accordance with GAP.

Recovery values for fresh control fortifications run concurrently with treated samples in all the 2004 growing season trials were within 84–108% (n = 7) for apple fruit. Recovery values for fresh control fortifications run concurrently with treated samples in all the 2005 growing season trials were within 74-110% (n = 26) for pears and apples. Recovery values for fresh control fortification run concurrently with treated samples in all the 2006 growing season trials

were within 86-114% (n = 16) for apples and pears. Most recoveries were within 70-110% and the relative standard deviations were less than 20% for all trials. Therefore, the analytical methods used performed well for the determination of chlorantraniliprole in treated crops.

CONCLUSION - EU POME TRIALS

Overall consistent residue behaviour of chlorantraniliprole on apples and pears (pome fruit) was found for three seasons of study in the northern and southern EU, for application and sampling conducted according to GAP. The residue data show that residues decline with increasing DALA with dissipation half-lives of 57, 27, 165, 47, 23, 30, 21, 48, 71, and 29 days for DuPont-14141, trials 1 (20SC), 1 (35WG), 2 (20SC), and 2 (35WG), DuPont-16577, trials 2, 3, 5, 6, 8, and 9, respectively. There does not seem to be any correlation between rates of decline and crop or formulation.

Residues in pome fruit were less than or equal to 0.13 mg/kg at 14 DALA, the target PHI, or later sampling intervals, in the twenty-two trials conducted in the 2004, 2005, and 2006 growing seasons in which Chlorantraniliprole 20SC or Chlorantraniliprole 35WG was applied.

The residue levels from apples treated with Chlorantraniliprole 35WG and Chlorantraniliprole 20SC formulations, were comparable according to the criteria defined in EU 7525/VI/1995 Rev. 7 (2001) App. D, for DuPont-14141, trials 1 and 2 conducted in northern and southern EU.

Residue data generated from all 2004, 2005, and 2006 field trials conducted with Chlorantraniliprole 35WG or Chlorantraniliprole 20SC will be considered as part of the EU pome fruit population for further residue population comparison.

A 2.2.2.2.3 GRAPES

Report: Foster, A.C., Cairns, S.D. (2005); Decline of DPX-E2Y45 residues in wine grapes (berries and small fruits) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - Europe, 2004

DuPont Report No.: DuPont-14139

Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Inveresk Research, Tranent, Scotland, UK

Testing Facility Report/Project No.: 684893

GLP: Yes

Certifying Authority: Department of Health (UK)

Report: Foster, A.C., Cairns, S.D., Hunter, T.M. (2006); Decline of DPX-E2Y45 residues in wine grapes (berries and small fruit) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - northern and southern Europe, 2005

DuPont Report No.: DuPont-16567

Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC. **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK

Testing Facility Report/Project No.: 687538

GLP: Yes

Certifying Authority: Department of Health (U.K.)

Report: Foster, A.C., Cairns, S.D., Hansford, R.J. (2007); Magnitude and decline of DPX-E2Y45 residues in wine grapes (berries and small fruit) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] – northern and southern Europe, 2006

DuPont Report No.: DuPont-19306

Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK

Testing Facility Report No.: 689577

GLP: Yes

Certifying Authority: Department of Health (UK)

MATERIALS AND METHODS

The first field program in the EU was conducted in 2004 with decline sites at one location in S. France and at one location in N. France. DPX-E2Y45-179 (20SC formulation) was applied once by foliar application at growth stage BBCH 73-75 to wine grapes (berries and small fruit) at a target application rate of 45.0 g ai/ha for a seasonal application rate of 45.0 g ai/ha (83% the maximum EU recommended rate of 54 g ai/ha).

Additional field programs in the EU were conducted in 2005 and 2006. Twelve reverse decline grapes trials were conducted, two in Spain, two in Germany, two in southern France, four in northern France and two in Italy. Seven magnitude of residues grape trials were conducted, three in Spain, one in Greece, one in northern France, and two in Germany. In 14 of 19 trials, a single foliar broadcast application of chlorantraniliprole (DPX-E2Y45-205, 20SC formulation) was applied at a target application rate of 3.5 g ai/hL (52.5 g ai/ha). In 1 of 19 trials, a single foliar broadcast application of chlorantraniliprole (DPX-E2Y45-205, 20SC formulation) was applied at a target application rate of 52.5 g ai/ha (7.0 g ai/hL) to represent reduced spray volumes consistent with the crop canopy and local practice. In the remaining 4 of 19 trials, conducted in France, a single foliar broadcast application of chlorantraniliprole (DPX-E2Y45-205, 20SC formulation) was applied at target application rates of 35.0 g ai/ha (17.5 g ai/hL) or 40 g ai/ha (10 g ai/hL) to represent low-volume applications consistent with the crop canopy and local practice. No surfactants or adjuvants were added to the applications.

The target application rates for the 2005 and 2006 seasons correspond to 97% maximum EU recommended ground rate of 54 g ai/ha for standard-volume spray applications. The target application rates for the 2005 and

2006 seasons low-volume applications are 117% and 133%, respectively, the minimum EU recommended application rate of 30 g ai/ha.

The applications were made according to the use patterns described in Table 115 and Table 116 and sampling intervals described in Table 117 and Table 118. The targeted PHI under GAP is 30 days.

Table 115
Study Use Patterns for 2004 and 2005 growing seasons

		Application		

Trial Identification (City, State/Region, Country, Year)	EP[a]	Method/Timing	Vol, GPA[b] (L/ha)	Rate (lb ai/A) (g ai/ha)[c]	Rate (g ai/hL)	RTI[d] (days)	Total Rate (lb ai/A) (g ai/ha)[c]	Tank Mix Adjuvants	Reference
Trial 01 (Les Charmes/ Bourgogne, N. France, 2004)	20SC	Foliar/ 60 DBH[e]	159 (1490)	0.042 (47.08)	3.16	--	0.042 (47.08)	None	DuPont-14139
Trial 02 (Villié Morgon/Rhône-Alpes, S. France, 2004)	20SC	Foliar/ 60 DBH	163 (1523)	0.043 (47.93)	3.14	--	0.043 (47.93)	None	DuPont-14139
Trial 01 (Los Palacios, Andalucia, Spain, 2005)	20SC	Foliar Broadcast/ 90 DBH	160.5 (1500)	0.047 (52.59)	3.51	NA	0.047 (52.59)	None	DuPont-16567
	20SC	Foliar Broadcast/ 56 DBH	162.0 (1514)	0.047 (53.01)	3.50	NA	0.047 (53.01)	None	
	20SC	Foliar Broadcast/ 45 DBH	158.7 (1483)	0.046 (51.97)	3.50	NA	0.046 (51.97)	None	
	20SC	Foliar Broadcast/ 28 DBH	160.7 (1502)	0.047 (52.59)	3.50	NA	0.047 (52.59)	None	
	20SC	Foliar Broadcast/ 14 DBH	161.4 (1509)	0.047 (53.01)	3.51	NA	0.047 (53.01)	None	
	20SC	Foliar Broadcast/ 0 DBH	160.9 (1504)	0.047 (52.8)	3.51	NA	0.047 (52.8)	None	

Table 115
Study Use Patterns for 2004 and 2005 growing seasons (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Reference
		Method/Timing	Vol, GPA[b] (L/ha)	Rate (lb ai/A) (g ai/ha)[c]	Rate (g ai/hL)	RTI[d] (days)	Total Rate (lb ai/A) (g ai/ha)[c]		
Trial 02 (Veldenz Rhineland-Palatinate, Germany, 2005)	20SC	Foliar Broadcast/ 90 DBH	66.2 (619)	0.048 (54.26)	8.77	NA	0.048 (54.26)	None	DuPont-16567
	20SC	Foliar Broadcast/ 56 DBH	76.9 (719)	0.045 (50.42)	7.01	NA	0.045 (50.42)	None	
	20SC	Foliar Broadcast/ 45 DBH	84.1 (786)	0.049 (55.10)	7.01	NA	0.049 (55.10)	None	
	20SC	Foliar Broadcast/ 28 DBH	82.5 (771)	0.048 (54.10)	7.02	NA	0.048 (54.10)	None	
	20SC	Foliar Broadcast/ 14 DBH	79.0 (738)	0.046 (51.76)	7.01	NA	0.046 (51.76)	None	
	20SC	Foliar Broadcast/ 0 DBH	79.0 (738)	0.046 (51.76)	7.01	NA	0.046 (51.76)	None	
Trial 03 (Lamié, Rhône-Alpes, S. France, 2005)	20SC	Foliar Broadcast/ 84 DBH	20.9 (195)	0.030 (34.02)	17.45	NA	0.030 (34.02)	None	DuPont-16567
	20SC	Foliar Broadcast/ 55 DBH	21.7 (203)	0.032 (35.69)	17.58	NA	0.032 (35.69)	None	
	20SC	Foliar Broadcast/ 41 DBH	21.9 (205)	0.032 (35.90)	17.51	NA	0.032 (35.90)	None	
	20SC	Foliar Broadcast/ 29 DBH	22.1 (207)	0.032 (36.31)	17.54	NA	0.032 (36.31)	None	
	20SC	Foliar Broadcast/ 15 DBH	21.9 (205)	0.032 (35.90)	17.51	NA	0.032 (35.90)	None	
	20SC	Foliar Broadcast/ 0 DBH	21.2 (198)	0.031 (34.64)	17.49	NA	0.031 (34.64)	None	

Table 115
Study Use Patterns for 2004 and 2005 growing seasons (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Reference
		Method/Timing	Vol, GPA[b] (L/ha)	Rate (lb ai/A) (g ai/ha)[c]	Rate (g ai/hL)	RTI[d] (days)	Total Rate (lb ai/A) (g ai/ha)[c]		
Trial 04 (Marfaux, Champagne-Ardennes, N. France, 2005)	20SC	Foliar Broadcast/ 84 DBH	155.9 (1457)	0.046 (51.13)	3.51	NA	0.046 (51.13)	None	DuPont-16567
	20SC	Foliar Broadcast/ 56 DBH	164.6 (1538)	0.048 (53.84)	3.50	NA	0.048 (53.84)	None	
	20SC	Foliar Broadcast/ 46 DBH	158.6 (1482)	0.046 (51.97)	3.51	NA	0.046 (51.97)	None	
	20SC	Foliar Broadcast/ 28 DBH	155.3 (1452)	0.045 (50.92)	3.51	NA	0.045 (50.92)	None	
	20SC	Foliar Broadcast/ 14 DBH	157.3 (1470)	0.046 (51.55)	3.51	NA	0.046 (51.55)	None	
	20SC	Foliar Broadcast/ 0 DBH	158.1 (1478)	0.046 (51.76)	3.50	NA	0.046 (51.76)	None	
Trial 05 (Fleury-La-Riviere, Champagne, N. France, 2005)	20SC	Foliar Broadcast/ 84 DBH	21.3 (199)	0.031 (34.85)	17.51	NA	0.031 (34.85)	None	DuPont-16567
	20SC	Foliar Broadcast/ 56 DBH	21.1 (197)	0.031 (34.44)	17.48	NA	0.031 (34.44)	None	
	20SC	Foliar Broadcast/ 46 DBH	21.9 (205)	0.032 (35.90)	17.51	NA	0.032 (35.90)	None	
	20SC	Foliar Broadcast/ 28 DBH	21.5 (201)	0.031 (35.27)	17.55	NA	0.031 (35.27)	None	
	20SC	Foliar Broadcast/ 14 DBH	20.9 (195)	0.031 (34.23)	17.55	NA	0.031 (34.23)	None	
	20SC	Foliar Broadcast/ 0 DBH	21.1 (197)	0.031 (34.44)	17.48	NA	0.031 (34.44)	None	

Table 115
Study Use Patterns for 2004 and 2005 growing seasons (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Reference
		Method/Timing	Vol, GPA[b] (L/ha)	Rate (lb ai/A) (g ai/ha)[c]	Rate (g ai/hL)	RTI[d] (days)	Total Rate (lb ai/A) (g ai/ha)[c]		
Trial 06 (Miradolo Terme, Lombardia, Italy, 2005)	20SC	Foliar Broadcast/ 88 DBH	155.7 (1455)	0.045 (50.92)	3.50	NA	0.045 (50.92)	None	DuPont-16567
	20SC	Foliar Broadcast/ 53 DBH	158.7 (1485)	0.046 (51.97)	3.50	NA	0.046 (51.97)	None	
	20SC	Foliar Broadcast/ 45 DBH	160.7 (1502)	0.047 (52.59)	3.50	NA	0.047 (52.59)	None	
	20SC	Foliar Broadcast/ 29 DBH	161.2 (1507)	0.047 (52.80)	3.50	NA	0.047 (52.80)	None	
	20SC	Foliar Broadcast/ 15 DBH	160.1 (1496)	0.047 (52.38)	3.50	NA	0.047 (52.38)	None	
	20SC	Foliar Broadcast/ 0 DBH	159.2 (1488)	0.047 (52.18)	3.51	NA	0.047 (52.18)	None	

[a] EP = End-use Product
[b] Gallons per acre (Litres/hectare)
[c] lb active ingredient per acre (grams active ingredient per hectare)
[d] Retreatment Interval
[e] DBH = Days before harvest

Table 116
Study Use Pattern for 2006 growing season

		Application		

Test Identification (City, State/Region, Country, /Year)	EP[a]	Method/Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] (days)	Total Rate (g ai/ha)	Tank Mix Ad-juvants	Ref
Test 01 (Los Palacios y Villafranca, Andalucia, Spain, 2006)	20SC	Foliar Broadcast/ 90 day DBH	1490	52.18	3.50	NA	52.18	None	DuPont-19306
	20SC	Foliar Broadcast/ 56 day DBH	1496	52.38	3.50	NA	52.38	None	DuPont-19306
	20SC	Foliar Broadcast/ 31 day DBH	1511	52.80	3.49	NA	52.80	None	DuPont-19306
	20SC	Foliar Broadcast/ 14 day DBH	1520	53.22	3.50	NA	53.22	None	DuPont-19306
	20SC	Foliar Broadcast/ 0 day DBH	1506	52.59	3.49	NA	52.59	None	DuPont-19306
Test 02 (Villalba del Alcor, Andalucia, Spain, 2006)	20SC	Foliar Broadcast/ 90 day DBH	1495	52.18	3.49	NA	52.18	None	DuPont-19306
	20SC	Foliar Broadcast/ 56 day DBH	1510	52.80	3.50	NA	52.80	None	DuPont-19306
	20SC	Foliar Broadcast/ 28 day DBH	1492	52.18	3.50	NA	52.18	None	DuPont-19306
Test 03 (Marfaux, Champagne-Ardenne, N. France, 2006)	20SC	Foliar Broadcast/ 87 day DBH	405	40.49	10.00	NA	40.49	None	DuPont-19306
	20SC	Foliar Broadcast/ 53 day DBH	397	39.86	10.04	NA	39.86	None	DuPont-19306
	20SC	Foliar Broadcast/ 30 day DBH	398	39.86	10.02	NA	39.86	None	DuPont-19306
	20SC	Foliar Broadcast/ 14 day DBH	398	39.86	10.02	NA	39.86	None	DuPont-19306
	20SC	Foliar Broadcast/ 0 day DBH	395	39.65	10.04	NA	39.65	None	DuPont-19306

Table 116
Study Use Pattern for 2006 growing season (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Ad-juvants	Ref
		Method/Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] (days)	Total Rate (g ai/ha)		
Test 04 (Veldenz, Rhineland-Palatinate Germany, 2006)	20SC	Foliar Broadcast/ 83 day DBH	1514	52.94	3.50	NA	52.94	None	DuPont-19306
	20SC	Foliar Broadcast/ 56 day DBH	1505	52.60	3.50	NA	52.60	None	DuPont-19306
	20SC	Foliar Broadcast/ 30 day DBH	1481	51.77	3.50	NA	51.77	None	DuPont-19306
	20SC	Foliar Broadcast/ 14 day DBH	1510	52.77	3.50	NA	52.77	None	DuPont-19306
	20SC	Foliar Broadcast/ 0 day DBH	1486	51.94	3.50	NA	51.94	None	DuPont-19306
Test 05 (Miradolo, Lombardia, Italy, 2006)	20SC	Foliar Broadcast/ 90 day DBH	1509	52.80	3.50	NA	52.80	None	DuPont-19306
	20SC	Foliar Broadcast/ 54 day DBH	1493	52.18	3.49	NA	52.18	None	DuPont-19306
	20SC	Foliar Broadcast/ 32 day DBH	1526	53.43	3.50	NA	53.43	None	DuPont-19306
	20SC	Foliar Broadcast/ 14 day DBH	1507	52.59	3.49	NA	52.59	None	DuPont-19306
	20SC	Foliar Broadcast/ 0 day DBH	1490	52.18	3.50	NA	52.18	None	DuPont-19306

Table 116
Study Use Pattern for 2006 growing season (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Ad-juvants	Ref
		Method/Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] (days)	Total Rate (g ai/ha)		
Test 06 (Lancié, Rhône-Alpes S. France, 2006)	20SC	Foliar Broadcast/ 90 day DBH	398	39.86	10.02	NA	39.86	None	DuPont-19306
	20SC	Foliar Broadcast/ 54 day DBH	391	39.24	10.04	NA	39.24	None	DuPont-19306
	20SC	Foliar Broadcast/ 30 day DBH	399	40.07	10.04	NA	40.07	None	DuPont-19306
	20SC	Foliar Broadcast/ 14 day DBH	396	39.65	10.01	NA	39.65	None	DuPont-19306
	20SC	Foliar Broadcast/ 0 day DBH	413	41.32	10.00	NA	41.32	None	DuPont-19306
Test 07 (Les Charmes, Bourgogne, N. France, 2006)	20SC	Foliar Broadcast/ 81 day DBH	1518	53.01	3.49	NA	53.01	None	DuPont-19306
	20SC	Foliar Broadcast/ 49 day DBH	1487	51.97	3.49	NA	51.97	None	DuPont-19306
	20SC	Foliar Broadcast/ 24 day DBH	1510	52.80	3.50	NA	52.80	None	DuPont-19306
	20SC	Foliar Broadcast/ 11 day DBH	1496	52.38	3.50	NA	52.38	None	DuPont-19306
	20SC	Foliar Broadcast/ 0 day DBH	1513	52.80	3.49	NA	52.80	None	DuPont-19306
Test 08 (La Roche Vineuse, Bour-gogne, N. France, 2006)	20SC	Foliar Broadcast/ 90 day DBH	1522	53.22	3.50	NA	53.22	None	DuPont-19306
	20SC	Foliar Broadcast/ 55 day DBH	1531	53.43	3.49	NA	53.43	None	DuPont-19306
	20SC	Foliar Broadcast/ 31 day DBH	1516	53.01	3.50	NA	53.01	None	DuPont-19306

Table 116
Study Use Pattern for 2006 growing season (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] (days)	Total Rate (g ai/ha)		
Test 09 (Verdu, Lleida Spain, 2006)	20SC	Foliar Broadcast/ 90 day DBH	1519	53.01	3.49	NA	53.01	None	DuPont-19306
	20SC	Foliar Broadcast/ 55 day DBH	1502	52.59	3.50	NA	52.59	None	DuPont-19306
	20SC	Foliar Broadcast/ 31 day DBH	1497	52.38	3.50	NA	52.38	None	DuPont-19306
Test 10 (Sant Marti de Malda, Lleida, Spain, 2006)	20SC	Foliar Broadcast/ 92 day DBH	1503	52.59	3.50	NA	52.59	None	DuPont-19306
	20SC	Foliar Broadcast/ 56 day DBH	1510	52.80	3.50	NA	52.80	None	DuPont-19306
	20SC	Foliar Broadcast/ 31 day DBH	1507	52.59	3.49	NA	52.59	None	DuPont-19306
Test 11 (Kesten, Rhineland-Palatinate, Germany, 2006)	20SC	Foliar Broadcast/ 83 day DBH	1515	52.97	3.50	NA	52.97	None	DuPont-19306
	20SC	Foliar Broadcast/ 56 day DBH	1501	52.48	3.50	NA	52.48	None	DuPont-19306
	20SC	Foliar Broadcast/ 30 day DBH	1508	52.73	3.50	NA	52.73	None	DuPont-19306
Test 12 (Anchialos, Thessaloniki, Central Macedonia. Greece, 2006)	20SC	Foliar Broadcast/ 90 day DBH	1506	52.64	3.50	NA	52.64	None	DuPont-19306
	20SC	Foliar Broadcast/ 56 day DBH	1518	53.06	3.50	NA	53.06	None	DuPont-19306
	20SC	Foliar Broadcast/ 30 day DBH	1516	52.64	3.47	NA	52.64	None	DuPont-19306

Table 116
Study Use Pattern for 2006 growing season (continued)

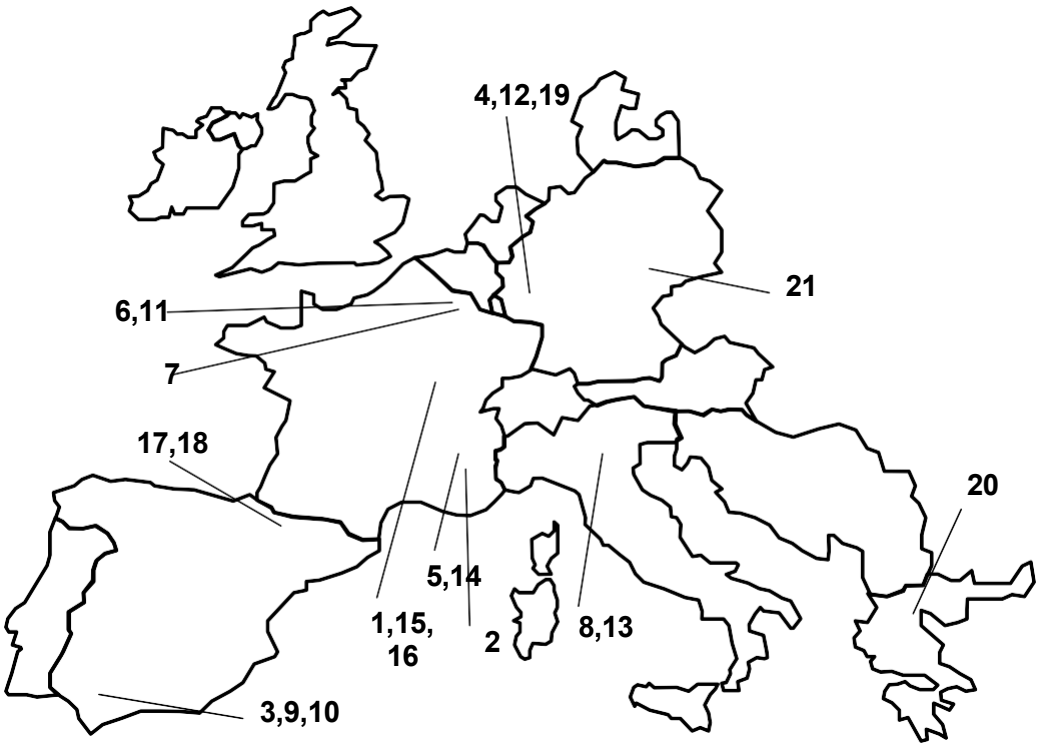
Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Ad-juvants	Ref
		Method/Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] (days)	Total Rate (g ai/ha)		
Test 13 (Radebeul, Saxony Germany, 2006)	20SC	Foliar Broadcast/ 90 day DBH	1574	55.2	3.51	NA	55.2	None	DuPont-19306
	20SC	Foliar Broadcast/ 57 day DBH	1495	52.4	3.51	NA	52.4	None	DuPont-19306
	20SC	Foliar Broadcast/ 30 day DBH	1563	54.8	3.51	NA	54.8	None	DuPont-19306

[1] EP = End-use Product
[2] DBH = Days before harvest
[3] RTI = Retreatment Interval
NA = Not Applicable

A total of two normal decline trials (1 in southern EU, 1 in northern EU), twelve reverse decline trials (6 in southern EU, 6 in northern EU), and seven magnitude of residue trials (4 in southern EU, 3 in northern EU) were conducted over three growing seasons, 2004, 2005, and 2006. A summary of these wine grape studies is given below. Locations of the wine grape trial sites are given in Figure 18.

Figure 18

Map: Chlorantraniliprole EU wine grape (berries and small fruit) trial sites



Map No.	Reference, Trial No.	Location
1	DuPont-14139, 1	Les Charmes, Bourgogne, France (north)
2	DuPont-14139, 2	Villié Morgon, Rhône-Alpes, France (south)
3	DuPont-16567, 1	Los Palacios, Andalucia, Spain
4	DuPont-16567, 2	Veldenz, Rhineland-Palatinate, Germany
5	DuPont-16567, 3	Lamié, Rhône-Alpes, France (south)
6	DuPont-16567, 4	Marfaux, Champagne-Ardennes France (north)
7	DuPont-16567, 5	Fleury-La-Riviere, Champagne France (north)
8	DuPont-16567, 6	Miradolo Terme, Lombardia, Italy
9	DuPont-19306, 1	Los Palacios y Villafranca, Andalucia, Spain
10	DuPont-19306, 2	Villalba del Alcor, Andalucia, Spain
11	DuPont-19306, 3	Marfaux, Champagne-Ardenne, France (north)
12	DuPont-19306, 4	Veldnez, Rhineland-Palatinate, Germany
13	DuPont-19306, 5	Miradolo, Lombardia, Italy
14	DuPont-19306, 6	Lancié, Rhône-Alpes, France (south)
15	DuPont-19306, 7	Les Charmes, Bourgogne, France (north)
16	DuPont-19306, 8	La Roche Vineuse, Bourgogne, France (north)
17	DuPont-19306, 9	Verdu, Lleida, Spain
18	DuPont-19306, 10	Sant Marti de Malda, Lleida, Spain
19	DuPont-19306, 11	Kesten, Rhineland-Palatinate, Germany
20	DuPont-19306, 12	Anchialos, Thessaloniki, Central Macedonia, Greece
21	DuPont-19306, 13	Radebeul, Saxony, Germany

A wine grape residue data summary (in mg/kg) is presented in Table 117, Table 118, and

Table 119. To generate these data, the following analysis information pertains.

Analysis method: LC-MS/MS method (DuPont-13295) developed as the chlorantraniliprole residue method for determining residues of chlorantraniliprole in/on crops.

Analyte:	Chlorantraniliprole
Extraction:	Analyte extracted from crop matrices with acetonitrile following water pre-soak.
Clean-up:	SAX (Strong Anion Exchange) and HLB (Hydrophilic Lipophilic Balanced) Solid Phase Extraction (SPE) cartridges
Chromatography:	LC
Detection:	Mass spectrometer detection (MS/MS) in APCI positive ion mode. Two ion transitions are acquired 284 m/z → 177 m/z and 484 m/z → 453 m/z. The former transition is used for quantification and the second transition for confirmation. In cases where a significant interference is detected in the former transition the latter transition may be used for quantification purposes
LOQ	0.010 mg/kg

Storage stability: All samples were analysed within 8 months of sampling. Chlorantraniliprole residues are stable in a variety of crops including predominantly water-, oil-, protein-, and starch-containing commodities as represented by fruits, a fruiting vegetable, a root crop, a non-oily grain, and an oilseed (apple, grape, tomato, leaf lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay, and ginned cotton seed) for at least 24 months when stored frozen at -20 ± 10°C (see Point IIA 6.1.1 of this document). Therefore, no degradation is expected to have occurred between harvest and analysis.

Table 117
Residues of chlorantraniliprole in wine grapes (berries and small fruit) from 2004 and 2005 supervised trials

Trial Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate lb ai/A (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c,d]	Ref
Trial 01 (Les Charmes, Bourgogne, N. France, 2004)	20SC	Wine Grapes/ Pinot Noir	Wine Grape Berries	0.042 (47.08)	30 44 59 75	0.022 0.012 0.016 0.014	DuPont-14139
Trial 02 (Villié Morgon, Rhône-Alpes, S. France, 2004)	20SC	Wine Grapes / Gamay	Wine Grape Berries	0.043 (47.93)	30 45 60 75	0.058 0.016 0.010 0.008	DuPont-14139
Trial 01 (Los Palacios,		Wine		0.047 (52.8)	(-1 h) (+1h)	nd 0.039	DuPont-
				0.047 (53.01)	14	0.011	
				0.047 (52.59)	28	0.018	

Andalucia, Spain, 2005	20SC	Grapes / Mer-lot	Grapes	0.046 (51.97)	45	0.013	16567
				0.047 (53.01)	56	0.016	
				0.047 (52.59)	90	0.031	
Trial 02 (Veldenz Rhineland-Palatinate, Germany, 2005)	20SC	Wine Grapes/ Müler-Thurgau	Grapes	0.046 (51.76)	(-1 h) (+1h)	nd 0.094	DuPont-16567
				0.046 (51.76)	14	0.097	
				0.048 (54.10)	28	0.12	
				0.049 (55.10)	45	0.051	
				0.045 (50.42)	56	0.055	
				0.048 (54.26)	90	0.017	
Trial 03 (Lamié, Rhône-Alpes, S. France, 2005)	20SC	Wine Grapes/ Gameny	Grapes	0.031 (34.64)	(-1 h) (+1h)	nd 0.009	DuPont-16567
				0.032 (35.90)	15	0.013	
				0.032 (36.31)	29	0.010	
				0.032 (35.90)	41	0.019	
				0.032 (35.69)	55	0.004	
				0.030 (34.02)	84	nd	

Table 117
Residues of chlorantraniliprole in wine grapes (berries and small fruit) from 2004 and 2005 supervised trials (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate lb ai/A (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c,d]	Ref
Trial 04 (Marfaux, Champagne-Ardennes, N. France, 2005)	20SC	Wine Grapes/ Chardonnay	Grapes	0.046 (51.76)	(-1 h) (+1h)	nd 0.034	DuPont-16567
				0.046 (51.55)	14	0.031	
				0.045 (50.92)	28	0.018	
				0.046 (51.97)	46	0.012	
				0.048 (53.84)	56	0.021	
				0.046 (51.13)	84	nd	
Trial 05 (Fleury-La-Riviere, Champagne, N. France, 2005)	20SC	Wine Grapes/ Meunier	Grapes	0.031 (34.44)	(-1 h) (+1h)	nd 0.029	DuPont-16567
				0.031 (34.23)	14	0.014	
				0.031 (35.27)	28	0.019	
				0.032 (35.90)	46	0.005	
				0.031			

				(34.44)			
				0.031 (34.85)	90	nd	
Trial 06 (Miradolo Terme, Lombardia, Italy, 2005)	20SC	Wine Grapes/ Trebbiano	Grapes	0.047 (52.18)	(-1 h) (+1h)	nd 0.25	DuPont-16567
				0.047 (52.38)	15	0.074	
				0.047 (52.80)	29	0.15	
				0.047 (52.59)	45	0.052	
				0.046 (51.97)	53	0.046	
				0.045 (50.92)	88	0.011	

[a] EP = End-use Product
[b] DALA = Days after last application (Days between last application and sampling)
[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.
For each decline trial, the highest residue value for any sample collected at the target PHI or later is underlined.
[d] Control specimens were collected and analyzed. No detectable residues, nd, were found in all instances

Table 118
Residues of chlorantraniliprole in wine grapes (berries and small fruit) from 2006 EU supervised trials

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg) [c,d]	Ref
Test 01 (Los Palacios y Villafranca, Andalucia, Spain, 2006)	20SC	Wine Grapes / Merlot	Wine Grape Berries	-	(-1 h)	nd	DuPont-19306
				52.59	0 day (+1 h)	0.011	
				53.22	14 day	0.057	
				52.80	31 day	0.026	
				52.38	56 day	0.039	
				52.18	90 day	0.022	
Test 02 (Villalba del Alcor, Andalucia, Spain, 2006)	20SC	Wine Grapes / Zalema	Wine Grape Berries	52.18	28 day	0.033	DuPont-19306
				52.80	56 day	0.009	
				52.18	90 day	nd	
Test 03 (Marfaux, Champagne-Ardenne, N. France, 2006)	20SC	Wine Grapes/ Chardonnay	Wine Grape Berries	-	(-1 h)	nd	DuPont-19306
				39.65	0 day (+1 h)	nd	
				39.86	14 day	0.035	
				39.86	30 day	0.014	
				39.86	53 day	0.004	
				40.49	87 day	nd	
Test 04 (Veldnez, Rhineland-Palatinate Germany, 2006)	20SC	Wine Grapes/ Müller-Thurgau	Wine Grape Berries	-	(-1 h)	nd	DuPont-19306
				51.94	0 day (+1 h)	nd	
				52.77	14 day	0.075	
				51.77	30 day	0.074	
				52.60	56 day	0.041	
				52.94	83 day	0.025	
Test 05 (Mir-		Wine		-	(-1 h)	nd	
				52.18	0 day (+2 h)	0.21	
				52.59	14 day	0.028	

adolo, Lombardia, Italy, 2006)	20SC	Grapes/ Trebbiano	Wine Grape Berries	53.43	32 day	0.13	DuPont-19306
				52.18	54 day	0.029	
				52.50	90 day	0.013	
Test 06 (Lancié, Rhône-Alpes, S. France, 2006)	20SC	Wine Grapes / Gaunay	Wine Grape Berries	-	(-1 h)	nd	DuPont-19306
				41.32	0 day (+1 h)	0.045	
				39.65	14 day	0.009	
				40.07	30 day	0.008	
				39.24	54 day	nd	
				39.86	90 day	nd	

Table 118
Residues of chlorantraniliprole in wine grapes (berries and small fruit) from 2006 EU supervised trials (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg) [c,d]	Ref
Test 07 (Les Charmes, Bourgogne, N. France, 2006)	20SC	Wine Grapes / Pinot	Wine Grape Berries	-	(-1 h)	nd	DuPont-19306
				52.80	0 day (+1h)	0.055	
				52.38	11 day	0.058	
				52.80	24 day	0.030	
				51.97	49 day	0.024	
				53.01	81 day	0.015	
Test 08 (La Roche Vineuse, Bourgogne, N. France, 2006)	20SC	Wine Grapes/ Chardonnay	Wine Grape Berries	53.01	31 day	0.036	DuPont-19306
				53.43	55 day	0.013	
				53.22	90 day	0.012	
Test 09 (Verdu, Lleida Spain, 2006)	20SC	Wine Grapes/ Macaben	Wine Grape Berries	52.38	31 day	0.061	DuPont-19306
				52.59	56 day	0.017	
				53.01	90 day	0.016	
Test 10 (Sant Marti de Malda, Lleida, Spain, 2006)	20SC	Wine Grapes / Syrah	Wine Grape Berries	52.59	31 day	0.080	DuPont-19306
				52.80	56 day	0.041	
				52.59	92 day	0.016	
Test 11 (Kesten, Rhineland-Palatinate Germany, 2006)	20SC	Wine Grapes/ Dornfelder	Wine Grape Berries	52.73	30 day	0.044	DuPont-19306
				52.48	56 day	0.026	
				52.97	83 day	0.017	
Test 12 (Anchialos, Thessaloniki, Central Macedonia Greece, 2006)	20SC	Wine Grapes/ Muschat	Wine Grape Berries	52.64	30 day	0.036	DuPont-19306
				53.06	56 day	0.010	
				52.64	90 day	0.011	
Test 13 (Radebeul, Saxo-	20SC	Wine Grapes	Wine Grape	54.80	30 day	0.061	DuPont-
				52.40	57 day	0.068	

ny Germany, 2006)		/ Kerner	Berries	55.20	90 day	0.013	19306

[a] EP = End-use Product
[b] DALA = Days after last application (Days between last application and sampling)
[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.
[d] Control specimens were collected and analyzed. No detectable residues, nd, were found in all instances

Table 119

Summary of residue data from EU wine grape field trials with chlorantraniliprole

Commodity	EP[a]	Total Application Rate (g ai/ha)	DALA/PHI (days)	Residue Levels in ppm (mg/kg)						
				n[b]	Min.[b]	Max.[b]	HAFT[b]	Median[b] (STMdR)	Mean[b] (STMR)	Std. Dev.[b]
Chlorantraniliprole										
Wine grapes	20SC	--	-0[c]	12	<0.004	<0.004	<0.004	<0.004	<0.004	,
		34.02-55.10	0	12	<0.004	0.25	0.25	0.037	0.065	0.081
			14-15	12	0.009	0.097	0.097	0.033	0.042	0.030
			28-30	21	0.008	0.15	0.15	0.036	0.050	0.041
			41-46	8	0.005	0.052	0.052	0.015	0.023	0.018
			53-60	21	<0.004	0.068	0.068	0.017	0.024	0.018
			75-90	21	<0.004	0.031	0.031	0.013	0.013	0.007

[a] EP = End-use Product
[b] N = number of individual specimens,
Min = minimum individual specimen residue,
Max = maximum individual specimen residue,
HAFT = Highest Average residue from one Field Trial; (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set),
Median = median of individual specimen residues,
Mean = mean of individual specimen residues,
Std Dev = standard deviation of mean
[c] Shortly before the last application
Residues of nd (not detectable) were considered to be the LOD (0.004 mg/kg) for mean and median calculations.

Recovery data: Recovery data for fortifications run concurrently with the treated samples are given below to demonstrate the validity of the analytical method.

Table 120
Summary of concurrent recoveries of chlorantraniliprole from wine grapes – DuPont-14139 (2004 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (% ± %)
Concurrent Fortifications – Chlorantraniliprole				
Wine grape berries	0.010 0.10	2 2	90, 95 105, 77	92 ± 12

Table 121
Summary of concurrent recoveries of chlorantraniliprole from wine grapes – DuPont-16567 (2005 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (rsd) (% ± % (%))
Concurrent Fortifications – Chlorantraniliprole				
Wine Grapes	0.010	6	75, 107, 91, 87, 90, 88	90 ± 10 (12)
	0.10	6	96, 94, 84, 84, 91, 85	89 ± 5.4 (6.1)
Overall				89 ± 7.9 (8.8)

Table 122
Summary of concurrent recoveries of chlorantraniliprole from wine grapes – DuPont-19306 (2006 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (rsd) (% ± % (%))
Wine Grapes	0.010	10	92, 82, 80, 86, 95, 97, 80, 72, 78, 79	84 ± 8 (10)
	0.10	10	99, 110, 64, 67, 80, 76, 91, 85, 78, 79	83 ± 14 (17)
	0.30	2	82, 79	80
Overall		22		83 ± 11 (13)

RESULTS AND DISCUSSION

The residue studies presented herein were carried out in five EU countries in the 2004, 2005, and 2006 growing seasons and provide data relevant to conditions in the wine grape-growing regions of the northern and southern EU.

All of the analytical work associated with the studies was performed at Charles River Laboratories, Tranent, EH33 2NE, Scotland. The analytical work was carried out during three different time periods: first time for the season 2004 residue trials, in the spring of 2006 for the 2005 residue trials, and in the winter of 2006-7 for the 2006 residue trials.

In the EU, residues in wine grapes were less than or equal to 0.15 mg/kg at 30 DALA, the target PHI, or later sampling intervals, in the twenty-one trials conducted in 2004, 2005, and 2006 in which Chlorantraniliprole 20SC was applied. Dissipation half-lives for chlorantraniliprole in wine grapes from 2 normal decline residue trials conducted in 2004, 6 reverse decline residue trials conducted in 2005, and 6 reverse decline residue trials conducted in 2006 were 101, 16, 35, 76, 33, 23, 21, 12, 41, 28, 12 and 41days for

DuPont-14139, trials 1 and 2, DuPont-16567, trials 2, 3, 4, 5, and 6, and DuPont-19306, trials 3, 4, 5, 6, and 7, respectively. No decline of residues was observed in DuPont-16567, trial 1 or DuPont-19306, trial 1.

The study use patterns for all 2004, 2005, and 2006 trials corresponded to 63-102% maximum EU recommended ground rate of 54 g ai/ha/season dependent upon crop canopy, spacing, and cultural practice. The study use patterns for the sixteen 2004, 2005, and 2006 standard-volume trials corresponded to 87-102% maximum EU recommended ground rate of 54 g ai/ha/season dependent upon crop canopy, spacing, and cultural practice. The study use patterns for the 5 low-volume trials corresponded to 113%-138% minimum EU recommended application rate of 30 g ai/ha. Additionally, all 2004, 2005, and 2006 trials resulted in similar

chlorantraniliprole residues on wine grapes, therefore data generated from all field trials will be considered as part of the EU wine grape residue population for further residue population comparison.

All trials show an overall consistent residue profile will be found when chlorantraniliprole is applied in accordance with GAP.

Recovery values for fresh control fortifications run concurrently with treated samples in all the trials were within 64-110% (n = 38) for wine grapes. Most recoveries were within 70–110% and the relative standard deviations were less than 20% for all trials. Therefore, the analytical methods used performed well for the determination of chlorantraniliprole in treated crops.

CONCLUSION – EU WINE GRAPE TRIALS

Overall consistent residue behaviour of chlorantraniliprole on wine grapes was found for three seasons of study in the northern and southern EU, for application and sampling conducted according to GAP. Residues in wine grapes were less than or equal to 0.15 mg/kg at 30 DALA, the target PHI, or later sampling intervals, in the 21 trials conducted in 2004, 2005, and 2006 in which Chlorantraniliprole 20SC was applied.

The residue data show that residues do not consistently decline in wine grapes with increasing DALA. At 12 of 14 decline trials, dissipation half-lives of 101, 16, 35, 76, 33, 23, 21, 12, 41, 28, 12 and 41days were calculated and there was no decline of residues at the remaining two trials.

The data generated from all 2004, 2005, and 2006 field trials will be considered as part of the EU wine grape residue population for further residue population comparison

A 2.2.2.2.4 POTATO

Report: Foster, A.C., Davidson, J., Cairns, S.D. (2005); Decline of DPX-E2Y45 residues in potato tubers

following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - Northern Europe, 2004

DuPont Report No.: DuPont-14143

Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC. **Deviations:** None

Testing Facility: Charles River Laboratories (formerly Inveresk Research), Tranent, Scotland, UK

Testing Facility Report/Project No.: 685373

GLP: Yes

Certifying Authority: Department of Health (UK)

Report: Foster, A.C., Cairns, S.D. (2006); Magnitude of DPX-E2Y45 residues in potatoes (potato group) following foliar applications of DPX-E2Y45 20SC [200 g a.s./L (w/v); 18.5% (w/w)] - northern and southern Europe, 2005

DuPont Report No.: DuPont-16565

Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC. **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK

Testing Facility Report/Project No.: 687517

GLP: Yes

Certifying Authority: Department of Health (UK)

Report: Foster, A.C., Cairns, S.D. (2007); Magnitude of DPX-E2Y45 residues in potatoes (potato group) following foliar applications of DPX-E2Y45 20SC [200 g as/L (w/v); 18.5% (w/w)] - northern and southern Europe, 2006

DuPont Report No.: DuPont-18748

Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC. **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK

Testing Facility Report No.: 689561

GLP: Yes

Certifying Authority: Department of Health (UK)

MATERIALS AND METHODS

The first field program of two decline trials was conducted in 2004 at two locations in Poland. DPX-E2Y45-179 (SC formulation) was applied twice by foliar application at a target application rate of 10 g ai/ha, for a seasonal application rate of 20 g ai/ha (83% maximum EU recommended rate of 24 g ai/ha). The first application (A1) occurred at growth stage BBCH 44-46, 35 days before the predicted harvest date. The second application (A2) occurred at growth stage BBCH

47, 13-14 days after A1, (longer than the minimum EU recommended interval of 10 days) and therefore 21-22 days before the commercial harvest date according to the use patterns described in Table 229 and sampling intervals described in Table 231.

The second and third field programs of four normal decline and four magnitude of residue trials were conducted in 2005 and 2006 at one location in Spain, two in Greece, one in Germany, one location in Italy, one in Poland, and two in northern France. DPX-E2Y45-205 (20SC formulation) was applied twice by foliar application at the target rate of 12.5 g ai/ha for a seasonal application rate of 25 g ai/ha (104% maximum EU recommended rate of 24 g ai/ha). In 2005, the applications of Chlorantraniliprole 20SC were made at 14 ± 1 day intervals (longer than the minimum EU recommended interval of 10 days). In 2006, the applications of Chlorantraniliprole 20SC were made at 9-11-day intervals. In both growing seasons, the last application occurred 14-15 days before normal harvest according to the use patterns described in Table 229 and Table 230 and sampling intervals described in Table 231 and Table 232. No surfactants or adjuvants were added to the applications. The targeted PHI under GAP is 14 days.

Table 229

Study Use Pattern – 2004 and 2005 growing seasons

Trial Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, GPA[c] (L/ha)	Rate lb ai/A (g ai/ha)[d]	Rate g ai/hL[e]	RTI[f] Days	Total Rate lb ai/A (g ai/ha)[d]		
Trial 01 Rozbity Kamien, Mazowsze, Poland, 2004	20SC	Foliar/ 14 DBFH[e]	53.8 (503)	0.0094 (10.51)	(2.09)	--	0.019 (21.02)	None	DuPont-14143
		Foliar/ 0 DBFH	53.8 (503)	0.0094 (10.51)	(2.09)	14		None	
Trial 02 Zawady/Repki, Mazowsze, Poland, 2004	20SC	Foliar Broadcast/ 13 DBFH	54.1 (506)	0.0096 (10.72)	(2.12)	--	0.019 (21.44)	None	DuPont-14143
		Foliar Broadcast/ 0 DBFH	54.1 (506)	0.0096 (10.72)	(2.12)	13		None	
Trial 01 Sanlucar la Mayor E-41804, Andalucia Spain, 2005	20SC	Foliar Broadcast/ 28 DBH	63.6 (594)	0.011 (12.31)	2.07	--	0.022 (25.04)	None	DuPont-16565
		Foliar Broadcast/ 14 DBH	64.8 (606)	0.011 (12.73)	2.10	14		None	
Trial 02 Chalkidona, GR-57007, Thessaloniki, Central Macedonia, Greece, 2005	20SC	Foliar Broadcast/ 28 DBH	67.2 (628)	0.012 (13.11)	2.09	--	0.023 (25.98)	None	DuPont-16565
		Foliar Broadcast/ 14 DBH	66.0 (617)	0.011 (12.87)	2.09	14		None	
Trial 03 Goch-Nierswalde, D-47574, North Rhine-Westphalia, Germany, 2005	20SC	Foliar Broadcast/ 28 DBH	66.0 (617)	0.011 (12.87)	2.09	--	0.023 (25.67)	None	DuPont-16565
		Foliar Broadcast/ 14	65.6 (613)	0.011 (12.80)	2.09	14		None	

		DBH							
Trial 04 Allouagne, F-62157, Nord Pas de Calais, N. France, 2005	20SC	Foliar Broadcast/ 28 DBH	65.3 (610)	0.011 (12.73)	2.09	--	0.023 (25.67)	None	DuPont-16565
		Foliar Broadcast/ 14 DBH	66.2 (619)	0.012 (12.94)	2.09	14		None	

[a] EP = End-use Product
[b] DBFH = Days before first harvest; DBH = Days before harvest
[c] Gallons (US) per acre (Litres/hectare)
[d] lb active ingredient per acre (grams active ingredient per hectare)
[e] g active substance/hL (gram active substance per hectolitre or 100 L)
[f] Retreatment Interval

Table 230

Study Use Pattern – 2006 growing season

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol (L/ha)	g ai/ha[c]	g ai/hL[d]	RTI[e] Days	Total Rate (g ai/ha)[c]		
Test 01 Chalkidona, Central Macedonia, Greece, 2006	20SC	Foliar Broadcast/ 24 day DBH	607	12.67	2.09	-	25.42	None	DuPont-18748
		Foliar Broadcast/ 14 day DBH	611	12.75	2.09	10		None	
Test 02 Allouagne, Nord Pas de Calais, France (North), 2006	20SC	Foliar Broadcast/ 25 day DBH	607	12.73	2.10	-	25.04	None	DuPont-18748
		Foliar Broadcast/ 14 day DBH	590	12.31	2.09	11		None	
Test 03 Tortona, Piemonte, Italy, 2006	20SC	Foliar Broadcast/ 24 day DBH	593	12.31	2.08	-	25.25	None	DuPont-18748
		Foliar Broadcast/ 15 day DBH	617	12.94	2.10	9		None	
Test 04 Rozbity Kamień, Podlasie Region, Poland, 2006	20SC	Foliar Broadcast/ 24 day DBH	598	14.61	2.44	-	29.01	None	DuPont-18748
		Foliar Broadcast/ 15 day DBH	595	14.40	2.42	9		None	

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] grams active ingredient per hectare
[d] g active substance/hL (gram active substance per hectoliter or 100 L)

e Retreatment Interval

A total of 8 magnitude of residue and 2 normal decline residue trials (6 in the northern EU, 4 in the southern EU) were conducted in the growing seasons of 2004, 2005, and 2006. A summary of these potato studies is given below. Locations of the potato trial sites are given in Figure 36.

Figure 36

Map: Chlorantraniliprole EU potato trial sites



Map No.	Reference, Trial No.	Location
1	DuPont-14143, 1	Rozbity Kamien, Mazowsze, Poland
2	DuPont-14143, 2	Zawady, Repki, Mazowsze, Poland
3	DuPont-16565, 1	Sanlucar la Mayor, Andalucia, Spain
4	DuPont-16565, 2	Chalkidona, Thessaloniki, Central Macedonia, Greece
5	DuPont-16565, 3	Goch-Nierswalde, North Rhine-Westphalia, Germany
6	DuPont-16565, 4	Allouagne, Nord-Pas-de-Calais, France (north)
7	DuPont-18748, 1	Chalkidona, Central Macedonia, Greece
8	DuPont-18748, 2	Allouagne, Nord Pas de Calais, France (north)
9	DuPont-18748, 3	Tortona, Piemonte, Italy
10	DuPont-18748, 4	Rozbity Kamień, Podlasie, Poland

A potato residue data summary (in mg/kg) is presented in Table 231, Table 232, and Table 233.

To generate these data, the following analysis information pertains.

Analysis method: LC-MS/MS method (DuPont-13295) developed as the chlorantraniliprole residue method for determining residues of chlorantraniliprole in/on crops.

Analyte:	Chlorantraniliprole
Extraction:	Analyte extracted from crop matrices with acetonitrile following water pre-soak.
Clean-up:	SAX (Strong Anion Exchange) and HLB (Hydrophilic Lipophilic Balanced) Solid Phase Extraction (SPE) cartridges
Chromatography:	LC
Detection:	Mass spectrometer detection (MS/MS) in APCI positive ion mode. Two ion transitions are acquired 284 m/z → 177 m/z and 484 m/z → 453 m/z. The former transition is used for quantification and the second transition for confirmation. In cases where a significant interference is detected in the former transition the latter transition may be used for quantification purposes
LOQ	0.010 mg/kg

Storage stability: All samples were analysed within 6 months of sampling. Chlorantraniliprole residues are stable in a variety of crops including predominantly water-, oil-, protein-, and starch-containing commodities as represented by fruits, a fruiting vegetable, a root crop, a non-oily grain, and an oilseed (apple, grape, tomato, leaf lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay, and ginned cotton seed) for at least 24 months when stored frozen at -20 ± 10°C (see Point IIA 6.1.1 in this document). Therefore, no degradation is expected to have occurred between harvest and analysis.

Table 231

Residues of chlorantraniliprole in potatoes from 2004 and 2005 EU supervised trials

Trial Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate lb ai/A (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c,d]	Ref
Trial 01 (Rozbity Kamien, Mazowsze, Poland, 2004)	20SC	Pota-to/ Irga	Potato Tubers	0.0187 (21.02)	*ca.* -1 h *ca.* +1 h 7 14 21 28	nd nd nd nd nd nd	DuPont-14143
Trial 02 (Zawa-dy, Repki, Ma-zowsze, Poland, 2004)	20SC	Pota-to/ Bila	Potato Tubers	0.0191 (21.44)	*ca.* -1 h *ca.* +3 h 7 14 22 28	nd nd nd nd nd nd	DuPont-14143
Trial 01 Sanlucar la Mayor E-41804, Andalucia Spain, 2005	20SC	Pota-to/ Li-seta	Pota-to Tuber	0.022 (25.04)	14	nd	DuPont-16565
Trial 02 (Chalkidona, GR-57007, Thessaloniki, Central Macedonia, Greece, 2005)	20SC	Pota-to/ Dailfa	Pota-to Tuber	0.023 (25.98)	14	nd	DuPont-16565
Trial 03 (Goch-Nierswalde, D-47574, North Rhine-Westphalia, Germany, 2005)	20SC	Pota-to/ Bintje	Pota-to Tuber	0.023 (25.67)	14	nd	DuPont-16565
Trial 04 (Allouagne, F-62157, Nord Pas de Calais, France (North), 2005)	20SC	Pota-to/ Amyla	Pota-to Tuber	0.023 (25.67)	14	nd	DuPont-16565

[a] EP = End-use Product

[b] DALA = Days after last application (Days between last application and sampling)

[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.

[d] Control specimens were collected and analyzed for the target 14 DALA sampling dates. No detectable residues, nd, were found in all instances.

Table 232

Residues of chlorantraniliprole in potatoes (potato group) from 2006 EU supervised trials

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c,d]	Ref
Test 01 Chalkidona, Central Macedonia, Greece, 2006	20SC	Potato/ Fabula	Potato Tuber	25.42	14	nd	DuPont-18748
Test 02 Allouagne, Nord Pas de Calais, France (North), 2006	20SC	Potato/ Amila	Potato Tuber	25.04	14	nd	DuPont-18748
Test 03 Tortona, Piemonte, Italy, 2006	20SC	Potato / Monna Lisa	Potato Tuber	25.25	15	nd	DuPont-18748
Test 04 Rozbity Kamień, Podlasie Region, Poland, 2006	20SC	Potato/ Irga	Potato Tuber	29.01	15	nd	DuPont-18748

[a] EP = End-use Product

[b] DALA = Days after last application (days between last application and sampling)

[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.

[d] Control specimens were collected and analyzed for the target 14 DALA sampling dates. No detectable residues, nd, were found in all instances.

Table 233

Summary of residue data from EU potato field trials with chlorantraniliprole

Commodity	EP[a]	Total Application Rate (g ai/ha)	DALA/PHI (days)	Residue Levels in ppm (mg/kg)						
				n[b]	Min.[b]	Max.[b]	HAFT[b]	Median[b] (STMdR)	Mean[b] (STMR)	Std. Dev.[b]
Chlorantraniliprole										
Potato Tubers	20SC	21.02-29.01	-0[c]	2	nd[d]	nd	nd	nd	nd	0.0
			0	2	nd	nd	nd	nd	nd	0.0
			7	2	nd	nd	nd	nd	nd	0.0
			14	10	nd	nd	nd	nd	nd	-
			21	2	nd	nd	nd	nd	nd	0.0
			28	2	nd	nd	nd	nd	nd	0.0

[a] EP = End-use Product
[b] N = number of individual specimens,
Min = minimum individual specimen residue,
Max = maximum individual specimen residue,
HAFT = Highest Average residue from one Field Trial; (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set),
Median = median of individual specimen residues,
Mean = mean of individual specimen residues,
Std Dev = standard deviation of mean
[c] Shortly before the last application
[d] The designation "nd" is used for treated samples/specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.

Recovery data: Recovery data for fortifications run concurrently with the treated samples are given below to demonstrate the validity of the analytical method.

Table 234
Summary of concurrent recoveries of chlorantraniliprole from potato tubers – DuPont-14143 (2004 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (% ± %)
Concurrent Fortifications – Chlorantraniliprole				
Potato tubers	0.010 0.10	4 4	80, 74, 98, 87 85, 88, 80, 78	84 ± 8

Table 235
Summary of concurrent recoveries of chlorantraniliprole from potato - DuPont-16565 (2005 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (rsd) % ± % (%)
Chlorantraniliprole				
Potato Tuber Overall	0.010	2	86, 84	85
	0.10	2	73, 84	78
	-	-	-	82 ± 6.2 (7.6)

Table 236
Summary of concurrent recoveries of chlorantraniliprole from potatoes – DuPont-18748 (2006 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (CV) % ± % (%)
Chlorantraniliprole				
Potato Tuber	0.010	2	96, 105	100 ± 6.6 (6.6)
	0.10	2	98, 90	94 ± 5.9 (6.3)
Overall	-	4	-	97 ± 6 (6)

RESULTS AND DISCUSSION

The residue studies presented herein were carried out in six different EU countries in the 2004, 2005, and 2006 growing seasons and provide data relevant to conditions in the potato-growing regions of the northern and southern EU.

All of the analytical work associated with the studies was performed at Charles River Laboratories, Tranent, EH33 2NE, Scotland. The analytical work was carried out during three different time periods: first time for the season 2004 residue trials, in the winter of 2005-6 for the 2005 residue trials, and in the autumn of 2006 for the 2006 residue trials.

In the EU region, no chlorantraniliprole residues were detected (<0.004 mg/kg) in any potato tuber specimens from any trial following treatment with Chlorantraniliprole 20SC at 88-121% of the EU maximum GAP rate of 24 g ai/ha/season. The retreatment interval tested in the 2004 and 2005 growing seasons was 14 days, slightly longer than the target EU retreatment interval of 10 days. Since chlorantraniliprole does not rapidly metabolise and residues do not rapidly decline, it is believed that the chlorantraniliprole residues on potato tubers at 14 DALA, resulting from 2 applications made 10 days apart would not significantly differ from the chlorantraniliprole residues 14 DALA resulting from 2 applications made 14 days apart. The trials conducted in 2006 verify that there are no detectable chlorantraniliprole residues on potato tubers treated with 10-day retreatment intervals. Half-lives of chlorantraniliprole residues in potato tubers could not be calculated as no residues were detected in any of the specimens.

All trials show an overall consistent residue profile (no quantifiable residues found in potato tubers) when chlorantraniliprole is applied in accordance with GAP.

Recovery values for fresh control fortifications run concurrently with treated samples in all the trials were within 73-105% (n = 16) for potato tubers. All of the recoveries were within 70–110% and the relative standard deviations were less than 20% for all trials. Therefore, the analytical methods used performed well for the determination of chlorantraniliprole in treated crops.

CONCLUSION – EU TRIALS

Overall consistent residue behaviour of chlorantraniliprole on potatoes was found for three seasons of study in the northern and southern EU for application and sampling conducted supportive of GAP. No chlorantraniliprole residues were detected (<0.004 mg/kg) in any potato tuber specimens from ten trials following treatment with Chlorantraniliprole 20SC at 88-121% of the EU maximum GAP rate of 24 g ai/ha. Half-lives of chlorantraniliprole residues in potato tubers could not be calculated as no residues were detected in any of the specimens.

Residue data generated from all 2004, 2005, and 2006 field trials will be considered as part of the EU potato residue population for further residue population comparison.

A 2.2.2.2.5 Cucumber and courgettes

Report: Foster, A.C., Cairns, S.D., Hansford, R.J. (2007a); Magnitude and decline of DPX-E2Y45 residues in protected cucumbers and courgettes (fruiting vegetables, edible-peel cucurbits) following foliar applications of DPX-E2Y45 35WG - Europe, 2006

DuPont Report No.: DuPont-18760

Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK

Testing Facility Report No.: 689671

GLP: Yes

Certifying Authority: Department of Health (UK)

MATERIALS AND METHODS

The field program was conducted in 2006 at two locations in each Spain, Italy, southern France, and the Netherlands, and one location in Greece. Specifically, three normal decline cucumber trials, two magnitude of residue cucumber trials, two normal decline courgette trials, and two magnitude of residue courgette trials were conducted.

Chlorantraniliprole (DPX-E2Y45-206, 35WG formulation) was applied twice at the target rate of 60 g ai/ha (4.0 g ai/hL) at both applications to protected cucumbers and courgettes, for a nominal seasonal application rate of 120 g ai/ha (119% maximum EU recommended rate of 100.8 g ai/ha/season). The applications of Chlorantraniliprole 35WG were made at 6-7-day intervals with the last application occurring at 0-1 days before the first commercial harvest for

(continuously ripening) protected cucumbers and courgettes, according to the use patterns described in Table 145 and sampling intervals described in Table 146. No surfactants or adjuvants were added to the applications. The targeted PHI under GAP is 1 day.

Table 145 Study Use Pattern

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 01 (Los Palacios, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 7 day DBH	1498	60.16	4.02	-	120.68	None	DuPont-18760
		Foliar Broadcast/ 0 day DBH	1506	60.52	4.02	7		None	
Test 02 (Los Palacios, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 7 day DBH	1501	60.16	4.01	-	120.68	None	DuPont-18760
		Foliar Broadcast/ 0 day DBH	1506	60.52	4.02	7		None	
Test 03 (Triginto di Mediglia, Lombardia, Italy, 2006)	35WG	Foliar Broadcast/ 7 day DBH	1459	58.38	4.00	-	120.32	None	DuPont-18760
		Foliar Broadcast/ 0 day DBH	1542	61.94	4.02	7		None	

Test 04 (Murello, Piemonte, Italy, 2006)	35WG	Foliar Broadcast/ 8 day DBH	1483	59.10	3.99	-	118.55	None	DuPont-18760
		Foliar Broadcast/ 1 day DBH	1487	59.45	4.00	7		None	
Test 05 (Pernes les Fontaines, Provence-Alpes-Côte d'Azur, S. France, 2006)	35WG	Foliar Broadcast/ 6 day DBH	1475	59.10	4.01	-	119.26	None	DuPont-18760
		Foliar Broadcast/ 0 day DBH	1505	60.16	4.00	6		None	
Test 06 (Lucenay, 69480, Rhône-Alpes, S. France, 2006)	35WG	Foliar Broadcast/ 8 day DBH	1510	60.16	3.98	-	119.61	None	DuPont-18760
		Foliar Broadcast/ 1 day DBH	1490	59.45	3.99	7		None	

Table 145
Study Use Pattern (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		

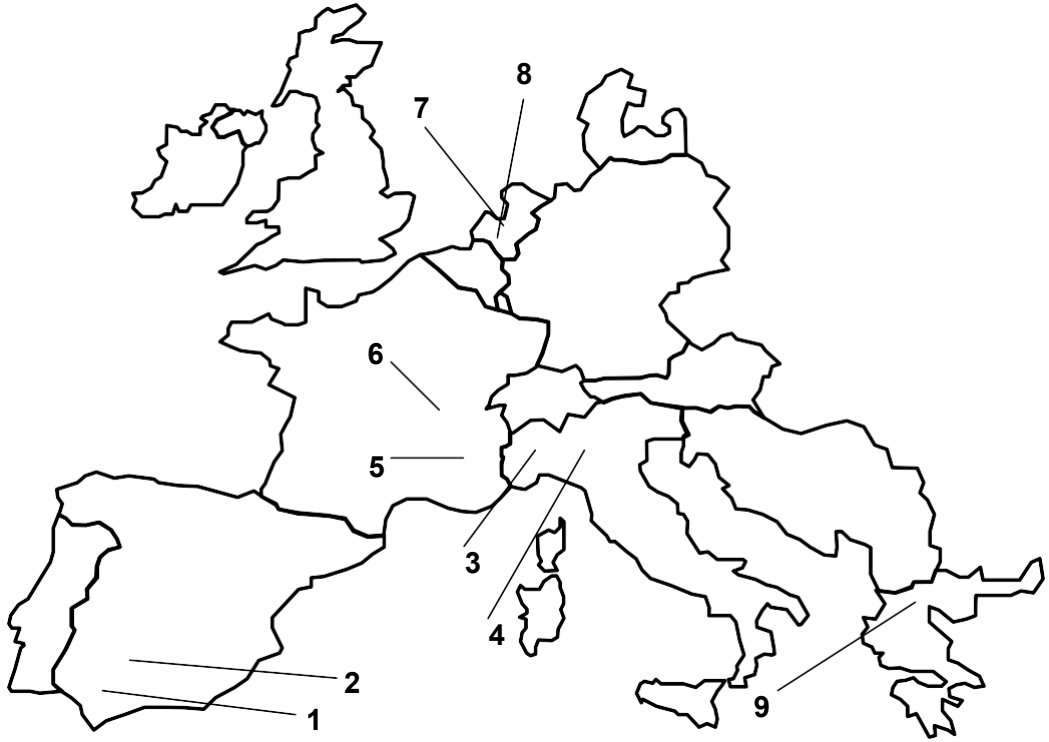
Test 07 (AB Siebengewal-de, The Nether-lands, 2006)	35WG	Foliar Broad cast/ 8 day DBH	1520	60.61	3.99	-	119.94	None	DuPont-18760
		Foliar Broad cast/ 1 day DBH	1488	59.33	3.99	7		None	
Test 08 (AB Siebengewal-de, The Neth-erlands, 2006)	35WG	Foliar Broad cast/ 8 day DBH	1513	60.43	3.99	-	121.11	None	DuPont-18760
		Foliar Broad cast/ 1 day DBH	1519	60.68	3.99	7		None	
Test 09 (Profitis, Thessalo-niki, Central Mac-edonia Greece, 2006)	35WG	Foliar Broad cast/ 7 day DBH	1489	59.73	4.01	-	120.43	None	DuPont-18760
		Foliar Broad cast/ 0 day DBH	1513	60.70	4.01	7		None	

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] RTI = Retreatment Interval

A total of 5 decline trials and 4 magnitude of residue trials were conducted in the growing season of 2006. A summary of these protected cucumbers and courgettes studies is given below. Locations of the protected cucumbers and courgettes trial sites are given in Figure 23.

Figure 23

Map: Chlorantraniliprole EU protected cucumbers and courgettes fruiting vegetables, edible-peel cucurbits) trial sites



Reference, Trial No.	Location
DuPont-18760, 1	Los Palacios, Andalucia, Spain
DuPont-18760, 2	Los Palacios, Andalucia, Spain
DuPont-18760, 3	Triginto di Mediglia, Lombardia, Italy
DuPont-18760, 4	Murello, Piemonte, Italy
DuPont-18760, 5	Pernes les Fontaines, Provence-Alpes-Côte d'Azur, France (south)

DuPont-18760, 6	Lucenay, Rhône-Alpes, France (south)
DuPont-18760, 7	AB Siebengewald, Limburg, The Netherlands
DuPont-18760, 8	AB Siebengewald, Limburg, The Netherlands
DuPont-18760, 9	Profitis, Thessaloniki, Central Macedonia, Greece

A protected cucumbers and courgettes residue data summary (in mg/kg) is presented in Table 146 and Table 147.

To generate these data, the following analysis and recovery information pertains.

Analysis method: LC-MS/MS method (DuPont-13295) developed as the chlorantraniliprole residue method for determining residues of chlorantraniliprole in/on crops.

Analyte:	Chlorantraniliprole
Extraction:	Analyte extracted from crop matrices with acetonitrile following water presoak.
Clean-up:	SAX (Strong Anion Exchange) and HLB (Hydrophilic Lipophilic Balanced) Solid Phase Extraction (SPE) cartridges
Chromatography:	LC
Detection:	Mass spectrometer detection (MS/MS) in APCI positive mode. Two ion transitions are acquired 284 m/z – 177 m/z and 484 m/z – 453 m/z. The former transition is used for quantification and the second transition for confirmation. In cases where a significant interference is detected in the former transition the latter transition may be used for quantification purposes
LOQ	0.010 mg/kg

Storage stability: All samples were analysed within 9 months of sampling. Chlorantraniliprole residues are stable in a variety of crops including predominantly water-, oil-, protein- and, starch-containing commodities as represented by fruits, a fruiting vegetable, a root crop, a non-oily grain, and an oilseed (apple, grape, tomato, leaf lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay, and ginned cottonseed) for at least 24 months when stored frozen at -20 ± 10°C (see Point IIA 6.1.1). Therefore, no degradation is expected to have occurred between harvest and analysis.

Table 146

Residues of chlorantraniliprole in protected cucumbers and courgettes (fruiting vegetables, edible-peel cucurbits) from supervised trials

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b] / PHI (days)	Residue ppm (mg/kg) [c,d]	Ref
Test 01 (Los Palacios, Andalucia, Spain, 2006)	35WG	Cucumber / Sol Verde	Whole Fruit	120.68	-0 +0 1 7 14 21	0.004 0.022 0.008 0.006 nd nd	DuPont-18760
Test 02 (Los Palacios, Andalucia, Spain, 2006)	35WG	Cucumber / Su-sa	Whole Fruit	120.68	-0 +0 1 7 14 21	0.030 0.026 0.10 0.031 0.032 0.013	DuPont-18760
Test 03 (Triginto di Mediglia, Lombardia, Italy, 2006)	35WG	Courgette / President	Whole Fruit	120.32	-0 +0 1 7 14 21	0.011 0.17 0.13 0.027 nd nd	DuPont-18760
Test 04 (Murello, Piemonte, Italy, 2006)	35WG	Courgette / Isot-ta	Whole Fruit	118.55	1	0.064	DuPont-18760
Test 05 (Pernes les Fontaines, Provence-Alpes-Côte d'Azur, S. France, 2006)	35WG	Courgette / Radiant	Whole Fruit	119.26	-0 +0 1 7 14 21	nd 0.029 0.021 0.009 nd nd	DuPont-18760
Test 06 (Lucenay, 69480, Rhône-Alpes, S. France, 2006)	35WG	Cucumber / Lous-tik	Whole Fruit	119.61	1	0.058	DuPont-18760

Test 07 (AB Siebengewalde, The Netherlands, 2006)	35WG	Courgette / Cora	Whole Fruit	119.94	1	0.016	DuPont-18760
Test 08 (AB Siebengewalde, The Netherlands, 2006)	35WG	Cucumber / Fit-ness	Whole Fruit	121.11	1	0.039	DuPont-18760

Table 146
Residues of chlorantraniliprole in protected cucumbers and courgettes (fruiting vegetables, edible-peel cucurbits) from supervised trials (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b] / PHI (days)	Residue ppm (mg/kg) [c,d]	Ref
Test 09 (Profit-is, Thessaloniki, Central Macedonia Greece, 2006)	35WG	Cucumber / Luberon	Whole Fruit	120.43	-0 +0 1 7 14 21	0.015 0.066 0.083 0.013 nd nd	DuPont-18760

[a] EP = End-use Product
[b] DALA = Days after last application (Days between last application and sampling)
[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.
[d] Control specimens were collected and analyzed for the target 1 DALA (trials 4, 6, 7 and 8) and 0 and 7 DALA (trials 1, 2, 3, 5 & 9) sampling dates. No detectable residues, nd, were found in all instances.

Table 147

Summary of residue data from cucumber and courgette field trials with chlorantraniliprole

Commodity	EP[a]	Total Application Rate (g ai/ha)	DALA/ PHI (days)	Residue Levels in ppm (mg/kg)						
				n[b]	Min.[b]	Max.[b]	HAFT[b]	Median[b] (STMdR)	Mean[b] (STMR)	Std. Dev.[b]
Chlorantraniliprole										
Cucumber and Courgette Fruit	35WG	58.38–60.43	-0[c]	5	nd	0.030	0.030	0.013	0.015	0.011
		118.55–121.11	+0[d]	5	0.022	0.17	0.17	0.029	0.063	0.063
			1	9	0.008	0.13	0.13	0.058	0.057	0.040
			7	5	0.006	0.031	0.031	0.013	0.017	0.011
			14	5	nd	0.032	0.032	nd	0.010	0.012
			21	5	nd	0.013	0.013	nd	0.006	0.004

[a] EP = End-use Product
[b] N = number of individual specimens,
Min = minimum individual specimen residue, Max = maximum individual specimen residue,
HAFT = Highest Average residue from one Field Test; (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set),
Median = median of individual specimen residues, Mean = mean of individual specimen residues,
Std Dev = standard deviation of mean
[c] Shortly before the last application
[d] Shortly after the last application

Recovery data: Recovery data for fortifications run concurrently with the treated samples are given below to demonstrate the validity of the analytical method.

Table 148

Summary of concurrent recoveries of chlorantraniliprole from protected cucumbers and courgettes

Matrix	Fortification Level in ppm (mg/kg)	Sample Size (n)	Recoveries (%)	Mean ± std. dev. (CV) (% ± % (%))
Chlorantraniliprole				

Cucumber Fruit	0.010 0.10 0.20	4 4 2	91, 79, 100, 104 75, 79, 92, 99 92, 96	93 ± 11 (12) 86 ± 11 (13) 94
Overall (Cucumber)	-	10	-	91 ± 10 (11)
Courgette Fruit	0.010 0.10 0.20	3 3 2	92, 104, 87 104, 95, 84 91, 99	94 ± 9 (9) 94 ± 10 (10) 95
Overall (Courgette)	-	8	-	95 ± 7 (8)

Statistics were calculated using non-rounded recovery values

RESULTS AND DISCUSSION

The residue studies presented in the chlorantraniliprole dossier were carried out in five different EU countries and provided data relevant to conditions in the protected cucumbers and courgettes-growing regions of the EU.

All of the analytical work associated with the studies was performed at Charles River Laboratories, Tranent, EH33 2NE, Scotland in the winter of 2006-7.

In the EU, residues in protected cucumbers and courgettes were less than or equal to 0.13 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in the 9 residue trials conducted in 2006 in which Chlorantraniliprole 35WG was applied at 118-120% maximum EU recommended rate of 100.8 g ai/ha/season.

In cucumbers, chlorantraniliprole residues ranged from 0.008 mg/kg to 0.10 mg/kg respectively at 1 DALA, following treatment with Chlorantraniliprole 35WG. In courgettes, chlorantraniliprole residues ranged from

0.016 mg/kg to 0.13 mg/kg respectively at 1 DALA, following treatment with Chlorantraniliprole 35WG.

Dissipation half-lives for chlorantraniliprole in cucumbers and courgettes were 5, 12, 3, 4, and 3 days for DuPont-18760 trials 1, 2, 3, 5, and 9, respectively.

All sets of data show an overall consistent residue profile when chlorantraniliprole is applied in accordance with GAP.

Recovery values for fresh control fortification run concurrently with treated samples in all the trials were within 75-104% (n = 18) for protected cucumbers and courgettes. All of the recoveries were within 70–110% and the relative standard deviations were <20% for all trials. Therefore, the analytical methods used performed well for the determination of chlorantraniliprole in treated crops.

CONCLUSION – EU PROTECTED EDIBLE-PEEL CUCURBIT TRIALS

Overall consistent residue behaviour of chlorantraniliprole on protected cucumbers and courgettes was found for one season of study in the EU, for application and sampling conducted according to GAP. Residues were less than or equal to 0.13 mg/kg at 1 DALA, the target PHI, or later sampling intervals, for protected cucumbers and courgettes. The residue data show that residues decline in protected cucumbers and courgettes with increasing DALA with dissipation half-lives of 5, 12, 3, 4, and 3 days.

The data generated from all 2006 residue trials will be considered as part of the EU protected edible-peel cucurbit residue population for further residue population comparison.

A 2.2.2.2.6 MELON

Report: Foster, A.C., Cairns, S.D., Hansford, R.J. (2007b); Magnitude and decline of DPX-E2Y45 residues in protected melons (fruiting vegetables, inedible-peel cucurbits) following foliar applications of DPX-E2Y45 35WG - Europe, 2006

DuPont Report No.: DuPont-18761

Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK

Testing Facility Report No.: 689687

GLP: Yes

Certifying Authority: Department of Health (UK)

MATERIALS AND METHODS

The field program was conducted in 2006. Four magnitude of residue and five normal decline melon trials were conducted, two in Spain, three in Italy, two in southern France and two in Greece. Chlorantraniliprole (DPX-E2Y45-206, 35WG formulation) was applied twice at the target rates 60.0 g ai/ha (4.0 g ai/hL) to protected melons for a seasonal application rate of 120.0 g ai/ha (119% maximum EU recommended rate of 100.8 g ai/ha/season). The applications of Chlorantraniliprole 35WG were made at 7-day intervals with the last application occurring at normal harvest, according to the use patterns described in Table 149 and sampling intervals described in Table 150. No surfactants or adjuvants were added to the applications. The targeted PHI under GAP is 1 day.

Table 149

Study Use Pattern – 2006 growing season

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol[c] (L/ha)	g ai/ha[d]	g ai/hL[e]	RTI[f] (days)	Total Rate (g as/ha)[d]		
Test 01 (Los Palacios y Villafranca, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 7 day DBH	1480	59.45	4.02	-	119.61	None	DuPont-18761
		Foliar Broadcast/ 0 day DBH	1501	60.16	4.01	7		None	
Test 02 (Casteldidone, Lombardia, Italy, 2006)	35WG	Foliar Broadcast/ 7 day DBH	1483	59.45	4.01	-	119.97	None	DuPont-18761
		Foliar Broadcast/ 0 day DBH	1510	60.52	4.01	7		None	
Test 03 (Lograto, Lombardia, Italy, 2006)	35WG	Foliar Broadcast/ 7 day DBH	1481	59.45	4.01	-	119.97	None	DuPont-18761
		Foliar Broadcast/ 0 day DBH	1509	60.52	4.01	7		None	
Test 04		Foliar Broadcast/ 8 day DBH	1519	60.52	3.98	-		None	

(Sanlucar de Barrameda, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 1 day DBH	1508	60.16	3.99	7	120.68	None	DuPont-18761
Test 05 (Pernes les Fontaines, Provence-Alpes-Côte d'Azur, S. France, 2006)	35WG	Foliar Broadcast/ 7 day DBH	1512	60.52	4.00	-	120.68	None	DuPont-18761
		Foliar Broadcast/ 0 day DBH	1496	60.16	4.02	7		None	
Test 06 (Profit-is, Central Macedonia, Greece, 2006)	35WG	Foliar Broadcast/ 7 day DBH	1506	60.42	4.01	-	119.04	None	DuPont-18761
		Foliar Broadcast/ 0 day DBH	1462	58.62	4.01	7		None	

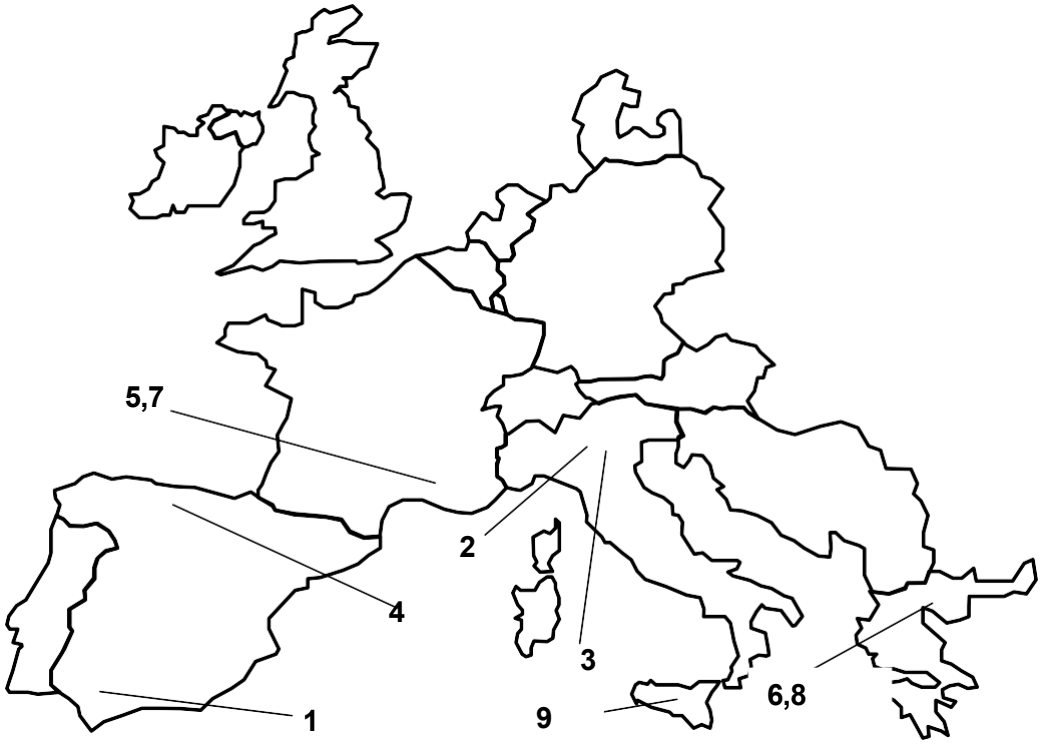
Table 149
Study Use Pattern – 2006 growing season (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol[c] (L/ha)	g ai/ha[d]	g ai/hL[e]	RTI[f] (days)	Total Rate (gas/ha)[d]		
Test 07 (Pernes les Fontaines, Provence-Alpes-Côte d'Azur, S. France, 2006)	35WG	Foliar Broadcast/ 7 day DBH	1510	60.16	3.98	-	120.68	None	DuPont-18761
		Foliar Broadcast/ 1 day DBH	1522	60.52	3.98	7		None	
Test 08 (Svoronos, Central Macedonia, Greece, 2006)	35WG	Foliar Broadcast/ 8 day DBH	1504	60.36	4.01	-	119.33	None	DuPont-18761
		Foliar Broadcast/ 1 day DBH	1469	58.97	4.01	7		None	
Test 09 (Contrada Pozzo Bollente, Sicily, Italy 2006)	35WG	Foliar Broadcast/ 8 day DBH	1455	58.01	3.99	-	118.42	None	DuPont-18761
		Foliar Broadcast/ 1 day DBH	1515	60.41	3.99	7		None	

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Liters/hectare
[d] grams active ingredient per hectare
[e] kg active substance/hL (kilogram active substance per hectoliter or 100 L)
[f] Retreatment IntervalA total of 5 decline and 4 magnitude of residue trials were conducted in the growing season of 2006. A summary of these protected melon studies is given below. Locations of the protected melon trial sites are given in Figure 24.

Figure 24

Map: Chlorantraniliprole EU protected melons (fruiting vegetables, inedible-peel cucurbits) trial sites



Reference, Test No.	Location
DuPont-18761, 1	Los Palacios y Villafranca, Andalucia, Spain
DuPont-18761, 2	Casteldidone, Lombardia, Italy
DuPont-18761, 3	Lograto, Lombardia, Italy
DuPont-18761, 4	Sanlucar de Barrameda, Andalucia, Spain
DuPont-18761, 5	Pernes les Fontaines, Provence-Alpes-Côte d'Azur, France (south)
DuPont-18761, 6	Profitis, Central Macedonia, Greece
DuPont-18761, 7	Pernes les Fontaines, Provence-Alpes-Côte d'Azur , France (south)
DuPont-18761, 8	Svoronos, Central Macedonia, Greece
DuPont-18761, 9	Contrada Pozzo Bollente, Sicily, Italy

A protected melon residue data summary (in mg/kg) is presented in Table 150 and Table 151.

To generate these data, the following analysis and recovery information pertains.

Analysis method: LC-MS/MS method (DuPont-13295) developed as the chlorantraniliprole residue method for determining residues of chlorantraniliprole in/on crops.

Analyte:	Chlorantraniliprole
Extraction:	Analyte extracted from crop matrices with acetonitrile following water presoak.
Clean-up:	SAX (Strong Anion Exchange) and HLB (Hydrophilic Lipophilic Balanced) Solid Phase Extraction (SPE) cartridges
Chromatography:	LC

Detection:	Mass spectrometer detection (MS/MS) in APCI positive mode. Two ion transitions are acquired 284 m/z – 177 m/z and 484 m/z – 453 m/z. The former transition is used for quantification and the second transition for confirmation. In cases where a significant interference is detected in the former transition the latter transition may be used for quantification purposes
LOQ	0.010 mg/kg

Storage stability: All samples were analysed within 6 months of sampling. Chlorantraniliprole residues are stable in a variety of crops including predominantly water-, oil-, protein- and, starch-containing commodities as represented by fruits, a fruiting vegetable, a root crop, a non-oily grain, and an oilseed (apple, grape, tomato, leaf lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay, and ginned cottonseed) for at least 24 months when stored frozen at -20 ± 10°C (see Point IIA 6.1.1). Therefore, no degradation is expected to have occurred between harvest and analysis.

Table 150
Residues of chlorantraniliprole in protected melons
(fruiting vegetables, inedible-peel cucurbits) from 2006 EU supervised trials

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg) [c,d] (calculated)[e]			Ref
						Peel	Pulp	(whole)	
Test 01 (Los Palacios y Villafranca, Andalucia, Spain, 2006)	35WG	Melon / Nicolas	Peel Pulp	59.45	-0	0.029	nd	0.013	DuPont-18761
				119.61	+0	0.074	0.005	0.030	
					1	0.014	nd	0.007	
					7	0.048	nd	0.019	
					14	0.022	nd	0.010	
					21	0.020	nd	0.009	
Test 02 (Casteldidone, Lombardia, Italy, 2006)	35WG	Melon / Macigno	Peel Pulp	59.45	-0	0.016	nd	0.011	DuPont-18761
				119.97	+0	0.081	0.005	0.049	
					1	0.037	nd	0.021	
					7	0.091	nd	0.038	
					14	0.069	nd	0.032	
					21	0.018	nd	0.009	
Test 03 (Lograto, Lombardia, Italy, 2006)	35WG	Melon / Macigno	Peel Pulp	59.45	-0	0.016	nd	0.009	DuPont-18761
				119.97	+0	0.027	nd	0.015	
					1	0.058	nd	0.030	
					7	0.025	nd	0.013	
					14	0.048	nd	0.021	
					21	0.015	nd	0.009	
Test 04 (Sanlucar de Barrameda, Andalucia, Spain, 2006)	35WG	Melon / Siglo	Peel Pulp	120.68	1	0.091	nd	0.032	DuPont-18761
Test 05 (Pernes les Fontaines, Provence-Alpes-Côte d'Azur , S. France, 2006)	35WG	Melon / Anasta	Peel Pulp	60.52	-0	0.018	nd	0.011	DuPont-18761
				120.68	+0	0.016	nd	0.010	
					1	0.017	nd	0.009	
					8	0.021	nd	0.010	
					14	0.018	nd	0.010	
					21	0.013	nd	0.008	

Test 06 (Profitis, Central Macedonia, Greece, 2006)	35WG	Melon / Gallia F1	Peel Pulp	60.42	-0	0.028	nd	0.014	DuPont-18761
					+0	0.040	nd	0.025	
				119.04	1	0.080	nd	0.032	
					7	0.026	nd	0.016	
					14	0.043	nd	0.016	
					21	0.049	nd	0.028	
Test 07 (Pernes les Fontaines, Provence-Alpes-Côte d'Azur , S. France, 2006)	35WG	Melon / Cesar	Peel Pulp	120.68	1	0.15	nd	0.068	DuPont-18761

Table 150
Residues of chlorantraniliprole in protected melons (fruiting vegetables, inedible-peel cucurbits) from 2006 EU supervised trials (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg) [c,d] (calculated)[e]			Ref
						Peel	Pulp	(whole)	
Test 08 (Svoronos, Central Macedonia, Greece, 2006)	35WG	Melon / Gallia F1	Peel Pulp	119.33	1	0.054	nd	0.023	DuPont-18761
Test 09 (Contrada Pozzo Bollente, Sicily, Italy 2006)	35WG	Melon / Cabrero	Peel Pulp	118.42	1	0.039	nd	0.019	DuPont-18761

[a] EP = End-use Product
[b] DALA = Days after last application (Days between last application and sampling)
[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.
[d] Control specimens were collected and analyzed for the target 0 DALA (Tests 1-5) and 14 DALA (Tests 1-2) sampling dates. No detectable residues, nd, were found in all instances.
[e] For the whole commodity, residues were calculated from pulp and peel residue concentration and fraction weights: (mg/kg)whole = [(mg/kg)pulp + [(mg/kg)peel × (kg peel/kg pulp)]] / [1 + (kg peel/kg pulp)]

Table 151
Summary of residue data from protected melon trials with chlorantraniliprole

Commodity	EP[a]	Total Application Rate (g ai/ha)	DALA/ PHI (days)	Residue Levels in ppm (mg/kg)						
				n[b]	Min.[b]	Max.[b]	HAFT[b]	Median[b] (STMdR)	Mean[b] (STMR)	Std. Dev.[b]
Chlorantraniliprole										
Melon Peel	35WG	59.45–60.52	-0[c]	5	0.016	0.029	--	0.018	0.021	0.007
		118.42–120.68	+0	5	0.016	0.081	--	0.040	0.048	0.029
			1	9	0.014	0.15	--	0.054	0.060	0.042
			7-8	5	0.021	0.091	--	0.026	0.042	0.029
			14	5	0.018	0.069	--	0.043	0.040	0.021
			21	5	0.013	0.049	--	0.018	0.023	0.015

Melon Pulp	35WG	59.45–60.52	-0[c]	5	nd	nd	--	nd	nd	0.000
		118.42–120.68	+0	5	nd	0.005	--	nd	0.004	0.001
			1	9	nd	nd	--	nd	nd	0.000
			7-8	5	nd	nd	--	nd	nd	0.000
			14	5	nd	nd	--	nd	nd	0.000
			21	5	nd	nd	--	nd	nd	0.000
Melon, Whole	35WG	59.45–60.52	-0[c]	5	0.009	0.014	--	0.011	0.012	0.002
		118.42–120.68	+0	5	0.010	0.049	--	0.025	0.026	0.015
			1	9	0.007	0.068	--	0.023	0.027	0.018
			7-8	5	0.010	0.038	--	0.016	0.019	0.011
			14	5	0.010	0.032	--	0.016	0.018	0.009
			21	5	0.008	0.028	--	0.009	0.013	0.009

[a] EP = End-use Product
[b] N = number of individual specimens,
Min = minimum individual specimen residue,
Max = maximum individual specimen residue,
HAFT = Highest Average residue from one Field Test; (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set),
Median = median of individual specimen residues,
Mean = mean of individual specimen residues,
Std Dev = standard deviation of mean
[c] Shortly before the last application

Recovery data: Recovery data for fortifications run concurrently with the treated samples are given below to demonstrate the validity of the analytical method.

Table 152

Summary of concurrent recoveries of chlorantraniliprole from protected melons – DuPont-18761

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (CV) (% ± % (%))
Chlorantraniliprole				
Melon Peel	0.010 0.10 0.30	7 7 2	74, 75, 90, 99, 110, 107, 126 76, 76, 74, 75, 107, 105, 108 116[b], 121[b]	97 ± 19 (20) 89 ± 17 (19) 119
Overall	-	16	-	96 ± 19 (20)
Melon Pulp	0.010 0.10	8 8 (7)	94, 90, 95, 100, 101, 91, 89, 95 85, 88, 88, 105, 108, 1[a], 101, 119[b]	94 ± 4 (5) 99 ± 13 (13)
Overall	-	15 [a,b]	-	97 ± 9 (9)

Statistics were calculated using non-rounded recovery values
[a] Result excluded from calculations, suspected extraction error
[b] Result outside of 70-110% limits, but included in calculations

RESULTS AND DISCUSSION

The residue studies presented in the chlorantraniliprole dossier were carried out in four different EU countries and provide data relevant to conditions in the protected melon-growing regions of the EU.

All of the analytical work associated with the studies was performed at Charles River Laboratories, Tranent, EH33 2NE, Scotland in the autumn-winter of 2006.

In the EU, residues in protected whole melons were less than or equal to 0.068 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in the 9 residue trials conducted in 2006 in which chlorantraniliprole was applied at 117-120% maximum EU recommended rate of 100.8 g

ai/ha/season. No chlorantraniliprole residues were detected in melon pulp at 1 DALA, the target PHI, or later sampling intervals, in all trials.

Dissipation half-lives for chlorantraniliprole in whole melons were 24, 13, 23, 110, and 100 days, for

DuPont-18761 trials 1, 2, 3, 5, and 6, respectively.

All sets of data show an overall consistent residue profile when chlorantraniliprole is applied in accordance with GAP.

Recovery values for fresh control fortification run concurrently with treated samples in all the trials were within 74-126% (n = 16) for protected melon tomatoes. Approximately 75% or more of the recoveries were within 70-110% and the relative standard deviations were ≤20% for all trials. Therefore, the analytical methods used performed well for the determination of chlorantraniliprole in treated crops.

CONCLUSION – EU PROTECTED INEDIBLE-PEEL CUCURBIT TRIALS

Overall consistent residue behaviour of chlorantraniliprole on protected melons was found for one season of study in the EU, for application and sampling conducted according to GAP. Dissipation half-lives for chlorantraniliprole in whole melons were 24, 13, 23, 110, and 100 days.

Residues in protected whole melons were less than or equal to 0.068 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in the 9 residue trials conducted in 2006. No chlorantraniliprole residues were detected in melon pulp at 1 DALA, the target PHI, or later sampling intervals, in all trials.

The data generated from all 2006 residue trials will be considered as part of the EU protected inedible-peel cucurbit residue population for further residue population comparison

A 2.2.2.2.7 Pepper

Report: Foster, A.C., Cairns, S.D., Hunter, T.M. (2006a); Magnitude and decline of DPX-E2Y45 residues in field peppers (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2005

DuPont Report No.: DuPont-16579
Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC

Deviations: None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK
Testing Facility Report/Project No.: 687590
GLP: Yes
Certifying Authority: Department of Health (U.K.)

Report: Foster, A.C., Cairns, S.D. (2006a); Magnitude and decline of DPX-E2Y45 residues in field hot peppers (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Southern Europe, 2005

DuPont Report No.: DuPont-16585

Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK
Testing Facility Report/Project No.: 687611
GLP: Yes
Certifying Authority: Department of Health (UK)

Report: Foster, A.C., Cairns, S.D. (2007a); Magnitude and decline of DPX-E2Y45 residues in field peppers (fruiting vegetables, Solanacea) following foliar applications of DPX-E2Y45 35WG - southern Europe, 2006

DuPont Report No.: DuPont-18753
Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC. **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK
Testing Facility Report No.: 689619
GLP: Yes
Certifying Authority: Department of Health (U.K.)

Report: Foster, A.C., Cairns, S.D. (2007f); Magnitude and decline of DPX-E2Y45 residues in field hot peppers (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - southern Europe, 2006

DuPont Report No.: DuPont-18765
Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC. **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK
Testing Facility Report No.: 689734
GLP: Yes
Certifying Authority: Department of Health (UK)

MATERIALS AND METHODS

The first field program was conducted in 2005 at three locations in Spain, two locations in Greece and at two locations in Italy. Two magnitude of residue and five reverse decline field pepper, including hot pepper, trials

were conducted. Chlorantraniliprole (DPX-E2Y45-178, 35WG formulation) was applied twice by foliar application at the target rates of 35 g ai/ha (3.5 g ai/hL) to field peppers, including hot peppers, for a seasonal application rate of 70 g ai/ha (83% maximum EU recommended rate of 84 g ai/ha/season). The second field program was conducted in 2006 at three locations in Spain, two locations in Greece, and two locations in Italy. Two magnitude of residue (MOR) and five reverse decline field pepper, including hot pepper, trials were conducted. Chlorantraniliprole (DPX-E2Y45-206, 35WG formulation) was applied twice at the target rates 40.0 g ai/ha to field peppers, including hot peppers, for a seasonal application rate of 80.0 g ai/ha (95% maximum EU recommended rate of 84 g ai/ha/season).

The applications of Chlorantraniliprole 35WG were made at 7-day (±1) intervals, according to the use patterns described in Table 157 and Table 158 and sampling intervals described in Table 159 and Table 160. Specimens were harvested from the residue decline treated plots immediately before the last application (0 DBLA) and then

+0, 1, 10, 21, and 35 days (BBCH 62-89) after the last application (DALA) to the treated plots. No surfactants or adjuvants were added to the applications. The targeted PHI under GAP is 1 day.

Table 157

Study Use Pattern – 2005 growing season

Test Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, GPA[c] (L/ha)	Rate lb ai/A (g ai/ha)[d]	Rate g ai/hL[e]	RTI[f] Days	Total Rate lb ai/A (g ai/ha)[d]		
Test 01 (Huelva, Andalucia. Spain, 2005)	35WG	Foliar Broadcast/ 7 DBH	107 (1004)	0.031 (35.10)	3.50	--	0.063 (70.56)	None	DuPont-16579
		Foliar Broadcast/ 1 DBH	108 (1006)	0.032 (35.46)	3.52	6		None	
Test 02 (Profitis, Central Macedonia, Greece, 2005)	35WG	Foliar Broadcast/ 7 DBH	102 (957)	0.030 (33.61)	3.51	--	0.061 (68.22)	None	DuPont-16579
		Foliar Broadcast/ 1 DBH	106 (986)	0.031 (34.61)	3.51	6		None	

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Gallons (US) per acre (Litres/hectare)
[d] lb active ingredient per acre (grams active ingredient per hectare)
[e] g active substance/hL (gram active substance per hectolitre or 100 L)
[f] Retreatment Interval

Table 157

Study Use Pattern – 2005 growing season (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, GPA[c] (L/ha)	Rate lb ai/A (g ai/ha)[d]	Rate g ai/hL[e]	RTI[f] Days	Total Rate lb ai/A (g ai/ha)[d]		
Test 03 (Murello, Piemonte, Italy, 2005)	35WG	Foliar Broadcast/ 42 DBH	108.7 (1016)	0.032 (35.82)	3.53	--	0.063 (70.92)	None	
		Foliar Broadcast/ 36 DBH	106.5 (995)	0.031 (35.10)	3.53	6		None	
	35WG	Foliar Broadcast/ 29 DBH	109.0 (1019)	0.032 (35.82)	3.52	--	0.064 (71.28)	None	
		Foliar Broadcast/ 21 DBH	108.4 (1013)	0.032 (35.46)	3.50	8		None	
		Foliar Broadcast/ 16 DBH	106.9 (999)	0.031 (35.10)	3.51	--	0.063	None	

	35WG	Foliar Broadcast/ 10 DBH	110.6 (1034)	0.032 (36.18)	3.50	6	(71.28)	None	DuPont-16579
	35WG	Foliar Broad-cast/ 7 DBH	108.9 (1018)	0.032 (35.82)	3.52	--	0.064 (71.28)	None	
		Foliar Broad-cast/ 1 DBH	107.7 (1007)	0.032 (35.46)	3.52	6		None	
	35WG	Foliar Broad-cast/ 7 DBH	106.9 (999)	0.031 (35.10)	3.51	--	0.062 (70.20)	None	
		Foliar Broad-cast/ 0 DBH	107.2 (1002)	0.031 (35.10)	3.50	7		None	

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Gallons (US) per acre (Litres/hectare)
[d] lb active ingredient per acre (grams active ingredient per hectare)
[e] g active substance/hL (gram active substance per hectolitre or 100 L)
[f] Retreatment Interval

Table 157

Study Use Pattern – 2005 growing season (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, GPA[c] (L/ha)	Rate lb ai/A (g ai/ha)[d]	Rate g ai/hL[e]	RTI[f] Days	Total Rate lb ai/A (g ai/ha)[d]		
Test 04 (Poirino, Piemonte, Italy, 2005)	35WG	Foliar Broadcast/ 43 DBH	106.2 (993)	0.031 (34.75)	3.50	--	0.062 (69.5)	None	DuPont-16579
		Foliar Broadcast/ 36 DBH	105.9 (990)	0.031 (34.75)	3.51	7		None	
	35WG	Foliar Broadcast/ 28 DBH	109.5 (1023)	0.032 (35.82)	3.50	--	0.064 (72.0)	None	
		Foliar Broadcast/ 21 DBH	110.3 (1031)	0.032 (36.18)	3.51	7		None	
	35WG	Foliar Broadcast/ 17 DBH	109.5 (1023)	0.032 (35.82)	3.50	--	0.064 (71.28)	None	
		Foliar Broadcast/ 10 DBH	108.6 (1015)	0.032 (35.46)	3.49	7		None	
	35WG	Foliar Broad-cast/ 8 DBH	109.7 (1025)	0.032 (35.82)	3.49	--	0.062 (69.85)	None	

		Foliar Broad-cast/ 1 DBH	103.8 (970)	0.030 (34.03)	3.51	7		None	
	35WG	Foliar Broad-cast/ 7 DBH	109.0 (1019)	0.032 (35.82)	3.52	--	0.064 (71.28)	None	
		Foliar Broad-cast/ 0 DBH	107.7 (1007)	0.032 (35.46)	3.52	7		None	

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Gallons (US) per acre (Litres/hectare)
[d] lb active ingredient per acre (grams active ingredient per hectare)
[e] g active substance/hL (gram active substance per hectolitre or 100 L)
[f] Retreatment Interval

Table 157

Study Use Pattern – 2005 growing season (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, GPA[c] (L/ha)	Rate lb ai/A (g ai/ha)[d]	Rate g ai/hL[e]	RTI[f] Days	Total Rate lb ai/A (g ai/ha)[d]		
Test 05 (Cortes de Navarra, Navarra, Spain, 2005)	35WG	Foliar Broadcast/ 43 DBH	106.2 (993)	0.031 (34.75)	3.50	--	0.063 (70.57)	None	DuPont-16579
		Foliar Broadcast/ 36 DBH	109.6 (1024)	0.032 (35.82)	3.50	7		None	
	35WG	Foliar Broadcast/ 29 DBH	106.6 (996)	0.031 (35.1)	3.52	--	0.063 (70.56)	None	
		Foliar Broadcast/ 21 DBH	108.2 (1011)	0.032 (35.46)	3.51	8		None	
	35WG	Foliar Broadcast/ 18 DBH	110.3 (1031)	0.032 (36.18)	3.51	--	0.064 (71.64)	None	
		Foliar Broadcast/ 11 DBH	107.8 (1008)	0.032 (35.46)	3.52	7		None	
	35WG	Foliar Broadcast/ 8 DBH	108.1 (1010)	0.032 (35.46)	3.51	--	0.064 (70.92)	None	
		Foliar Broad-cast/ 1 DBH	108.3 (1012)	0.032 (35.46)	3.50	7		None	
		Foliar Broadcast/ 7 DBH	108.3 (1012)	0.032 (35.46)	3.50	--		None	

	35WG	Foliar Broad-cast/ 0 DBH	109.2 (1021)	0.032 (35.82)	3.51	7	0.064 (71.28)	None	

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Gallons (US) per acre (Litres/hectare)
[d] lb active ingredient per acre (grams active ingredient per hectare)
[e] g active substance/hL (gram active substance per hectolitre or 100 L)
[f] Retreatment Interval

Table 157

Study Use Pattern – 2005 growing season (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, GPA[c] (L/ha)	Rate lb ai/A (g ai/ha)[d]	Rate g ai/hL[e]	RTI[f] Days	Total Rate lb ai/A (g ai/ha)[d]		
Trial 01 (Profitis, Central Macedonia, Greece, 2005)	35WG	Foliar Broadcast/ 42 DBH	107.7 (1007)	0.032 (35.46)	3.52	--	0.063 (70.28)	None	DuPont-16585
		Foliar Broadcast/ 35 DBH	105.8 (989)	0.031 (34.82)	3.52	7		None	
	35WG	Foliar Broadcast/ 28 DBH	105.8 (989)	0.031 (34.82)	3.52	--	0.062 (70.00)	None	
		Foliar Broadcast/ 21 DBH	106.9 (999)	0.031 (35.18)	3.52	7		None	
	35WG	Foliar Broadcast/ 17 DBH	106.6 (996)	0.031 (35.08)	3.52	--	0.062 (69.90)	None	
		Foliar Broadcast/ 10 DBH	105.8 (989)	0.031 (34.82)	3.52	7		None	
	35WG	Foliar Broadcast/ 8 DBH	106.6 (996)	0.031 (35.08)	3.52	--	0.061 (69.06)	None	
		Foliar Broad-cast/ 1 DBH	103.2 (965)	0.030 (33.98)	3.52	7		None	
	35WG	Foliar Broadcast/ 7 DBH	108.0 (1009)	0.032 (35.53)	3.52	--	0.063 (69.98)	None	
		Foliar Broad-cast/ 0 DBH	104.6 (978)	0.031 (34.45)	3.52	7		None	

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Gallons (US) per acre (Litres/hectare)
[d] lb active ingredient per acre (grams active ingredient per hectare)
[e] g active substance/hL (gram active substance per hectolitre or 100 L)
[f] Retreatment Interval

Table 157

Study Use Pattern – 2005 growing season (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, GPA[c] (L/ha)	Rate lb ai/A (g ai/ha)[d]	Rate g ai/hL[e]	RTI[f] Days	Total Rate lb ai/A (g ai/ha)[d]		
Trial 02 (Alpicat, Lleida, Spain, 2005)	35WG	Foliar Broadcast/ 42 DBH	107.8 (1008)	0.032 (35.46)	3.52	--	0.063 (70.21)	None	DuPont-16585
		Foliar Broadcast/ 35 DBH	105.2 (983)	0.031 (34.75)	3.54	7		None	
	35WG	Foliar Broadcast/ 29 DBH	108.2 (1011)	0.032 (35.46)	3.51	--	0.064 (71.28)	None	
		Foliar Broadcast/ 22 DBH	108.5 (1014)	0.032 (35.82)	3.53	7		None	
	35WG	Foliar Broadcast/ 18 DBH	107.5 (1005)	0.032 (35.46)	3.53	--	0.063 (70.21)	None	
		Foliar Broadcast/ 11 DBH	105.6 (987)	0.031 (34.75)	3.52	7		None	
	35WG	Foliar Broadcast/ 8 DBH	108.1 (1010)	0.032 (35.46)	3.51	--	0.064 (71.28)	None	
		Foliar Broadcast/ 1 DBH	109.3 (1022)	0.032 (35.82)	3.50	7		None	
	35WG	Foliar Broadcast/ 7 DBH	108.4 (1013)	0.032 (35.82)	3.54	--	0.064 (71.64)	None	
		Foliar Broadcast/ 0 DBH	109.0 (1019)	0.032 (35.82)	3.52	7		None	

a EP = End-use Product
b DBH = Days before harvest
c Gallons (US) per acre (Litres/hectare)
d lb active ingredient per acre (grams active ingredient per hectare)
e g active substance/hL (gram active substance per hectolitre or 100 L)
f Retreatment Interval

Table 158
Study Use Pattern – 2006 growing season

Test Identifi-		Application		

cation (City, State/Region, Country, /Year)	EP[a]	Meth-od/ Tim-ing[b]	Vol (L/ha)	(g ai/ha)	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)	Tank Mix Adjuvants	Ref
Test 01 (Villalba del Alcor, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 40 day DBH	998	39.52	3.96	-	79.04	None	DuPont-18753
		Foliar Broadcast/ 33 day DBH	994	39.52	3.98	7		None	
	35WG	Foliar Broadcast/ 28 day DBH	968	38.45	3.97	-	77.97	None	DuPont-18753
		Foliar Broadcast/ 21 day DBH	998	39.52	3.96	7		None	
	35WG	Foliar Broadcast/ 16 day DBH	1006	39.87	3.96	-	79.39	None	DuPont-18753
		Foliar Broadcast/ 10 day DBH	997	39.52	3.96	6		None	
	35WG	Foliar Broadcast/ 7 day DBH	1006	39.87	3.96	-	79.74	None	DuPont-18753
		Foliar Broadcast/ 1 day DBH	1007	39.87	3.96	6		None	
	35WG	Foliar Broadcast/ 7 day DBH	999	39.87	3.99	-	79.74	None	DuPont-18753
		Foliar Broadcast/ 0 day DBH	1004	39.87	3.97	7		None	

Table 158
Study Use Pattern – 2006 growing season (continued)

Test Identifi-cation (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Meth-od/ Tim-ing[b]	Vol (L/ha)	(g ai/ha)	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 02 (Poirino, Pie-monte, Italy, 2006)	35WG	Foliar Broadcast/ 43 day DBH	996	39.52	3.97	-	79.75	None	DuPont-18753
		Foliar Broad-cast/ 36 day DBH	1013	40.23	3.97	7		None	
	35WG	Foliar Broad-cast/ 29 day DBH	1023	40.58	3.97	-	80.10	None	DuPont-

		Foliar Broad-cast/ 22 day DBH	997	39.52	3.96	7		None	18753
	35WG	Foliar Broadcast/ 17 day DBH	1005	39.87	3.97	-	79.74	None	DuPont-18753
		Foliar Broad-cast/ 10 day DBH	1005	39.87	3.97	7		None	
	35WG	Foliar Broad-cast/ 8 day DBH	1028	40.94	3.98	-	81.17	None	DuPont-18753
		Foliar Broadcast/ 1 day DBH	1012	40.23	3.98	7		None	
	35WG	Foliar Broadcast/ 8 day DBH	998	39.52	3.96	-	80.10	None	DuPont-18753
		Foliar Broad-cast/ 0 day DBH	1018	40.58	3.99	8		None	
Test 03 (Villalba del Alcor, Andalucia, Spain, 2006)	35WG	Foliar Broad-cast/ 8 day DBH	1008	40.23	3.99	-	80.10	None	DuPont-18753
		Foliar Broadcast/ 1 day DBH	1003	39.87	3.98	7		None	
Test 04 (Profitis, Central Macedonia, Greece, 2006)	35WG	Foliar Broad-cast/ 7 day DBH	989	39.30	3.98	-	78.29	None	DuPont-18753
		Foliar Broad-cast/ 1 day DBH	981	38.99	3.98	6		None	

Table 158
Study Use Pattern – 2006 growing season (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate g ai/ha		
Test 01 (Los Palacios y Villafranca, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 42 day DBH	1008	40.23	3.99	-	80.46	None	DuPont-18765
		Foliar Broadcast/ 35 day DBH	1009	40.23	3.99	7		None	
	35WG	Foliar Broadcast/ 28 day DBH	1008	40.23	3.99	-	79.39	None	DuPont-18765
		Foliar Broadcast/ 21 day DBH	983	39.16	3.98	7		None	
		Foliar Broadcast/	1018	40.58	3.99	-		None	

	35WG	17 day DBH Foliar Broadcast/ 10 day DBH	1012	40.23	3.98	7	80.81	None	DuPont-18765
	35WG	Foliar Broadcast/ 8 day DBH Foliar Broadcast/ 1 day DBH	1008 1015	40.23 40.23	3.99 3.96	- 7	80.46	None None	DuPont-18765
	35WG	Foliar Broadcast/ 7 day DBH Foliar Broadcast/ 0 day DBH	1004 999	39.87 39.87	3.97 3.99	- 7	79.74	None None	DuPont-18765
Test 2 (Nea Magnisia, Thessaloniki, Greece, 2006)	35WG	Foliar Broadcast/ 42 day DBH Foliar Broadcast/ 36 day DBH	1017 1008	40.42 40.07	3.98 3.98	- 6	80.49	None None	DuPont-18765
	35WG	Foliar Broadcast/ 29 day DBH Foliar Broadcast/ 21 day DBH	1012 1007	40.23 40.02	3.98 3.98	- 8	80.25	None None	DuPont-18765
	35WG	Foliar Broadcast/ 17 day DBH Foliar Broadcast/ 10 day DBH	1005 1010	39.96 40.15	3.97 3.98	- 7	80.11	None None	DuPont-18765
	35WG	Foliar Broadcast/ 8 day DBH Foliar Broadcast/ 1 day DBH	968 997	38.48 39.65	3.98 3.98	- 7	78.13	None None	DuPont-18765
	35WG	Foliar Broadcast/ 7 day DBH Foliar Broadcast/ 0 day DBH	1012 1010	40.23 40.15	3.98 3.98	- 7	80.38	None None	DuPont-18765

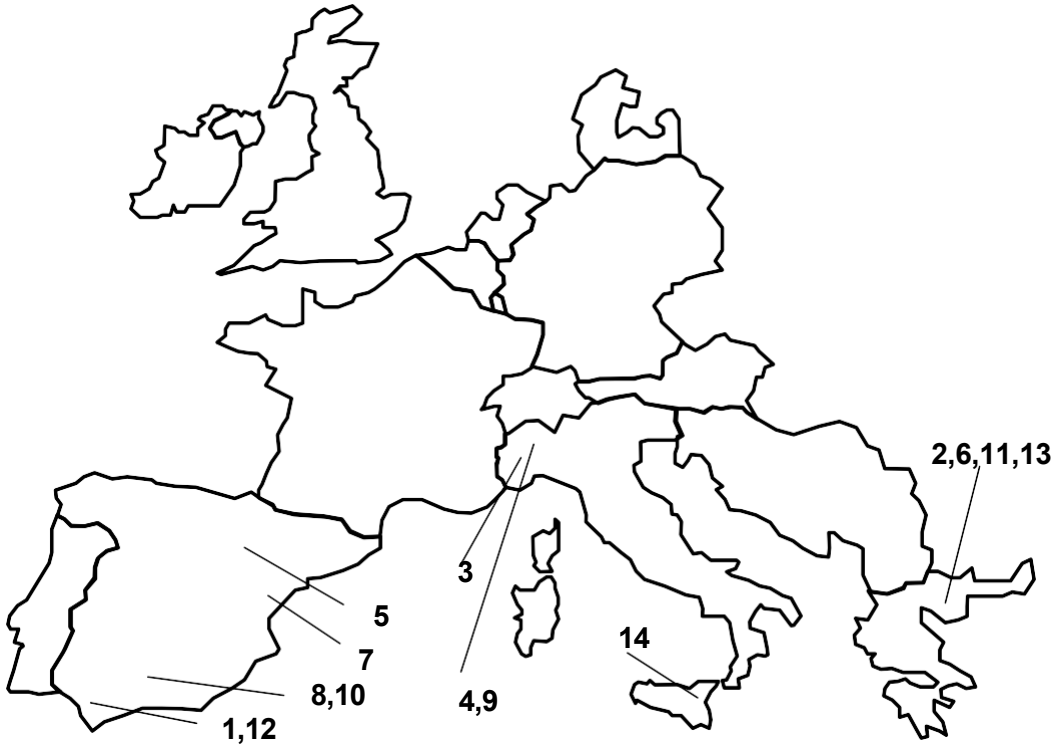
Table 158
Study Use Pattern – 2006 growing season (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate g ai/ha		
Test 03 (Contrada Gelso Bianco, Catania, Sicily, Italy, 2006)	35WG	Foliar Broadcast/ 42 day DBH	964	38.34	3.98	-	77.56	None	DuPont-18765
		Foliar Broadcast/ 35 day DBH	987	39.22	3.97	7		None	
	35WG	Foliar Broadcast/ 28 day DBH	1000	39.75	3.98	-	78.80	None	DuPont-18765
		Foliar Broadcast/ 21 day DBH	982	39.05	3.98	7		None	
	35WG	Foliar Broadcast/ 17 day DBH	971	38.6	3.97	-	77.65	None	DuPont-18765
		Foliar Broadcast/ 10 day DBH	982	39.05	3.98	7		None	
	35WG	Foliar Broadcast/ 8 day DBH	991	39.40	3.98	-	78.45	None	DuPont-18765
		Foliar Broadcast/ 1 day DBH	982	39.05	3.98	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	1009	40.11	3.98	-	81.45	None	DuPont-18765
		Foliar Broadcast/ 0 day DBH	1040	41.34	3.98	7		None	

[a] P = End-use Product
[b] DBH = Days before harvest
[c] Retreatment Interva

A total of 4 magnitude of residue trials and 10 reverse decline trials (all in the southern EU) were conducted in the growing seasons of 2005 and 2006. A summary of these field pepper trials is given below. Locations of the field pepper trial sites are given in Figure 26.

Figure 26
Map: Chlorantraniliprole southern EU field peppers (fruiting vegetables, solanacea) trial sites



Map No.	Reference, Trial No.	Location
1	DuPont-16579, 1	Huelva, 21860, Andalucia, Spain
2	DuPont-16579, 2	Profitis, GR 57200, Central Macedonia, Greece
3	DuPont-16579, 3	Murello, 12030, Piemonte, Italy
4	DuPont-16579, 4	Poirino, 10046, Piemonte, Italy
5	DuPont-16579, 5	Navarra, 31530, Spain
6	DuPont-16585, 1	Profitis, Central Macedonia, Greece
7	DuPont-16585, 2	Alpicat, Lleida, Spain
8	DuPont-18753, 1	Villalba del Alcor, Andalucia, Spain
9	DuPont-18753, 2	Poirino, Piemonte, Italy
10	DuPont-18753, 3	Villalba del Alcor, Andalucia, Spain
11	DuPont-18753, 4	Profitis, Central Macedonia, Greece
12	DuPont-18765, 1	Los Palacios y Villafranca, Andalucia, Spain
13	DuPont-18765, 2	Nea Magnisia, Thessaloniki, Central Macedonia, Greece
14	DuPont-18765, 3	Contrada Gelso Bianco, Catania, Sicily, Italy

A field pepper, including hot pepper, residue data summary (in mg/kg) is presented in Table 159, Table 160, and Table 161. To generate these data, the following analysis information pertains.

Analysis method: LC-MS/MS method (DuPont-13295) developed as the chlorantraniliprole residue method for determining residues of chlorantraniliprole in/on crops.

Analyte: Chlorantraniliprole

Extraction: Analyte extracted from crop matrices with acetonitrile following water pre-soak.

Clean-up: SAX (Strong Anion Exchange) and HLB (Hydrophilic Lipophilic Balanced) Solid Phase Extraction (SPE) cartridges

Chromatography: LC

Detection: Mass spectrometer detection (MS/MS) in APCI positive ion mode. Two ion transitions are acquired 284 m/z → 177 m/z and 484 m/z → 453 m/z. The former transition is used for quantification and the second transition for confirmation. In cases where a significant interference is detected in the former transition the latter transition may be used for quantification purposes.

LOQ: 0.010 mg/kg

Storage stability: All samples were analysed within 7 months of sampling. Chlorantraniliprole residues are stable in a variety of crops including predominantly water-, oil-, protein-, and starch-containing commodities as represented by fruits, a fruiting vegetable, a root crop, a non-oily grain, and an oilseed (apple, grape, tomato, leaf lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay, and ginned cottonseed) for at least 24 months when stored frozen at -20 ± 10°C (see Point IIA 6.1.1 of this document). Therefore, no degradation is expected to have occurred between harvest and analysis.

Table 159
Residues of chlorantraniliprole in field peppers (fruiting vegetables, solanacea) from 2005 EU supervised trials

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate lb ai/A (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c,d]	Ref
Test 01 (Huelva, Andalucia. Spain, 2005)	35WG	Field Pepper/ Palermo	Whole Fruit	0.063 (70.56)	1	0.022	DuPont-16579
Test 02 (Profitis, Central Macedonia, Greece, 2005)	35WG	Field Pepper/ Astor	Whole Fruit	0.061 (68.22)	1	0.037	DuPont-16579
Test 03 (Murello, Piemonte, Italy, 2005)	35WG	Field Pepper/ Quadrato Di Cuneo	Whole Fruit	0.062 (70.20)	(-1 h) (+1 h)	nd 0.014	DuPont-16579
				0.064 (71.28)	1	0.019	
				0.063 (71.28)	10	0.009	
				0.064 (71.28)	21	0.008	
				0.063 (70.92)	36	nd	
Test 04 (Poirino, Piemonte, Italy, 2005)	35WG	Field Pepper/ Lungo	Whole Fruit	0.064 (71.28)	(-1 h) (+2 h)	nd 0.028	DuPont-16579
				0.062 (69.85)	1	0.025	
				0.064 (71.28)	10	0.004	
				0.064 (72.00)	21	nd	

				0.062 (69.50)	36	nd	
Test 05 (Cortes de Navarra, Navarra, Spain, 2005)	35WG	Field Pepper/ California	Whole Fruit	0.064 (71.28)	(-1 h) (+2 h)	0.014 0.059	DuPont-16579
				0.064 (70.92)	1	0.066	
				0.064 (71.64)	11	0.060	
				0.063 (70.56)	21	0.020	
				0.063 (70.57)	36	0.026	

Table 159
Residues of chlorantraniliprole in field peppers (fruiting vegetables, solanacea) from 2005 EU supervised trials (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate lb ai/A (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c,d]	Ref
Trial 01 (Profitis, Central Macedonia, Greece, 2005)	35WG	Field Hot Pepper/ Local Magnisias	Whole Fruit	0.063 (69.98)	(-1 h) (+2h)	0.027 0.15	DuPont-16585
				0.061 (69.06)	1	0.13	
				0.062 (69.90)	10	0.032	
				0.062 (70.00)	21	0.036	
				0.063 (70.28)	35	0.028	
Trial 02 (Alpicat, Lleida, Spain, 2005)	35WG	Field Hot Pepper/ Guindilla roja riojana	Whole Fruit	0.064 (71.64)	(-1 h) (+2 h)	0.048 0.16	DuPont-16585
				0.064 (71.28)	1	0.20	
				0.063 (70.21)	11	0.070	
				0.064 (71.28)	22	0.059	
				0.063 (70.21)	35	0.019	

[a] EP = End-use Product
[b] DALA = Days after last application (days between last application and sampling)
[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues. For each decline trial, the highest residue value for any sample collected at the target PHI or later is underlined.
[d] Control specimens were collected and analyzed for the target 0 DALA sampling date. No detectable residues, nd, were found in all instances.

Table 160
Residues of chlorantraniliprole in field peppers (fruiting vegetables, solanacea) from 2006 EU supervised trials

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c,d]	Ref
Test 01 (Villalba del Alcor, Andalucia, Spain, 2006)	35WG	Pepper / Infante	Whole Fruit	39.87	(-1 h)	0.006	DuPont-18753
				79.74	(+2 h)	0.007	
				79.74	1	0.009	
				79.39	10	0.018	
				77.97	21	nd	
				79.04	33	nd	
Test 02 (Poirino, Piemonte, Italy, 2006)	35WG	Pepper / Corne di Bue	Whole Fruit	39.52	(-1 h)	0.023	DuPont-18753
				80.10	(+1 h)	0.044	
				81.17	1	0.049	
				79.74	10	0.010	
				80.10	22	nd	
				79.75	36	nd	
Test 03 (Villalba del Alcor, Andalucia, Spain, 2006)	35WG	Pepper / Italico	Whole Fruit	80.10	1	0.020	DuPont-18753
Test 04 (Profitis, Central Macedonia, Greece, 2006)	35WG	Pepper/ Stabilo	Whole Fruit	78.29	1	0.15	DuPont-18753
Test 01 (Los Palacios y Villafranca, Andalucia, Spain, 2006)	35WG	Field Hot Pepper/ Flame Flare	Whole Fruit	39.87	(-1 h)	0.014	DuPont-18765
				79.74	(+1 h)	0.16	
				80.46	1	0.11	
				80.81	10	0.056	
				79.39	21	0.040	
				80.46	35	0.018	
Test 02 (Nea Magnisia, Thessaloniki, Greece, 2006)	35WG	Field Hot Pepper/ Local Magnisias	Whole Fruit	40.23	(-1 h)	0.088	DuPont-18765
				80.38	(+2 h)	0.14	
				78.13	1	0.089	
				80.11	10	0.079	
				80.25	21	0.031	
				80.49	36	nd	

Table 160
Residues of chlorantraniliprole in field peppers (fruiting vegetables, solanacea) from 2006 EU supervised trials (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c,d]	Ref
[illegible]				40.11	(-1 h)	0.058	

trada Gelso Bianco, Catania, Sicily, Italy, 2006)	35WG	Field Hot Pepper/ Piros	Whole Fruit	81.45	(+2 h)	0.11	DuPont-18765
				78.45	1	0.18	
				77.65	10	0.10	
				78.80	21	0.060	
				77.56	35	0.009	

[a] EP = End-use Product
[b] DALA = Days after last application (Days between last application and sampling)
[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.
[d] Control specimens were collected and analyzed for the target 0 DALA sampling date. No detectable residues, nd, were found in all instances.

Table 161

Summary of residue data from EU field pepper trials with chlorantraniliprole

Commodity	EP[a]	Total Application Rate (g ai/ha)	DALA/PHI (days)	Residue Levels in ppm (mg/kg)						
				n[b]	Min.[b]	Max.[b]	HAFT[b]	Median[b] (STMdR)	Mean[b] (STMR)	Std. Dev.[b]
Chlorantraniliprole										
Field peppers, excluding hot peppers	35WG	68.22-81.45	-0[c]	5	nd[d]	0.023	0.023	0.006	0.010	0.008
			0	5	0.007	0.059	0.059	0.028	0.030	0.021
			1	9	0.009	0.15	0.15	0.025	0.044	0.043
			10-11	5	0.004	0.060	0.060	0.010	0.020	0.023
			21-22	5	nd	0.020	0.020	nd	0.008	0.007
			33-36	5	nd	0.026	0.026	nd	0.008	0.010
Field hot peppers			-0[c]	5	0.014	0.088	0.088	0.048	0.047	0.029
			0	5	0.11	0.16	0.16	0.15	0.14	0.021
			1	5	0.089	0.20	0.20	0.13	0.14	0.047
			10-11	5	0.032	0.10	0.10	0.070	0.067	0.025
			21-22	5	0.031	0.060	0.060	0.040	0.045	0.013
			33-36	5	nd	0.028	0.028	0.018	0.016	0.009

[a] EP = End-use Product
[b] N = number of individual specimens,
Min = minimum individual specimen residue,
Max = maximum individual specimen residue,
HAFT = Highest Average residue from one Field Test; (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set),
Median = median of individual specimen residues,
Mean = mean of individual specimen residues,
Std Dev = standard deviation of mean
[c] Shortly before the last application
[d] Residues of nd (not detectable) were considered to be the LOD (0.004 mg/kg) for mean and median calculations.

Recovery data: Recovery data for fortifications run concurrently with the treated samples are given below to demonstrate the validity of the analytical method.

Table 162
Summary of concurrent recoveries of chlorantraniliprole from field peppers – DuPont-16579 (2005 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (rsd) (% ± % (%))
Concurrent Fortifications – Chlorantraniliprole				
Field pepper fruit	0.010 0.10	6 6	87, 89, 99, 91, 116, 89 86, 79, 79, 84, 93, 93	95 ± 11 (12) 86 ± 6.4 (7.5)
Overall	-	-	-	90 ± 9.9 (11)

Table 163
Summary of concurrent recoveries of chlorantraniliprole from field hot peppers – DuPont-16585 (2005 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (% ± %)
Concurrent Fortifications – Chlorantraniliprole				
Field hot pepper fruit	0.010 0.10 0.30	2 2 2	78, 73 77, 71 89, 87	76 74 88
Overall	-	-	-	79 ± 7.5 (9.4)

Table 164
Summary of concurrent recoveries of chlorantraniliprole from field peppers – DuPont-18753 (2006 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (% ± % (%))
Chlorantraniliprole				
Field pepper fruit	0.010 0.10 0.20	4 4 2	82, 73, 101, 111 91, 89, 107, 96 104, 102	92 ± 18 (19) 96 ± 8 (8) 103
Overall	-	10	-	96 ± 12 (13)

Table 165
Summary of concurrent recoveries of chlorantraniliprole from field hot peppers – DuPont-18765 (2006 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	(RSD) (% ± % (%))
Chlorantraniliprole				
Field Hot Pepper Fruit	0.010 0.10 0.30	3 3 2	86%, 74%, 82% 78%, 72%, 85% 87%, 88%	81 ± 6 (8) 78 ± 6 (8) 87 ± 1 (1)
Overall	-	8		81 ± 6 (7)

RESULTS AND DISCUSSION

The residue studies presented herein were carried out in three different EU countries in the 2005 and 2006 growing seasons and provide data relevant to conditions in the field pepper-, including hot pepper-, growing regions of the southern EU.

All of the analytical work associated with the studies was performed at Charles River Laboratories, Tranent, EH33 2NE, Scotland in the winters of 2005 and 2006-7 for the 2005 and 2006 growing seasons, respectively.

In the southern EU, residues in field peppers, excluding hot peppers, were less than or equal to 0.15 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in nine trials conducted in 2005 and 2006 in which

Chlorantraniliprole 35WG was applied at 81-97% of the EU maximum GAP rate of 84 g ai/ha/season. Residues in field hot peppers were slightly higher, up to 0.20 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in five trials conducted in 2005 and 2006 in which Chlorantraniliprole 35WG was applied at 81-97% of the EU maximum GAP rate of 84 g ai/ha/season. Dissipation half-lives for chlorantraniliprole in field peppers, including hot peppers, were 19, 3, 23, 15, 11, 46, 7, 12, 8 and 9 days for DuPont-16579, trials 3, 4, and

5; DuPont-16585, trials 1 and 2; DuPont-18753 trials 1 and 2; and DuPont-18765 trials 1, 2 and 3, respectively. There does not seem to be any correlation between pepper variety (bell versus hot) and the dissipation rate.

All trials show an overall consistent residue profile when chlorantraniliprole is applied in accordance with GAP.

Recovery values for fresh control fortifications run concurrently with treated samples in all the trials were within 72-111% (n = 36) for field peppers, including hot peppers. Approximately 75% or more of the recoveries were within 70–110% and the relative standard deviations were less than 20% for all trials. Therefore, the analytical methods used performed well for the determination of chlorantraniliprole in treated crops.

CONCLUSION – EU FIELD-GROWN PEPPER TRIALS

Overall consistent residue behaviour of chlorantraniliprole on field-grown peppers, including hot peppers, was found for two seasons of study in the EU, for application and sampling conducted according to GAP. In the southern EU, residues in field peppers, excluding hot peppers, were less than or equal to 0.15 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in nine trials conducted in 2005 and 2006 in which Chlorantraniliprole 35WG was applied. Residues in field hot peppers were slightly higher, up to 0.20 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in five trials conducted in 2005 and 2006 in which Chlorantraniliprole 35WG was applied. The residue data show that residues decline in field peppers, including hot peppers, with increasing DALA with dissipation half-lives of 19, 3, 23, 15, 11, 46, 7, 12, 8 and 9 days. There does not seem to be any correlation between pepper variety (bell versus hot) and the dissipation rate.

The data generated from all 2005 and 2006 field trials will be considered as part of the EU field-grown pepper residue population for further residue population comparison.

Report: Foster, A.C., Cairns, S.D. (2006b); Magnitude and decline of DPX-E2Y45 residues in protected peppers (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2005

DuPont Report No.: DuPont-16580
Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK
Testing Facility Report/Project No.: 687627

GLP: Yes
Certifying Authority: Department of Health (U.K.)

Report: Foster, A.C., Cairns, S.D., Hunter, T.M. (2006b); Magnitude and decline of DPX-E2Y45 residues in protected hot peppers *Capsicum fructescens* (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2005

DuPont Report No.: DuPont-16586
Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK
Testing Facility Report/Project No.: 687606
GLP: Yes
Certifying Authority: Department of Health (U.K.)

Report: Foster, A.C., Cairns, S.D. (2007b); Magnitude and decline of DPX-E2Y45 residues in protected peppers (fruiting vegetables, Solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2006

DuPont Report No.: DuPont-18754
Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC. **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK
Testing Facility Report No.: 689624
GLP: Yes
Certifying Authority: Department of Health (U.K.)

Report: Foster, A.C., Cairns, S.D. (2007e); Magnitude and decline of DPX-E2Y45 residues in protected hot peppers (fruiting vegetables, Solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2006

DuPont Report No.: DuPont-18757
Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC. **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK
Testing Facility Report No.: 689713
GLP: Yes
Certifying Authority: Department of Health (U.K.)

MATERIALS AND METHODS

The field program was conducted in 2005 and 2006 at four locations in Spain, three locations in Greece, three locations in the Netherlands, three locations in France, and one location in Italy. Four magnitude of residue protected pepper trials and ten reverse decline protected pepper, including hot pepper, trials were conducted. In the first season, chlorantraniliprole (DPX-E2Y45-178, 35WG formulation) was applied twice by foliar application at the target rates of 3.5 g ai/hL (35 g ai/ha) to protected peppers, including hot peppers, for a seasonal application rate of 70 g ai/ha (80% maximum EU recommended rate of 87.5 g ai/ha/season). In the second season chlorantraniliprole (DPX-E2Y45-206, 35WG formulation) was applied twice at the target rates

43.75 g ai/ha (3.5 g ai/hL) to protected peppers, including hot peppers, for a seasonal application rate of

87.5 g ai/ha (100% maximum EU recommended rate). The applications of Chlorantraniliprole 35WG were made at 5-8-day intervals, according to the use patterns described in Table 166 and Table 167 and sampling intervals described in Table 168 and Table 169. Specimens were harvested from the

residue decline treated plots immediately before the last application (0 DBLA) and then +0, 1, 10, 21, and 35 days (BBCH 62-89) after the last application (DALA) to the treated plots. No surfactants or adjuvants were added to the applications. The targeted PHI under GAP is 1 day.

Table 166

Study Use Pattern for first season (2005-6 growing season)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol, GPA[c] (L/ha)	Rate lb ai/A (g ai/ha)[d]	Rate g ai/hL[e]	RTI[f] Days	Total Rate lb ai/A (g ai/ha)[d]		
Trial 01 (Los Palacios, Andalucia, Spain, 2005)	35WG	Foliar Broadcast/ 8 DBH	108 (1007)	0.032 (35.46)	3.52	--	0.064 (70.92)	None	DuPont-16580
		Foliar Broadcast/ 1 DBH	107 (1004)	0.032 (35.46)	3.53	7		None	
Trial 02 (Belfeld, Limburg, The Netherlands, 2005)	35WG	Foliar Broadcast/ 8 DBH	108 (1010)	0.032 (35.59)	3.52	--	0.063 (70.45)	None	DuPont-16580
		Foliar Broadcast/ 1 DBH	106 (990)	0.031 (34.86)	3.52	7		None	
Trial 03 (Meterik, Limburg, The Netherlands, 2005)	35WG	Foliar Broadcast/ 42 DBH	109 (1015)	0.032 (35.76)	3.52	--	0.063 (69.92)	None	DuPont-16580
		Foliar Broadcast/ 35 DBH	104 (970)	0.031 (34.16)	3.52	7		None	
	35WG	Foliar Broadcast/ 28 DBH	110 (1030)	0.032 (36.29)	3.52	--	0.063 (71.51)	None	
		Foliar Broadcast/ 21 DBH	107 (1000)	0.031 (35.22)	3.52	7		None	
	35WG	Foliar Broadcast/ 17 DBH	110 (1030)	0.032 (36.29)	3.52	--	0.064 (72.05)	None	
		Foliar Broadcast/ 10 DBH	109 (1015)	0.032 (35.76)	3.52	7		None	
	35WG	Foliar Broadcast/ 8 DBH	110 (1030)	0.032 (36.29)	3.52	--	0.064 (72.05)	None	
		Foliar Broadcast/ 1 DBH	109 (1015)	0.032 (35.76)	3.52	7		None	
	35WG	Foliar Broadcast/ 8 DBH	105 (985)	0.031 (34.69)	3.52	--	0.062 (69.38)	None	
		Foliar Broadcast/ 0 DBH	105 (985)	0.031 (34.69)	3.52	8		None	

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Gallons (US) per acre (Litres/hectare)
[d] lb active ingredient per acre (grams active ingredient per hectare)
[e] g active substance/hL (gram active substance per hectolitre or 100 L)
[f] Retreatment Interval

Table 166

Study Use Pattern for first season (2005-6 growing season) (continued)

Trial Identifi-		Application		

cation (City, State/Region, Country, Year)	EP[a]	Method/Timing[b]	Vol, GPA[c] (L/ha)	Rate lb ai/A (g ai/ha)[d]	Rate g ai/hL[e]	RTI[f] Days	Total Rate lb ai/A (g ai/ha)[d]	Tank Mix Adjuvants	Ref
Trial 04 (Pact, Rhône-Alpes, France, 2005)	35WG	Foliar Broadcast/ 42 DBH	106 (994)	0.031 (34.75)	3.50	--	0.063 (70.21)	None	DuPont-16580
		Foliar Broadcast/ 35 DBH	108 (1014)	0.032 (35.46)	3.50	7		None	
	35WG	Foliar Broadcast/ 28 DBH	108 (1005)	0.031 (35.10)	3.49	--	0.062 (70.20)	None	
		Foliar Broadcast/ 21 DBH	107 (1001)	0.031 (35.10)	3.51	7		None	
	35WG	Foliar Broadcast/ 17 DBH	108 (1006)	0.031 (35.10)	3.49	--	0.061 (68.77)	None	
		Foliar Broadcast/ 10 DBH	103 (965)	0.030 (33.67)	3.49	7		None	
	35WG	Foliar Broadcast/ 8 DBH	110 (1026)	0.032 (35.82)	3.49	--	0.064 (71.28)	None	
		Foliar Broadcast/ 1 DBH	109 (1017)	0.032 (35.46)	3.49	7		None	
	35WG	Foliar Broadcast/ 7 DBH	108 (1010)	0.032 (35.46)	3.51	--	0.064 (71.28)	None	
		Foliar Broadcast/ 0 DBH	110 (1024)	0.032 (35.82)	3.50	7		None	
Trial 05 (Profitis, Central Macedonia, Greece, 2005)	35WG	Foliar Broadcast/ 42 DBH	103 (961)	0.030 (33.84)	3.52	--	0.062 (69.13)	None	DuPont-16580
		Foliar Broadcast/ 35 DBH	107 (1002)	0.032 (35.29)	3.52	7		None	
	35WG	Foliar Broadcast/ 28 DBH	106 (988)	0.031 (34.82)	3.52	--	0.063 (70.21)	None	
		Foliar Broadcast/ 21 DBH	108 (1005)	0.032 (35.39)	3.52	7		None	
	35WG	Foliar Broadcast/ 17 DBH	104 (976)	0.031 (34.38)	3.52	--	0.063 (70.62)	None	
		Foliar Broadcast/ 10 DBH	110 (1029)	0.032 (36.24)	3.52	7		None	
	35WG	Foliar Broadcast/ 8 DBH	102 (954)	0.030 (33.60)	3.52	--	0.063 (70.28)	None	
		Foliar Broadcast/ 1 DBH	111 (1041)	0.033 (36.68)	3.52	7		None	
	35WG	Foliar Broadcast/ 7 DBH	108 (1010)	0.032 (35.56)	3.52	--	0.065 (71.97)	None	
		Foliar Broadcast/ 0 DBH	111 (1034)	0.033 (36.41)	3.52	7		None	

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Gallons (US) per acre (Litres/hectare)
[d] lb active ingredient per acre (grams active ingredient per hectare)
[e] g active substance/hL (gram active substance per hectolitre or 100 L)
[f] Retreatment Interval

Table 166

Study Use Pattern for first season (2005-6 growing season) (continued)

Trial Identifi-		Application		

cation (City, State/Region, Country, Year)	EP[a]	Method/Timing[b]	Vol, GPA[c] (L/ha)	Rate lb ai/A (g ai/ha)[d]	Rate g ai/hL[e]	RTI[f] Days	Total Rate lb ai/A (g ai/ha)[d]	Tank Mix Adjuvants	Ref
Trial 01 Los Palacios y Villafranca, Andalucia, Spain, 2006	35WG	Foliar Broadcast/ 41 DBH	109.2 (1021)	0.032 (35.50)	3.48	--	0.063 (71.00)	None	DuPont-16586
		Foliar Broadcast/ 35 DBH	108.4 (1013)	0.032 (35.50)	3.50	6		None	
		Foliar Broadcast/ 28 DBH	108.5 (1014)	0.032 (35.50)	3.50	--	0.063 (70.29)	None	
		Foliar Broadcast/ 21 DBH	106.5 (995)	0.031 (34.79)	3.50	7		None	
		Foliar Broadcast/ 17 DBH	109.8 (1026)	0.032 (35.86)	3.50	--	0.063 (71.01)	None	
		Foliar Broadcast/ 10 DBH	108.1 (1010)	0.031 (35.15)	3.48	7		None	
		Foliar Broadcast/ 7 DBH	108.4 (1013)	0.032 (35.50)	3.50	--	0.063 (70.65)	None	
		Foliar Broadcast/ 1 DBH	107.2 (1002)	0.031 (35.15)	3.51	7		None	
		Foliar Broadcast/ 7 DBH	109.6 (1024)	0.032 (35.86)	3.50	--	0.063 (70.65)	None	
		Foliar Broadcast/ 0 DBH	106.9 (999)	0.031 (34.79)	3.48	7		None	
Trial 02 TV Reuver, Limburg, Netherlands, 2005	35WG	Foliar Broadcast/ 42 DBH	110.3 (1031)	0.032 (36.32)	3.52	--	0.064 (71.54)	None	DuPont-16586
		Foliar Broadcast/ 35 DBH	107.0 (1000)	0.031 (35.22)	3.52	7		None	
		Foliar Broadcast/ 28 DBH	107.0 (1000)	0.031 (35.22)	3.52	--	0.064 (71.54)	None	
		Foliar Broadcast/ 21 DBH	110.3 (1031)	0.032 (36.32)	3.52	7		None	
		Foliar Broadcast/ 17 DBH	110.3 (1031)	0.032 (36.32)	3.52	--	0.065 (72.64)	None	
		Foliar Broadcast/ 10 DBH	110.3 (1031)	0.032 (36.32)	3.52	7		None	
		Foliar Broadcast/ 8 DBH	103.7 (969)	0.030 (34.12)	3.52	--	0.062 (69.34)	None	
		Foliar Broadcast/ 1 DBH	107.0 (1000)	0.031 (35.22)	3.52	7		None	
		Foliar Broadcast/ 8 DBH	107.0 (1000)	0.031 (35.22)	3.52	--	0.064 (71.54)	None	
		Foliar Broadcast/ 0 DBH	110.3 (1031)	0.032 (36.32)	3.52	8		None	

a EP = End-use Product
b DBH = Days before harvest
c Gallons (US) per acre (Litres/hectare)
d lb active ingredient per acre (grams active ingredient per hectare)
e g active substance/hL (gram active substance per hectolitre or 100 L)
f Retreatment Interval

Table 167
Study Use Pattern for second season (2006 growing season)

Test Identifica-		Application		

tion (City, State/Region, Country, /Year)	EP[a]	Meth-od/ Tim-ing[b]	Vol, (L/ha)	(g ai/ha)	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)	Tank Mix Adjuvants	Ref
Test 01 (Los Palacios y Villafranca, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 42 day DBH	1282	44.86	3.50	-	89.72	None	DuPont-18754
		Foliar Broadcast/ 35 day DBH	1277	44.86	3.51	7		None	
	35WG	Foliar Broadcast/ 27 day DBH	1272	44.50	3.50	-	89.36	None	
		Foliar Broadcast/ 22 day DBH	1286	44.86	3.49	5		None	
	35WG	Foliar Broadcast/ 16 day DBH	1277	44.86	3.51	-	89.36	None	
		Foliar Broadcast/ 10 day DBH	1268	44.50	3.51	6		None	
	35WG	Foliar Broadcast/ 8 day DBH	1270	44.50	3.50	-	89.00	None	
		Foliar Broadcast/ 1 day DBH	1273	44.50	3.50	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	1284	44.86	3.49	-	89.00	None	
		Foliar Broadcast/ 0 day DBH	1261	44.14	3.50	7		None	

Table 167
Study Use Pattern for second season (2006 growing season) (continued)

Test Identifica-tion (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Meth-od/ Tim-ing[b]	Vol, (L/ha)	(g ai/ha)	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 02 (Murello, Piemonte, Italy, 2006)	35WG	Foliar Broadcast/ 42 day DBH	1248	43.79	3.51	-	87.58	None	DuPont-
		Foliar Broadcast/ 35 day DBH	1250	43.79	3.50	7		None	
	35WG	Foliar Broadcast/ 28 day DBH	1252	43.79	3.50	-	89.36	None	
		Foliar Broadcast/ 22 day DBH	1301	45.57	3.50	6		None	
	35WG	Foliar Broadcast/ 18 day DBH	1249	43.79	3.51	-		None	

		Foliar Broadcast/ 11 day DBH	1287	45.21	3.51	7		None	18754
	35WG	Foliar Broadcast/ 7 day DBH	1259	44.14	3.51	-	88.28	None	
		Foliar Broadcast/ 1 day DBH	1262	44.14	3.50	6		None	
	35WG	Foliar Broadcast/ 7 day DBH	1280	44.86	3.50	-	89.36	None	
		Foliar Broadcast/ 0 day DBH	1267	44.50	3.51	7		None	
Test 03 (Pact, Rhône-Alpes, S. France, 2006)	35WG	Foliar Broadcast/ 7 day DBH	1246	43.79	3.51	-	87.22	None	DuPont-18754
		Foliar Broadcast/ 1 day DBH	1240	43.43	3.50	6		None	
Test 04 (Profitis, Central Macedonia, Greece, 2006)	35WG	Foliar Broadcast/ 8 day DBH	1289	45.90	3.56	-	91.47	None	DuPont-18754
		Foliar Broadcast/ 1 day DBH	1280	45.57	3.56	7		None	

Table 167
Study Use Pattern for second season (2006 growing season) (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	(g ai/ha)	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 01 (Los Palacios y Villafranca, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 42 day DBH	1245	43.43	3.49	-	86.86	None	DuPont-18757
		Foliar Broadcast/ 36 day DBH	1244	43.43	3.49	6		None	
	35WG	Foliar Broadcast/ 28 day DBH	1248	43.79	3.51	-	87.93	None	DuPont-18757
		Foliar Broadcast/ 21 day DBH	1256	44.14	3.51	7		None	
	35WG	Foliar Broadcast/ 17 day DBH	1252	43.79	3.50	-	87.93	None	DuPont-18757
		Foliar Broadcast/ 10 day DBH	1260	44.14	3.50	7		None	
	35WG	Foliar Broadcast/ 8 day DBH	1255	43.79	3.49	-	87.58	None	DuPont-18757
		Foliar Broadcast/ 1 day DBH	1255	43.79	3.49	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	1254	43.79	3.49	-	87.22	None	DuPont-18757
		Foliar Broadcast/ 0 day DBH	1242	43.43	3.50	7		None	

Table 167
Study Use Pattern for second season (2006 growing season) (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	(g ai/ha)	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 02 (Pact, Rhône-Alpes, S. France, 2006)	35WG	Foliar Broadcast/ 41 day DBH	1250	43.79	3.50	-	87.58	None	DuPont-18757
		Foliar Broadcast/ 35 day DBH	1247	43.79	3.51	6		None	
	35WG	Foliar Broadcast/ 28 day DBH	1261	44.14	3.50	-	88.64	None	DuPont-

		Foliar Broadcast/ 21 day DBH	1269	44.50	3.51	7		None	18757
	35WG	Foliar Broadcast/ 18 day DBH	1293	45.21	3.50	-	90.07	None	DuPont-18757
		Foliar Broadcast/ 10 day DBH	1284	44.86	3.49	8		None	
	35WG	Foliar Broadcast/ 7 day DBH	1295	45.21	3.49	-	89.35	None	DuPont-18757
		Foliar Broadcast/ 1 day DBH	1260	44.14	3.50	6		None	
	35WG	Foliar Broadcast/ 7 day DBH	1267	44.50	3.51	-	89.00	None	DuPont-18757
		Foliar Broadcast/ 0 day DBH	1276	44.50	3.49	7		None	

Table 167
Study Use Pattern for second season (2006 growing season) (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	(g ai/ha)	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 03 (Profitis, Central Macedonia, Greece, 2006)	35WG	Foliar Broadcast/ 41 day DBH	1291.67	45.22	3.50	-	88.12	None	DuPont-18757
		Foliar Broadcast/ 34 day DBH	1225.76	42.90	3.50	7		None	
	35WG	Foliar Broadcast/ 27 day DBH	1268.18	44.39	3.50	-	87.14	None	DuPont-18757
		Foliar Broadcast/ 20 day DBH	1221.21	42.75	3.50	7		None	
	35WG	Foliar Broadcast/ 16 day DBH	1280.30	44.82	3.50	-	89.77	None	DuPont-18757
		Foliar Broadcast/ 10 day DBH	1284.09	44.95	3.50	6		None	
	35WG	Foliar Broadcast/ 8 day DBH	1287.88	45.08	3.50	-	88.70	None	DuPont-18757
		Foliar Broadcast/ 1 day DBH	1246.21	43.62	3.50	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	1284.09	44.95	3.50	-	88.55	None	DuPont-18757
		Foliar Broadcast/	1245.45	43.60	3.50	7		None	

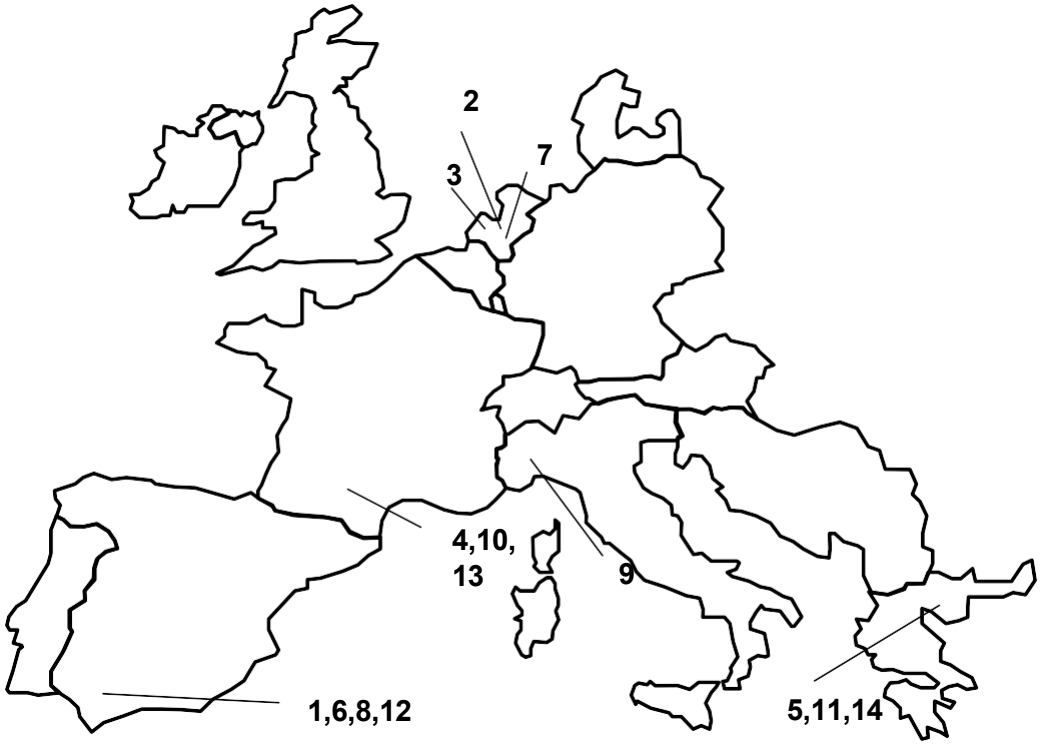
		0 day DBH							

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] Retreatment Interval

A total of 4 magnitude of residue trials and 10 reverse decline trials in the EU were conducted on protected peppers, including hot peppers, in the growing seasons of 2005 and 2006. A summary of these protected pepper trials is given below. Locations of the protected pepper trial sites are given in Figure 27.

Figure 27

Map: Chlorantraniliprole EU protected pepper (fruiting vegetables, solanacea) trial sites



Map No	Reference, Trial No.	Location
1	DuPont-16580, 1	Los Palacios, Andalucia, Spain
2	DuPont-16580, 2	Belfeld, Limburg, The Netherlands
3	DuPont-16580, 3	Meterik, Limburg, The Netherlands
4	DuPont-16580, 4	Pact, Rhône-Alpes, France (southern)
5	DuPont-16580, 5	Profitis, Central Macedonia, Greece
6	DuPont-16586, 1	Los Palacios y Villafranca, E-41720, Andalucia, Spain
7	DuPont-16586, 2	TV Reuver, NL-5953, Limburg, The Netherlands
8	DuPont-18754, 1	Los Palacios y Villafranca, Andalucia, Spain
9	DuPont-18754, 2	Murello, Piemonte, Italy
10	DuPont-18754, 3	Pact, Rhône-Alpes, France (southern)
11	DuPont-18754, 4	Profitis, Central Macedonia, Greece
12	DuPont-18757, 1	Los Palacios y Villafranca, Andalucia, Spain

13	DuPont-18757, 2	Pact, Rhône-Alpes, France (southern)
14	DuPont-18757, 3	Profitis, Central Macedonia, Greece

A protected pepper and hot pepper residue data summary (in mg/kg) is presented in Table 168, Table 169, and Table 170.

To generate these data, the following analysis information pertains.

Analysis method: LC-MS/MS method (DuPont-13295) developed as the chlorantraniliprole residue method for determining residues of chlorantraniliprole in/on crops.

Analyte: Chlorantraniliprole

Extraction: Analyte extracted from crop matrices with acetonitrile following water pre-soak.

Clean-up: SAX (Strong Anion Exchange) and HLB (Hydrophilic Lipophilic Balanced) Solid Phase Extraction (SPE) cartridges

Chromatography: LC

Detection: Mass spectrometer detection (MS/MS) in APCI positive ion mode. Two ion transitions are acquired 284 m/z → 177 m/z and 484 m/z → 453 m/z. The former transition is used for quantification and the second transition for confirmation. In cases where a significant interference is detected in the former transition the latter transition may be used for quantification purposes

LOQ: 0.010 mg/kg

Storage stability: All samples were analysed within 6 months of sampling. Chlorantraniliprole residues are stable in a variety of crops including predominantly water-, oil-, protein-, and starch-containing commodities as represented by fruits, a fruiting vegetable, a root crop, a non-oily grain, and an oilseed (apple, grape, tomato, leaf lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay, and ginned cotton seed) for at least 24 months when stored frozen at -20 ± 10°C (see Point IIA 6.1.1 in this document). Therefore, no degradation is expected to have occurred between harvest and analysis.

Table 168

Residues of chlorantraniliprole in protected peppers (fruiting vegetables, solanacea) from 2005-6 EU supervised trials

Trial Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate lb ai/A (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c,d]	Ref
Trial 01 (Los Palacios, Andalucia, Spain, 2005)	35WG	Pepper/ Italico	Whole Fruit	0.064 (70.92)	1	0.048	DuPont-16580

Trial 02 Belfeld, Limburg, The Netherlands, 2005)	35WG	Pepper/ Derby	Whole Fruit	0.063 (70.45)	1	0.049	DuPont-16580
Trial 03 (Meterik, Limburg, The Netherlands, 2005)	35WG	Pepper/ Corsica	Whole Fruit	0.062 (69.38)	(-1 h) (+2 h)	0.022 0.051	DuPont-16580
				0.064 (72.05)	1	0.058	
				0.064 (72.05)	10	0.023	
				0.063 (71.51)	21	0.022	
				0.063 (69.92)	35	0.019	
Trial 04 (Pact, Rhône-Alpes, France, 2005)	35WG	Pepper/ Hannibal	Whole Fruit	0.064 (71.28)	(-1 h) (+1 h)	0.018 0.033	DuPont-16580
				0.064 (71.28)	1	0.055	
				0.061 (68.77)	10	0.062	
				0.062 (70.2)	21	0.044	
				0.063 (70.21)	35	0.054	
Trial 05 (Profitis, Central Macedonia, Greece, 2005)	35WG	Pepper/ Astor	Whole Fruit	0.063 (71.97)	(-1 h) (+2 h)	nd 0.014	DuPont-16580
				0.063 (70.28)	1	0.023	
				0.063 (70.62)	10	0.035	
				0.063 (70.21)	21	0.052	
				0.062 (69.13)	35	0.029	

[a] EP = End-use Product
[b] DALA = Days after last application (days between last application and sampling)
[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues. For each decline trial, the highest residue value for any sample collected at the target PHI or later is underlined.
[d] Control specimens were collected and analyzed for the target 0 DALA sampling date. No detectable residues, nd, were found in all instances.

Table 168

Residues of chlorantraniliprole in protected peppers (fruiting vegetables, solanacea) from 2005-6 EU supervised trials (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate lb ai/A (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c,d]	Ref
Trial 01 Los Palacios y Villafranca, Andalucia, Spain, 2006	35WG	Hot peppers / Flame	Whole Fruit	0.063 (70.65)	(-1 h) (+2 h)	0.050 0.23	DuPont-16586
				0.063 (70.65)	1	0.15	
				0.063 (71.01)	10	0.11	
				0.063 (70.29)	21	0.12	

				0.063 (71.00)	35	0.17	
Trial 02 TV Reuver, Limburg, The Netherlands, 2005	35WG	Hot peppers / Piedno RZ	Whole Fruit	0.064 (71.54)	(-1 h) (+1 h)	0.016 0.053	DuPont-16586
				0.062 (69.34)	1	0.039	
				0.065 (72.64)	10	0.064	
				0.064 (71.54)	21	0.037	
				0.064 (71.54)	35	0.054	

[a] EP = End-use Product
[b] DALA = Days after last application (days between last application and sampling)
[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.
For each decline trial, the highest residue value for any sample collected at the target PHI or later is underlined.
[d] Control specimens were collected and analyzed for the target sampling date. No detectable residues, nd, were found in all instances.

Table 169

Residues of chlorantraniliprole in protected peppers (fruiting vegetables, solanacea) from 2006 EU supervised trials

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg) [c,d]	Ref
Test 01 (Los Palacios y Villafranca, Spain, 2006)	35WG	Pepper / Palermo	Whole Fruit	44.86	(-1 h)	0.022	DuPont-18754
				89.00	(+1 h)	0.14	
				89.00	1	0.062	
				89.36	10	0.072	
				89.36	22	0.004	
				89.72	35	nd	
Test 02 (Murello, Piemonte, Italy, 2006)	35WG	Pepper / Quadrato di Cuneo	Whole Fruit	44.86 89.36 88.28 89.00 89.36 87.58	(-1 h) (+1 h) 1 11 22 35	0.013 0.059 0.025 0.029 0.024 0.026	DuPont-18754
Test 03 (Pact, Rhône-Alpes, France, 2006)	35WG	Pepper / Hannibal	Whole Fruit	87.22	1	0.11	DuPont-18754
Test 04 (Profitis, Central Macedonia, Greece, 2006)	35WG	Pepper/ Raiko	Whole Fruit	91.47	1	0.036	DuPont-18754
Test 01 (Los Palacios y Villafranca, Spain, 2006)	35WG	Protected Hot Pepper/ Flame Flare	Whole Fruit	43.79 87.22 87.58 87.93 87.93 86.86	(-1 h) (+2 h) 1 10 21 36	0.068 0.23 0.14 0.32 0.57[e] 0.11	DuPont-18757

Test 02 (Pact, Rhône-Alpes, France, 2006)	35WG	Protected Hot Pepper/ Nour	Whole Fruit	44.50 89.00 89.35 90.07 88.64 87.58	(-1 h) (+1 h) 1 10 21 35	0.077 0.11 0.15 0.16 0.10 0.063	DuPont-18757
Test 03 (Profit-is, Central Macedonia, Greece, 2006)	35WG	Protected Hot Pepper/ Raiko	Whole Fruit	44.95 88.55 88.70 89.77 87.14 88.12	(-1 h) (+2 h) 1 10 20 34	0.22 0.34 0.37 0.39 0.11 0.011	DuPont-18757

[a] EP = End-use Product
[b] DALA = Days after last application (Days between last application and sampling)
[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.
[d] Control specimens were collected and analyzed for the target sampling date. No detectable residues, nd, were found in all instances.
[e] Residue is the mean result of 0.61, 0.57 and 0.53 mg/kg residue values.

Table 170

Summary of residue data from EU protected pepper trials with chlorantraniliprole

Commodity	EP[a]	Total Application Rate (g ai/ha)	DALA/ PHI (days)	Residue Levels in ppm (mg/kg) n[b]	Min.[b]	Max.[b]	HAFT[b]	Median[b] (STMdR)	Mean[b] (STMR)	Std. Dev.[b]
Chlorantraniliprole										
Protected peppers, excluding hot peppers	35WG	68.8-91.47	-0[c]	5	nd[d]	0.022	0.022	0.018	0.016	0.008
			0	5	0.014	0.14	0.14	0.051	0.059	0.048
			1	14	0.023	0.11	0.11	0.049	0.052	0.026
			10-11	5	0.023	0.072	0.072	0.035	0.044	0.022
			21-22	5	0.004	0.052	0.052	0.024	0.029	0.019
			35	5	nd	0.054	0.054	0.026	0.026	0.018
Protected hot peppers			-0[c]	5	0.016	0.22	0.22	0.068	0.086	0.078
			0	5	0.053	0.33	0.33	0.23	0.19	0.11
			1	5	0.039	0.37	0.37	0.15	0.17	0.12
			10	5	0.064	0.39	0.39	0.16	0.21	0.14
			21	5	0.037	0.57	0.57	0.11	0.19	0.22
			35	5	0.011	0.17	0.17	0.063	0.082	0.061

[a] EP = End-use Product
[b] N = number of individual specimens,
Min = minimum individual specimen residue,
Max = maximum individual specimen residue,
HAFT = Highest Average residue from one Field Trial; (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set),
Median = median of individual specimen residues,
Mean = mean of individual specimen residues,
Std Dev = standard deviation of mean
[c] Shortly before the last application
[d] Residues of nd (not detectable) were considered to be the LOD (0.004 mg/kg) for mean and median calculations.

Recovery data: Recovery data for fortifications run concurrently with the treated samples are given below to demonstrate the validity of the analytical method.

Table 171
Summary of concurrent recoveries of chlorantraniliprole from protected pepper – DuPont-16580 (2005 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (rsd) % ± % (%)
Chlorantraniliprole				
Protected pepper fruit	0.010 0.10	5 5	90, 77, 80, 76, 83 68, 71, 83, 85, 97	81 ± 5.8 (7.2) 81 ± 12 (15)
Overall				81 ± 8.7 (11)

Table 172
Summary of concurrent recoveries of chlorantraniliprole from protected hot peppers – DuPont-16586 (2005 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (rsd) (% ± % (%))
Concurrent Fortifications – Chlorantraniliprole				
Protected hot pepper fruit	0.010 0.10 0.30	3 3 2	84, 94, 110 78, 78, 93 90, 101	96 ± 13 (14) 83 ± 8.4 (10) 96 ± 7.6 (8.0)
Overall				91 ± 11 (12)

Table 173
Summary of concurrent recoveries of chlorantraniliprole from protected peppers – DuPont-18754 (2006 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (RSD) (% ± % (%))
Chlorantraniliprole				
Protected pep-per fruit	0.010 0.10 0.20	4 4 2	93, 97, 103, 93 88, 93, 85, 87 75, 77	97 ± 5 (5) 88 ± 4 (4) 76
Overall	-	10	-	89 ± 9 (10)

Table 174
Summary of concurrent recoveries of chlorantraniliprole from protected hot peppers–DuPont-18757 (2006 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (RSD) (% ± % (%))
Chlorantraniliprole				
Protected hot pepper fruit	0.010 0.10 0.70	5 5 2	92, 110, 86, 103, 103 94, 86, 83, 88, 97 77, 79	99 ± 10 (10) 89 ± 6 (6) 78
Overall	-	12		91 ± 10 (11)

RESULTS AND DISCUSSION

The residue studies presented herein were carried out in five different EU countries in the 2005 and 2006 growing seasons and provide data relevant to conditions in the protected pepper-growing regions of the EU.

All of the analytical work associated with the studies was performed at Charles River Laboratories, Tranent, EH33 2NE, Scotland in the winters of 2005-6 and 2006-7.

In the EU, residues in protected peppers, excluding hot peppers, were less than or equal to 0.11 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in nine trials conducted in 2005 and 2006 in which

Chlorantraniliprole 35WG was applied at 79-105% of the EU maximum GAP rate of 87.5 g ai/ha/season. Residues in protected hot peppers were higher, up to 0.57 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in five trials conducted in 2005 and 2006 in which Chlorantraniliprole 35WG was applied at 79-105% of the EU maximum GAP rate of 87.5 g ai/ha/season. Dissipation half-lives for chlorantraniliprole in protected peppers, including hot peppers, were 23, 165, 5, 52, 34, and 7 days for DuPont-16580, trial 3; DuPont-16586, trial 1, DuPont-18754, trials 1 and 2, and DuPont-18757, trials 2 and 3, respectively. No decline of residues was found for the remaining four decline trials, DuPont-16580, trials 4 and 5; DuPont-16586, trial 2; and DuPont-18757, trial 1. There does not seem to be any correlation between pepper variety (bell versus hot) and the dissipation rate.

All trials show an overall consistent residue profile when chlorantraniliprole is applied in accordance with GAP.

Recovery values for fresh control fortifications run concurrently with treated samples in all the trials were within 68-110% (n = 40) for protected peppers, including hot peppers. All of the recoveries were within 70-110% and the relative standard deviations were <20% for all trials. Therefore, the analytical methods used performed well for the determination of chlorantraniliprole in treated crops.

CONCLUSION – EU PROTECTED PEPPER TRIALS

Overall consistent residue behaviour of chlorantraniliprole on protected peppers, including hot peppers, was found for two seasons of study in the EU, for application and sampling conducted according to GAP. In the EU, residues in protected peppers, excluding hot peppers, were less than or equal to 0.11 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in nine trials conducted in 2005 and 2006 in which Chlorantraniliprole 35WG was applied. Residues in protected hot peppers were higher, up to 0.57 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in five trials conducted in 2005 and 2006 in which Chlorantraniliprole 35WG was applied. The residue data show that residues do not consistently decline in protected peppers, including hot peppers, with increasing DALA. At six of ten decline trials, dissipation half-lives of 23, 165, 5, 52, 34, and 7 days were calculated and there was no decline of residues at the remaining four trials. There does not seem to be any correlation between pepper variety (bell versus hot) and the dissipation rate.

The data generated from all 2005 and 2006 field trials will be considered as part of the EU protected pepper residue population for further residue population comparison.

A 2.2.2.2.8 TOMATO

Report: Foster, A.C., Cairns, S.D., Davidson, J. (2005); Decline of DPX-E2Y45 residues in protected tomatoes(solanacea vegetables) following foliar applications of DPX-E2Y45 35WG – southern Europe, 2004

DuPont Report No.: DuPont-14154
Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Inveresk Research, Tranent, Scotland, UK
Testing Facility Report/Project No.: 684956
GLP: Yes
Certifying Authority: Department of Health (UK)

Report: Foster, A.C., Cairns, S.D. (2006d); Magnitude and decline of DPX-E2Y45 residues in protected tomatoes (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2005

DuPont Report No.: DuPont-16582
Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK
Testing Facility Report/Project No.: 687653
GLP: Yes
Certifying Authority: Department of Health (U.K.)

Report: Foster, A.C., Cairns, S.D., Hunter, T.M. (2006c); Magnitude and decline of DPX-E2Y45 residues in protected cherry tomatoes (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2005

DuPont Report No.: DuPont-16584
Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK
Testing Facility Report/Project No.: 687648
GLP: Yes
Certifying Authority: Department of Health (U.K.)

Report: Foster, A.C., Cairns, S.D. (2007c); Magnitude and decline of DPX-E2Y45 residues in protected tomatoes (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2006

DuPont Report No.: DuPont-18755
Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC. **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK
Testing Facility Report No.: 689598
GLP: Yes
Certifying Authority: Department of Health (U.K.)

Report: Foster, A.C., Cairns, S.D. (2007g); Magnitude and decline of DPX-E2Y45 residues in protected cherry tomatoes (fruiting vegetables, solanacea) following foliar applications of DPX-E2Y45 35WG - Europe, 2006

DuPont Report No.: DuPont-18769
Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK
Testing Facility Report No.: 689729
GLP: Yes
Certifying Authority: Department of Health (UK)

MATERIALS AND METHODS

The first field program was conducted in 2004 with normal decline trials at one location each in Spain and Italy. DPX-E2Y45-178 (35WG formulation) was applied twice by foliar application to protected omatoes at a target application rate 45 g ai/ha, for a seasonal application rate of 90 g ai/ha (71% maximum EU recommended rate of 126 g ai/ha to protected tomatoes). The first application (A1) occurred 15 days before the predicted commercial harvest date. The second application (A2) occurred 10 days after A1, (longer than the minimum EU recommended interval of 7 days) and therefore, 5 days before predicted commercial harvest according to the use patterns described in Table 183 and sampling intervals described in Table 185.

The second field program was conducted in 2005-6. Five normal decline trials were conducted, one in France, two in Spain, and two in the Netherlands. In addition, two magnitude of residue trials were conducted, one in the Netherlands and one in Greece. Chlorantraniliprole (DPX-E2Y45-178, 35WG formulation) was applied twice by foliar application at the target rates of 3.5 g ai/hL (52.5 g ai/ha) to protected tomatoes, including cherry tomatoes, for a seasonal application rate of 105 g ai/ha (83% maximum EU recommended rate of 126 g ai/ha to protected tomatoes). The applications of Chlorantraniliprole 35WG were made at 7-day (± 1) intervals with the last application occurring on the day of the first commercial harvest for (continuously ripening) protected tomatoes, according to the use patterns described in Table 183 and sampling intervals described in Table 185.

The third field program was conducted in 2006 at two locations in Spain, one location in Greece, two locations in France and two locations in Italy. Two magnitude of residue and five normal decline trials were conducted. Chlorantraniliprole (DPX-E2Y45-206, 35WG formulation) was applied twice at the target rates of 60 g ai/ha (4.0 g ai/hL) to protected tomatoes, including cherry tomatoes, for a seasonal application rate of 120 g ai/ha (95% maximum EU recommended rate of 126 g ai/ha to protected tomatoes). The applications of Chlorantraniliprole 35WG were made at 6-7-day intervals with the last application occurring approximately 0-1 days before the first commercial harvest, for this continuously ripening crop, according to the use patterns described in Table 184 and sampling intervals described in Table 186.

No surfactants or adjuvants were added to the applications in any growing season. The targeted PHI under GAP is 1 day.

Table 183
Study Use Pattern – 2004 and 2005 growing seasons

Trial Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Ad-juvants	Ref
		Method/Timing[b]	Vol, GPA[c] (L/ha)	Rate lb ai/A (g ai/ha)[d]	Rate (g ai/hL)[e]	RTI[f] Days	Total Rate lb ai/A (g ai/ha)[d]		
Trial 01 (Mediglia, Lombardia, Italy, 2004)	35WG	Foliar/ 10 DBFH[e]	160 (1498)	0.041 (45.85)	3.06	--	0.082 (92.06)	None	DuPont-14154
		Foliar/ 0 DBFH	161 (1507)	0.041 (46.21)	3.07	10		None	
Trial 02 (Los Palacios, Andalucia, Spain, 2004)	35WG	Foliar/ 10 DBFH	162 (1518)	0.041 (46.21)	3.04	--	0.082 (92.06)	None	DuPont-14154
		Foliar/ 0 DBFH	161 (1505)	0.041 (45.85)	3.05	10		None	
Trial 01 (Los Palacios y Villafranca, Andalucia, Spain, 2005)	35WG	Foliar Broadcast/ 7 DBH	160.5 (1500)	0.047 (52.30)	3.49	--	0.094 (104.96)	None	DuPont-16582
		Foliar Broadcast/ 0 DBH	161 (1505)	0.047 (52.66)	3.50	7		None	
Trial 02 (Siebengewald, Limburg, Netherlands, 2005)	35WG	Foliar Broadcast/ 7 DBH	160.5 (1500)	0.047 (52.39)	3.49	--	0.094 (105.55)	None	DuPont-16582
		Foliar Broadcast/ 0 DBH	162.8 (1522)	0.047 (53.16)	3.49	7		None	
Trial 03 (Wellerlooi, Limburg, Netherlands, 2005)	35WG	Foliar Broadcast/ 7 DBH	167.2 (1563)	0.049 (54.57)	3.49	--	0.098 (109.42)	None	DuPont-16582
		Foliar Broadcast/ 1 DBH	163.8 (1531)	0.049 (54.85)	3.58	7		None	
Trial 04 (Profitis, Thessaloniki, Central Macedonia, Greece, 2005)	35WG	Foliar Broadcast/ 7 DBH	156.5 (1463)	0.046 (51.08)	3.49	--	0.091 (101.72)	None	DuPont-16582
		Foliar Broadcast/ 1 DBH	155.1 (1450)	0.045 (50.64)	3.49	7		None	
Trial 05 (Moissieu, Pact, Rhône-Alpes,	35WG	Foliar Broadcast/ 7 DBFH	159.0 (1486)	0.046 (51.94)	3.50	--	0.094 (105.31)	None	DuPont-16582
		Foliar Broadcast/	162.8	0.048					

France, 2005)		0 DBFH	(1522)	(53.37)					

Table 183
Study Use Pattern – 2004 and 2005 growing seasons (continued)

Trial Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/Timing[b]	Vol, GPA[c] (L/ha)	Rate lb ai/A (g ai/ha)[d]	Rate (g ai/hL)[e]	RTI[f] Days	Total Rate lb ai/A (g ai/ha)[d]		
Test 01 (Los Palacios y Villafranca, Andalucia Spain, 2006)	35WG	Foliar Broadcast/ 7 DBFH	160.2 (1497)	0.047 (52.30)	3.49	--	0.094 (104.96)	None	DuPont-16584
		Foliar Broadcast/ 0 DBFH	160.9 (1504)	0.047 (52.66)	3.50	7		None	
Test 02 (AB Siebengewald, Limburg, The Netherlands, 2005)	35WG	Foliar Broadcast/ 7 DBFH	162.0 (1514)	0.047 (52.87)	3.49	--	0.094 (105.26)	None	DuPont-16584
		Foliar Broadcast/ 0 DBFH	160.5 (1500)	0.047 (52.39)	3.49	7		None	

[a] EP = End-use Product
[b] DBFH = Days before first harvest; DBH = Days before harvest
[c] Gallons (US) per acre (Litres/hectare)
[d] lb active ingredient per acre (grams active ingredient per hectare)
[e] g active substance/hL (gram active substance per hectolitre or 100 L)
[f] Retreatment Interval

Table 184
Study Use Pattern – 2006 growing season

Test Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 01 (Triginto di Mediglia, Lombardia, Italy, 2006)	35WG	Foliar Broadcast/ 7 day DBH	1488	59.45	4.00	-	118.19	None	DuPont-18755
		Foliar Broadcast/ 0 day DBH	1471	58.74	3.99	7		None	
Test 02 (Pact, S. Rhône-Alpes, France, 2006)	35WG	Foliar Broadcast/ 8 day DBH	1554	62.30	4.01	-	122.46	None	DuPont-18755

		Foliar Broadcast/ 1 day DBH	1506	60.16	3.99	7		None	
Test 03 (Lleida, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 7 day DBH	1500	60.16	4.01	-	120.32	None	DuPont-18755
		Foliar Broad-cast/ 0 day DBH	1502	60.16	4.01	7		None	
Test 04 (Profitis, Central Macedonia, Greece, 2006)	35WG	Foliar Broadcast/ 8 day DBH	1481	59.31	4.01	-	120.15	None	DuPont-18755
		Foliar Broadcast/ 1 day DBH	1519	60.84	4.00	7		None	
Test 01 (Los Palacios y Villafranca, Andalucia, Spain, 2006-2007)	35WG	Foliar Broad-cast/ 7 day DBH	1502	59.81	3.98	-	119.97	None	DuPont-18769
		Foliar Broad-cast/ 0 day DBH	1510	60.16	3.98	7		None	

Table 184
Study Use Pattern – 2006 growing season (continued)

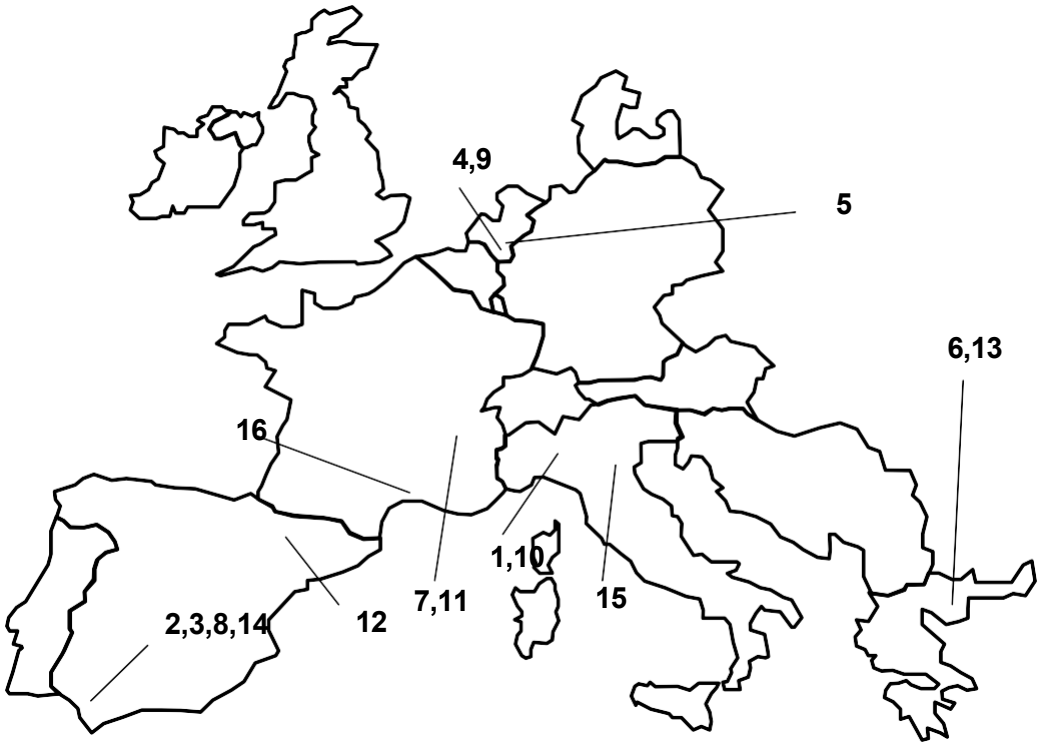
Test Identification (City, State/Region, Country, Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 02 (Roncoferraro, Lombardia, Italy, 2006)	35WG	Foliar Broadcast/ 6 day DBH	1503	59.81	3.98	-	120.33	None	DuPont-18769
		Foliar Broadcast/ 0 day DBH	1521	60.52	3.98	6		None	
Test 03 (Caphan, Provence-Alpes-Côte d'Azur, S. France, 2006)	35WG	Foliar Broadcast/ 7 day DBH	1472	58.74	3.99	-	119.97	None	DuPont-18769
		Foliar Broadcast/ 0 day DBH	1540	61.23	3.98	7		None	

[a] EP = End-use Product

[b] DBH = Days before harvest
[c] Retreatment Interval

A total of 4 magnitude of residue trials and 12 normal decline trials (five in Spain, three in the Netherlands, three in Italy, two in Greece, and three in southern France) were conducted over three growing seasons (2004, 2005-6, and 2006). A summary of these trials is given below. Locations of the protected tomatoes trial sites are given in Figure 29.

Figure 29
Map: Chlorantraniliprole EU protected tomatoes (fruiting vegetables, solanacea) trial sites



Map No.	Reference, Trial No.	Location
1	DuPont-14154, 1	Mediglia, Lombardia, Italy
2	DuPont-14154, 2	Los Palacios, Andalucia, Spain
3	DuPont-16582, 1	Los Palacios y Villafranca, Andalucia, Spain
4	DuPont-16582, 2	Siebengewald, Limburg, The Netherlands
5	DuPont-16582, 3	Wellerlooi, Limburg, The Netherlands
6	DuPont-16582, 4	Profitis, Central Macedonia, Greece
7	DuPont-16582, 5	Moissieu, Pact, Rhônes-Alpes, France (south)
8	DuPont-16584, 1	Los Palacios y Villafranca, E-41720, Andalucia, Spain
9	DuPont-16584, 2	AB Siebengewald, NL-5853, Limburg, The Netherlands
10	DuPont-18755, 1	Triginto di Mediglia, Lombardia, Italy
11	DuPont-18755, 2	Pact, Rhône-Alpes, France (south)
12	DuPont-18755, 3	Lleida, Cataluña, Spain
13	DuPont-18755, 4	Profitis, Central Macedonia, Greece
14	DuPont-18769, 1	Los Palacios y Villafranca, Andalucia, Spain
15	DuPont-18769, 2	Roncoferraro, Lombardia, Italy
16	DuPont-18769, 3	Caphan, Provence-Alpes-Côte d'Azur, France (south)

A protected tomatoes, including cherry tomatoes, residue data summary (in mg/kg) is presented in Table 185, Table 186, and Table 187.

To generate these data, the following analysis information pertains.

Analysis method: LC-MS/MS method (DuPont-13295) developed as the chlorantraniliprole residue method for determining residues of chlorantraniliprole in/on crops.

Analyte:	Chlorantraniliprole
Extraction:	Analyte extracted from crop matrices with acetonitrile following water pre-soak.
Clean-up:	SAX (Strong Anion Exchange) and HLB (Hydrophilic Lipophilic Balanced) Solid Phase Extraction (SPE) cartridges
Chromatography:	LC
Detection:	Mass spectrometer detection (MS/MS) in APCI positive ion mode. Two ion transitions are acquired 284 m/z → 177 m/z and 484 m/z → 453 m/z. The former transition is used for quantification and the second transition for confirmation. In cases where a significant interference is detected in the former transition the latter transition may be used for quantification purposes
LOQ:	0.010 mg/kg

Storage stability: All samples were analysed within 10 months of sampling. Chlorantraniliprole residues are stable in a variety of crops including predominantly water-, oil-, protein-, and starch-containing commodities as represented by fruits, a fruiting vegetable, a root crop, a non-oily grain, and an oilseed (apple, grape, tomato, leaf lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay, and ginned cotton seed) for at least 24 months when stored frozen at -20 ± 10°C (see Point IIA 6.1.1 of this document). Therefore, no degradation is expected to have occurred between harvest and analysis.

Table 185
Residues of chlorantraniliprole in protected tomatoes, including cherry tomatoes (fruiting vegetables, solanacea) from 2004 and 2005 EU supervised trials

Trial Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate lb ai/A (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c]	Ref
Trial 01 (Mediglia, Lombardia, Italy, 2004)	35WG	Protected Tomatoes/ Albenga	Protected Tomato Fruit	0.082 (92.06)	(–1 h) 0 (+1 h) 1 3 5 7 10	nd 0.021 0.012 0.018 0.011 0.010 0.017	DuPont-14154

Trial 02 (Los Palacios, Andalucia, Spain, 2004)	35WG	Protected Tomatoes/ Bond	Protected Tomato Fruit	0.082 (92.06)	(–1 h) 0 (+2 h) 1 3 5 7 10	nd 0.012 0.010 0.008 0.011 0.015 0.011	DuPont-14154
Trial 01 Los Palacios y Villafranca, Andalucia, Spain, 2005	35WG	Protected Tomatoes/ Bond	Whole Fruit	0.094 (104.96)	(-1 h) (+2 h) 1 10 21 35	0.005 0.015 0.008 0.012 0.008 0.007	DuPont-16582
Trial 02 Siebengewald, Limburg, Netherlands, 2005	35WG	Protected Tomatoes/ Pannory	Whole Fruit	0.094 (105.55)	(-1 h) (+2 h) 1 10 21 35	0.008 0.034 0.029 0.027 0.034 0.021	DuPont-16582
Trial 03 Wellerlooi, Limburg, Netherlands, 2005	35WG	Protected Tomatoes/ Relaxx	Whole Fruit	0.098 (109.42)	1	0.095	DuPont-16582
Trial 04 Profitis, Thessaloniki, Central Macedonia, Greece, 2005	35WG	Protected Tomatoes/ Alma	Whole Fruit	0.091 (101.72)	1	nd	DuPont-16582
Trial 05 Moissieu, Pact, Rhône-Alpes, France, 2005	35WG	Protected Tomatoes/ Félicia	Whole Fruit	0.094 (105.31)	(-1 h) (+2 h) 1 10 21 35	nd 0.008 nd 0.007 0.015 0.008	DuPont-16582

Table 185
Residues of chlorantraniliprole in protected tomatoes, including cherry tomatoes (fruiting vegetables, solanacea) from 2004 and 2005 EU supervised trials (continued)

Trial Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate lb ai/A (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg)[c]	Ref
Test 01 Los Palacios y Villafranca, Andalucia, Spain, 2006	35WG	Protected Cherry Tomato / Lupita	Whole Fruit	0.094 (104.96)	(-1 h) (+2 h) 1 10 21 35	nd 0.016 0.015 nd 0.022 0.028	DuPont-16584
Test 02 AB Siebengewald, Limburg, The Netherlands, 2005	35WG	Protected Cherry Tomato / Efwee 100	Whole Fruit	0.094 (105.26)	(-1 h) (+2 h) 1 10 21 35	0.035 0.095 0.079 0.067 0.066 0.051	DuPont-16584

[a] EP = End-use Product
[b] DALA = Days after last application (Days between last application and sampling)
[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.
For each decline trial, the highest residue value for any sample collected at the target PHI or later is underlined.

Table 186
Residues of chlorantraniliprole in protected tomatoes, including cherry tomatoes (fruiting vegetables, solanacea) from 2006 EU supervised trials

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg) [c,d]	Ref
Test 01 Trigolo di Mediglia, Lombardia, Italy, 2006	35WG	Tomatoes/ Oskar	Whole Fruit	118.19	(-1 h) (+1 h) 1 10 21 35	0.013 0.043 0.028 0.012 0.037 0.027	DuPont-18755
Test 02 Pact, Rhône-Alpes S. France, 2006	35WG	Tomatoes/ Felicia	Whole Fruit	122.46	1	0.079	DuPont-18755
Test 03 Lleida, Cataluña, Spain, 2006	35WG	Tomatoes/ Caramba	Whole Fruit	120.32	(-1 h) (+2 h) 1 11 21 35	0.023 0.072 0.061 0.039 0.028 0.022	DuPont-18755
Test 04 Profitis, Central Macedonia, Greece, 2006	35WG	Tomatoes/ Alma	Whole Fruit	120.15	1	0.009	DuPont-18755
Test 01 (Los Palacios y Villafranca, Andalucia, Spain, 2006-2007)	35WG	Cherry Tomato / Lupita	Whole Fruit	 119.97	(-1 h) (+2 h) 1 10 21 45	0.037 0.12 0.11 0.10 0.071 0.044	DuPont-18769
Test 02 (Roncoferraro, Lombardia, Italy, 2006)	35WG	Cherry Tomato / Fiolino	Whole Fruit	 120.33	(-1 h) (+2 h) 1 10 22 36	0.061 0.066 0.090 0.011e 0.031 0.010	DuPont-18769
Test 03 (Caphan, Provence-Alpes-Cote d'Azur, S. France, 2006)	35WG	Cherry Tomato / Severino	Whole Fruit	 119.97	(-1 h) (+2 h) 1 10 21 35	0.080 0.11 0.088 0.15 0.15 0.099	DuPont-18769

Table 187
Summary of residue data from EU protected tomatoes field trials with chlorantraniliprole

Commodity	EP[a]	Total Application Rate (g ai/ha)	DALA/ PHI (days)	Residue Levels in ppm (mg/kg)						
				n[b]	Min.[b]	Max.[b]	HAFT[b]	Median[b] (STMdR)	Mean[b] (STMR)	Std. Dev.[b]
Chlorantraniliprole										
			-0[c]	7	nd[d]	0.023	0.023	0.005	0.009	0.007

Protected toma-toes, ex-cluding cherry tomatoes	35WG	92.06-122.46	0	7	0.008	0.072	0.072	0.021	0.029	0.023
			1	11	nd	0.095	0.095	0.012	0.031	0.033
			3	2	0.008	0.018	0.018	0.013	0.013	0.007
			5	2	0.011	0.011	0.011	0.011	0.011	0.000
			7	2	0.010	0.015	0.015	0.013	0.013	0.004
			10-11	8	nd	0.039	0.039	0.012	0.016	0.012
			21-22	5	0.008	0.037	0.037	0.028	0.024	0.012
			35-45	5	0.007	0.027	0.027	0.021	0.017	0.009
Protected cherry toma-toes			-[c]	5	nd[d]	0.080	0.080	0.037	0.043	0.029
			0	5	0.016	0.12	0.12	0.095	0.081	0.042
			1	5	0.015	0.11	0.11	0.088	0.076	0.036
			3	2	0.008	0.018	0.018	0.013	0.013	0.007
			5	2	0.011	0.011	0.011	0.011	0.011	0.000
			7	2	0.010	0.015	0.015	0.013	0.013	0.004
			10-11	5	nd	0.15	0.15	0.067	0.066	0.061
			21-22	5	0.022	0.15	0.15	0.066	0.068	0.051
			35-45	5	0.010	0.099	0.099	0.044	0.046	0.033

[a] EP = End-use Product
[b] N = number of individual specimens,
Min = minimum individual specimen residue,
Max = maximum individual specimen residue,
HAFT = Highest Average residue from one Protected Trial; (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set),
Median = median of individual specimen residues,
Mean = mean of individual specimen residues,
Std Dev = standard deviation of mean
[c] Shortly before the last application
[d] The designation "nd" is used for treated samples/specimens for which no peak was observed or residue was <LOD (below the limit of detection; 0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.

Recovery data: Recovery data for fortifications run concurrently with the treated samples are given below to demonstrate the validity of the analytical method.

Table 188

Summary of concurrent recoveries of chlorantraniliprole from protected tomato fruit – DuPont-14154 (2004 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (% ± %)
Concurrent Fortifications – Chlorantraniliprole				
Tomato fruit	0.01 0.1	4 3	72, 78, 76, 71 72, 91, 99, (46[a])	80 ± 11

[a] Outlying data point removed from further calculations.

Table 189

Summary of concurrent recoveries of chlorantraniliprole from protected tomatoes – DuPont-16582 (2005 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (rsd) (% ± % (%))
Concurrent Fortifications – Chlorantraniliprole				
Tomato Fruit	0.010	6	101, 90, 104, 107, 101, 107	102± 6.4 (6.3)
	0.10	6	87, 90, 95, 93, 95, 94	92 ± 3.1 (3.4)
Overall	-	-	-	97 ± 6.8 (7.0)

Table 190
Summary of concurrent recoveries of chlorantraniliprole from protected cherry tomatoes – DuPont-16584 (2005 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (rsd) % ± % (%)
Chlorantraniliprole				
Tomato Fruit	0.010 0.10	4 4	102, 102, 75, 75 95, 89, 82, 76	88 ± 16 (18) 85 ± 8.0 (9.4)
Overall				87 ± 12 (13)

Table 191
Summary of concurrent recoveries of chlorantraniliprole from protected tomatoes – DuPont-18755 (2006 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (RSD) (% ± % (%))
Chlorantraniliprole				
Tomatoes	0.010 0.10	2 2	132, 84 91, 90	108 ± 33.7 (31) 90 ± 0.4 (1)
Overall	-	4	-	99 ± 22 (22)

Table 192
Summary of concurrent recoveries of chlorantraniliprole from protected cherry tomatoes – DuPont-18769 (2006 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	(RSD) (% ± % (%))
Chlorantraniliprole				
Tomato Fruit	0.010 0.10 0.20	4 4 2	86, 90, 94, 99 80, 93, 84, 81 94, 97	92 ± 5.5 (6) 84 ± 5.8 (7) 95 ± 2.2 (2)

Overall		10		90 ± 7 (7)

RESULTS AND DISCUSSION

The residue studies presented herein were carried out in five EU countries in the 2004, 2005-6, and 2006 growing seasons and provide data relevant to conditions in the protected tomato-, including cherry tomato-, growing regions of the EU.

All of the analytical work associated with the studies was performed at Charles River Laboratories, Tranent, EH33 2NE, Scotland. The analytical work was carried out during two different time periods: first time for the season 2004 residue trials, in the spring of 2006 for the 2005-6 residue trials, and in the winter of 2006-7 for the 2006 residue trials.

In the EU, residues in protected tomatoes, excluding cherry tomatoes, were less than or equal to 0.095 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in the eleven residue trials conducted in 2004, 2005-6 and 2006 in which chlorantraniliprole was applied at 73-97% of the maximum EU recommended rate of 126 g ai/ha/season. Residues in protected cherry tomatoes were slightly higher, up to 0.15 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in the five residue trials conducted in 2005-6 and 2006 in which chlorantraniliprole was applied at 73-97% of the maximum EU recommended rate of 126 g ai/ha/season.

Dissipation half-lives for chlorantraniliprole in protected tomatoes, including cherry tomatoes, were 33, 47, 79, 47, 21, 32, and 14 days in DuPont-14154, trial 1; DuPont-16582, trials 1 and 2; DuPont-16584, trial 2; DuPont-18755, trial 3; and DuPont-18769, trials 1 and 2, respectively. No decline of residues was found for the remaining five decline trials, DuPont-14154, trial 2; DuPont-16582, trial 5; DuPont-16584, trial 1; DuPont-18755, trial 1; and DuPont-18769, trial 3. There does not seem to be any correlation between tomato variety and the dissipation rate.

The study use patterns for the 2005-6 and 2006 trials support the EU GAP. For the 2004 trials, the retreatment interval was 10 days, longer than the target 7-day retreatment interval. Given the chlorantraniliprole residue

dissipation half-lives determined in the protected tomato trials (33 days to no decline), the chlorantraniliprole residues at 1 DALA resulting from 2 applications made 7 days apart will not significantly differ from the chlorantraniliprole residues at 1 DALA resulting from 2 applications made 10 days apart. Additionally, the 2004 trials resulted in similar chlorantraniliprole residues on tomatoes as the 2005-6 and 2006 trials, therefore data generated from all field trials will be considered as part of the EU protected tomato residue population for further residue population comparison.

All trials show an overall consistent residue profile will be found in protected tomato fruit when chlorantraniliprole is applied in accordance with GAP.

Recovery values for fresh control fortifications run concurrently with treated samples in all the trials were within 76-132% (n = 41) for protected tomatoes, including cherry tomatoes. Approximately 75% or more of the recoveries were within 70-110% and the relative standard deviations were ≤22% for all trials. Therefore, the analytical methods used performed well for the determination of chlorantraniliprole in treated crops.

CONCLUSION – EU PROTECTED TOMATO TRIALS

Overall consistent residue behaviour of chlorantraniliprole on protected tomatoes, including cherry tomatoes, was found for three seasons of study in the EU, for application and sampling conducted according to GAP. Residues in protected tomatoes, excluding cherry tomatoes, were less than or equal to 0.095 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in the eleven residue trials conducted in 2004, 2005-6 and 2006 in which chlorantraniliprole was applied. Residues in protected cherry tomatoes were slightly higher, up to

0.15 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in the five residue trials conducted in 2005-6 and 2006 in which chlorantraniliprole was applied. The residue data show that residues do not consistently decline in protected tomatoes, including cherry tomatoes, with increasing DALA. At seven of twelve decline trials, dissipation half-lives of 33, 47, 79, 47, 21, 32, and 14 days were calculated and there was no decline of residues at the remaining five decline trials. There does not seem to be any correlation between tomato variety and the dissipation rate.

The data generated from all 2005 and 2006 field trials will be considered as part of the EU protected tomato residue population for further residue population comparison.

A 2.2.2.2.9 Lettuce and Lamb's Lettuce

Report: Foster, A.C., Cairns, S.D. (2007); Magnitude and decline of DPX-E2Y45 residues in protected lettuce including Lambs lettuce (leaf vegetables) following foliar applications of DPX-E2Y45 35WG - Europe, 2006

DuPont Report No.: DuPont-18764

Guidelines: European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC. **Deviations:** None

Testing Facility: Charles River Laboratories, Tranent, Scotland, UK

Testing Facility Report No.: 689708

GLP: Yes

Certifying Authority: Department of Health (U.K.)

MATERIALS AND METHODS

The field program was conducted in 2006 at two locations in the Netherlands, one location in Greece, three locations in France, four locations in Italy and at four locations in Spain. Four magnitude of residue (MOR) trials and ten reverse decline trials were conducted in protected lettuce, including lambs lettuce. Chlorantraniliprole (DPX-E2Y45-206, 35WG formulation) was applied twice as a foliar broadcast spray at a target application rate of 40.0 g ai/ha, for a seasonal application rate of 80.0 g ai/ha, 95% maximum EU recommended rate of 84 g ai/ha/season.

The applications of Chlorantraniliprole 35WG were made at 6-8-day intervals with the last application occurring approximately 0-28 days before normal harvest according to the use patterns described in Table 214 and sampling intervals described in Table 215. No surfactants or adjuvants were added to the applications. The targeted PHI under GAP is 1 day.

Table 214
Study Use Pattern

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 01 (Los Palacios y Villafranca, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 35 day DBH	1020	40.58	3.98	-	80.11	None	DuPont-18764
		Foliar Broadcast/ 28 day DBH	1003	39.53	3.94	7		None	
	35WG	Foliar Broadcast/ 21 day DBH	1006	39.89	3.97	-	79.78	None	DuPont-18764
		Foliar Broadcast/ 14 day DBH	1008	39.89	3.96	7		None	
	35WG	Foliar Broadcast/ 14 day DBH	1005	39.89	3.97	-	79.43	None	DuPont-18764
		Foliar Broadcast/ 7 day DBH	1004	39.53	3.94	7		None	
	35WG	Foliar Broadcast/ 8 day DBH	1006	39.89	3.97	-	79.43	None	DuPont-18764
		Foliar Broadcast/ 1 day DBH	1004	39.53	3.94	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	1004	39.53	3.94	-	79.07	None	DuPont-18764
		Foliar Broadcast/ 0 day DBH	1004	39.53	3.94	7		None	

Table 214
Study Use Pattern (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 02 (Los Palacios y Villafranca, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 35 day DBH	1008	39.89	3.96	-	79.78	None	DuPont-18764
		Foliar Broadcast/ 28 day DBH	1009	39.89	3.95	7		None	
	35WG	Foliar Broadcast/ 21 day DBH	989	39.19	3.96	-	79.08	None	DuPont-18764
		Foliar Broadcast/ 14 day DBH	1005	39.89	3.97	7		None	
	35WG	Foliar Broadcast/ 14 day DBH	1004	39.53	3.94	-	79.77	None	DuPont-18764
		Foliar Broadcast/ 7 day DBH	1015	40.24	3.96	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	1023	40.60	3.97	-	80.13	None	DuPont-18764
		Foliar Broadcast/ 1 day DBH	1003	39.53	3.94	6		None	
	35WG	Foliar Broadcast/ 7 day DBH	1023	40.60	3.97	-	80.83	None	DuPont-18764
		Foliar Broadcast/ 0 day DBH	1015	40.24	3.96	7		None	
Test 03 (Barbate, Cadiz, Andalucia, Spain, 2006)	35WG	Foliar Broadcast/ 8 day DBH	1008	33.18	3.29	-	66.36	None	DuPont-18764
		Foliar Broadcast/ 1 day DBH	1003	33.18	3.31	7		None	

Table 214
Study Use Pattern (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
		Foliar							

Test 04 (Azzano S. Paolo, Lombardia, Italy, 2006)	35WG	Broadcast/ 35 day DBH	978	39.16	4.00	-	78.35	None	DuPont-18764
		Foliar Broadcast/ 29 day DBH	993	39.19	3.95	6		None	
	35WG	Foliar Broadcast/ 20 day DBH	985	38.83	3.94	-	78.36	None	DuPont-18764
		Foliar Broadcast/ 14 day DBH	1003	39.53	3.94	6		None	
	35WG	Foliar Broadcast/ 14 day DBH	1006	39.89	3.97	-	80.13	None	DuPont-18764
		Foliar Broadcast/ 7 day DBH	1016	40.24	3.96	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	1013	39.89	3.94	-	79.43	None	DuPont-18764
		Foliar Broadcast/ 1 day DBH	1003	39.53	3.94	6		None	
	35WG	Foliar Broadcast/ 7 day DBH	971	38.47	3.96	-	77.66	None	DuPont-18764
		Foliar Broadcast/ 0 day DBH	990	39.19	3.96	7		None	

Table 214
Study Use Pattern (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 05 (Azzano S. Paolo, Lombardia, Italy, 2006)	35WG	Foliar Broadcast/ 35 day DBH	988	39.52	4.00	-	78.68	None	DuPont-18764
		Foliar Broadcast/ 28 day DBH	978	39.16	4.00	7		None	
	35WG	Foliar Broadcast/ 21 day DBH	998	39.87	3.99	-	79.39	None	DuPont-18764
		Foliar Broadcast/ 14 day DBH	987	39.52	4.00	7		None	
	35WG	Foliar Broadcast/ 14 day DBH	986	39.16	3.97	-	79.74	None	DuPont-18764
		Foliar Broadcast/ 7 day DBH	1021	40.58	3.97	7		None	

	35WG	Foliar Broad-cast/ 7 day DBH	983	39.16	3.98	-	78.32	None	DuPont-18764
		Foliar Broad-cast/ 1 day DBH	984	39.16	3.98	6		None	
	35WG	Foliar Broadcast/ 7 day DBH	984	39.16	3.98	-	80.10	None	DuPont-18764
		Foliar Broadcast/ 0 day DBH	1024	40.94	4.00	7		None	
Test 06 (Triginto di Mediglia, Lombardia, Italy, 2006)	35WG	Foliar Broad-cast/ 7 day DBH	995	39.52	3.97	-	79.75	None	DuPont-18764
		Foliar Broadcast/ 1 day DBH	1012	40.23	3.98	7		None	

Table 214
Study Use Pattern (continued)

Test Identifi-cation (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Meth-od/ Tim-ing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 07 (Vivy, Pays-de-la-Loirre, N. France, 2006)	35WG	Foliar Broad-cast/ 35 day DBH	1029	40.60	3.95	-	80.00	None	DuPont-18764
		Foliar Broadcast/ 28 day DBH	997	39.40	3.95	7		None	
	35WG	Foliar Broadcast/ 21 day DBH	1048	41.40	3.95	-	82.60	None	DuPont-18764
		Foliar Broad-cast/ 14 day DBH	1042	41.20	3.95	7		None	
	35WG	Foliar Broadcast/ 14 day DBH	1010	39.90	3.95	-	80.70	None	DuPont-18764
		Foliar Broadcast/ 7 day DBH	1032	40.80	3.95	7		None	
	35WG	Foliar Broad-cast/ 8 day DBH	980	38.70	3.95	-	77.30	None	DuPont-18764
		Foliar Broad-cast/	976	38.60	3.95	7		None	

		1 day DBH							
	35WG	Foliar Broadcast/ 7 day DBH	1026	40.50	3.95	-	79.90	None	DuPont-18764
		Foliar Broadcast/ 0 day DBH	998	39.95	3.91	7		None	

Table 214
Study Use Pattern (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 08 (Lucenay, Rhône-Alpes, S. France, 2006)	35WG	Foliar Broadcast/ 35 day DBH	979	38.83	3.97	-	77.30	None	DuPont-18764
		Foliar Broadcast/ 28 day DBH	975	38.47	3.95	7		None	
	35WG	Foliar Broadcast/ 21 day DBH	970	38.47	3.97	-	77.30	None	DuPont-18764
		Foliar Broadcast/ 14 day DBH	986	38.83	3.94	7		None	
	35WG	Foliar Broadcast/ 14 day DBH	1012	39.89	3.94	-	80.13	None	DuPont-18764
		Foliar Broadcast/ 7 day DBH	1019	40.24	3.95	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	979	38.83	3.97	-	77.30	None	DuPont-18764
		Foliar Broadcast/ 1 day DBH	976	38.47	3.94	6		None	
	35WG	Foliar Broadcast/ 7 day DBH	1012	39.89	3.94	-	80.13	None	DuPont-18764
		Foliar Broadcast/ 0 day DBH	1018	40.24	3.95	7		None	
Test 09 (Pernes les Fontaines, Provence-Alpes-Côte d'Azur, S. France, 2006)	35WG	Foliar Broadcast/ 8 day DBH	1035	40.95	3.96	-	81.55	None	DuPont-18764
		Foliar Broadcast/ 1 day DBH	1028	40.60	3.95	8		None	

Table 214
Study Use Pattern (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 10 (Venlo, Limburg, The Netherlands, 2006)	35WG	Foliar Broadcast/ 35 day DBH	483	38.54	7.98	-	79.74	None	DuPont-18764
		Foliar Broadcast/ 28 day DBH	517	41.2	7.97	7		None	
	35WG	Foliar Broadcast/ 21 day DBH	500	39.87	7.97	-	81.07	None	DuPont-18764
		Foliar Broadcast/ 14 day DBH	517	41.2	7.97	7		None	
	35WG	Foliar Broadcast/ 14 day DBH	517	41.2	7.97	-	79.74	None	DuPont-18764
		Foliar Broadcast/ 7 day DBH	483	38.54	7.98	7		None	
	35WG	Foliar Broadcast/ 8 day DBH	500	39.87	7.97	-	79.74	None	DuPont-

		Foliar Broad-cast/ 1 day DBH	500	39.87	7.97	7		None	18764
	35WG	Foliar Broadcast/ 7 day DBH	500	39.87	7.97	-	79.74	None	DuPont-18764
		Foliar Broadcast/ 0 day DBH	500	39.87	7.97	7		None	

Table 214
Study Use Pattern (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
	35WG	Foliar Broad-cast/ 36 day DBH	1001	39.87	3.98	-	80.10	None	DuPont-18764
		Foliar Broadcast/ 30 day DBH	1012	40.23	3.98	6		None	
	35WG	Foliar Broadcast/ 22 day DBH	996	39.53	3.97	-	79.43	None	DuPont-18764
		Foliar Broad-cast/ 15 day DBH	1006	39.89	3.97	7		None	

Test 11 (Murchante, Navarra, Spain, 2006)	35WG	Foliar Broadcast/ 15 day DBH	1004	39.53	3.94	-	79.07	None	DuPont-18764
		Foliar Broadcast/ 8 day DBH	1000	39.53	3.95	7		None	
	35WG	Foliar Broadcast/ 8 day DBH	1015	40.24	3.96	-	80.48	None	DuPont-18764
		Foliar Broadcast/ 1 day DBH	1021	40.24	3.94	7		None	
	35WG	Foliar Broadcast/ 8 day DBH	997	39.53	3.97	-	78.72	None	DuPont-18764
		Foliar Broadcast/ 0 day DBH	994	39.19	3.94	8		None	

Table 214
Study Use Pattern (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
	35WG	Foliar Broadcast/ 35 day DBH	500	39.87	7.97	-	81.07	None	DuPont-

		Foliar Broadcast/ 28 day DBH	517	41.20	7.97	7		None	18764
	35WG	Foliar Broadcast/ 21 day DBH	517	41.20	7.97	-	81.07	None	DuPont-18764
		Foliar Broad-cast/ 14 day DBH	500	39.87	7.97	7		None	
Test 12 (Boekend, Limburg, The Netherlands, 2006)	35WG	Foliar Broadcast/ 14 day DBH	517	41.20	7.97	-	82.40	None	DuPont-18764
		Foliar Broadcast/ 7 day DBH	517	41.20	7.97	7		None	
	35WG	Foliar Broad-cast/ 8 day DBH	517	41.20	7.97	-	81.07	None	DuPont-18764
		Foliar Broad-cast/ 1 day DBH	500	39.87	7.97	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	517	41.20	7.97	-	79.74	None	DuPont-18764
		Foliar Broadcast/ 0 day DBH	483	38.54	7.98	7		None	
Test 13 (Profit-is, Thessaloniki, Greece, 2006)	35WG	Foliar Broad-cast/ 8 day DBH	997	39.39	3.95	-	78.69	None	DuPont-18764
		Foliar Broadcast/ 1 day DBH	994	39.30	3.95	7		None	

Table 214
Study Use Pattern (continued)

Test Identification (City, State/Region, Country, /Year)	EP[a]	Application						Tank Mix Adjuvants	Ref
		Method/ Timing[b]	Vol, (L/ha)	g ai/ha	g ai/hL	RTI[c] Days	Total Rate (g ai/ha)		
Test 14 (Treviolo, Lombardia, Italy, 2006)	35WG	Foliar Broadcast/ 35 day DBH	1020	40.58	3.98	-	80.45	None	DuPont-18764
		Foliar Broadcast/ 28 day DBH	997	39.87	4.00	7		None	
	35WG	Foliar Broadcast/ 22 day DBH	969	38.8	4.00	-	77.96	None	DuPont-18764
		Foliar Broadcast/ 14 day DBH	986	39.16	3.97	8		None	
	35WG	Foliar Broadcast/ 14 day DBH	973	38.8	3.99	-	78.67	None	DuPont-18764
		Foliar Broadcast/ 7 day DBH	997	39.87	4.00	7		None	
	35WG	Foliar Broadcast/ 7 day DBH	1017	40.58	3.99	-	80.81	None	DuPont-18764
		Foliar Broadcast/ 1 day DBH	1013	40.23	3.97	6		None	

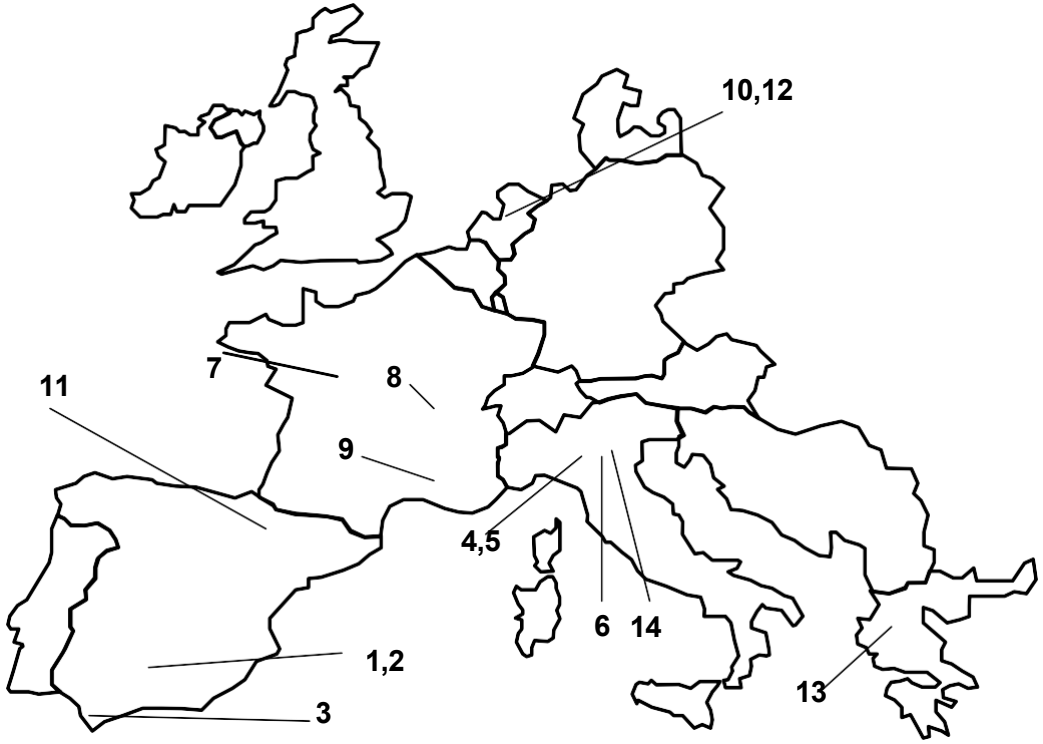
	35WG	Foliar Broad-cast/ 7 day DBH	988	39.52	4.00	-	79.04	None	DuPont-18764
		Foliar Broadcast/ 0 day DBH	994	39.52	3.98	7		None	

[a] EP = End-use Product
[b] DBH = Days before harvest
[c] RTI = Retreatment Interval

A total of 14 residue trials were conducted in the growing season of 2006. A summary of these protected lettuce studies is given below. Locations of the protected lettuce trial sites are given in Figure 23.

Figure 33

Map: Chlorantraniliprole EU protected lettuce (leaf vegetables) trial sites



Reference, Test No.	Location
DuPont-18764, 1	Los Palacios y Villafranca, Andalucia, Spain
DuPont-18764, 2	Los Palacios, Andalucia, Spain
DuPont-18764, 3	Barbate, Cadiz, Andalucia, Spain
DuPont-18764, 4	Azzano S. Paolo, Lombardia, Italy
DuPont-18764, 5	Azzano S. Paolo, Lombardia, Italy
DuPont-18764, 6	Triginto di Mediglia, Lombardia, Italy
DuPont-18764, 7	Vivy, Pays-de-la-Loire, France (north)
DuPont-18764, 8	Lucenay, Rhône-Alpes, France (south)

DuPont-18764, 9	Pernes les Fontaines, Provence-Alpes-Côte d'Azur, France (south)
DuPont-18764, 10	Venlo, Limburg, The Netherlands
DuPont-18764, 11	Murchante, Navarra, Spain
DuPont-18764, 12	Boekend, Limburg, The Netherlands
DuPont-18764, 13	Profitis, Thessaloniki, Greece
DuPont-18764, 14	Treviolo, Lombardia, Italy

A protected lettuce residue data summary (in mg/kg) is presented in Table 215 and Table 216.

To generate these data, the following analysis and recovery information pertains.

Analysis method: LC-MS/MS method (DuPont-13294) developed as the chlorantraniliprole residue method for determining residues of chlorantraniliprole in/on crops.

Analyte:	Chlorantraniliprole
Extraction:	Analyte extracted from crop matrices with acetonitrile following water presoak.
Clean-up:	SAX (Strong Anion Exchange) and HLB (Hydrophilic Lipophilic Balanced) Solid Phase Extraction (SPE) cartridges
Chromatography:	LC
Detection:	Mass spectrometer detection (MS/MS) in APCI positive mode. Two ion transitions are acquired 284 m/z – 177 m/z and 484 m/z – 453 m/z. The former transition is used for quantification and the second transition for confirmation. In cases where a significant interference is detected in the former transition the latter transition may be used for quantification purposes
LOQ	0.010 mg/kg

Storage stability: All samples were analysed within 10 months of sampling. Chlorantraniliprole residues are stable in a variety of crops including predominantly water-, oil-, protein- and, starch-containing commodities as represented by fruits, a fruiting vegetable, a root crop, a non-oily grain, and an oilseed (apple, grape, tomato, leaf lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay, and ginned cottonseed) for at least 24 months when stored frozen at -20 ± 10°C (see Point IIA 6.1.1). Therefore, no degradation is expected to have occurred between harvest and analysis.

Table 215
Residues of chlorantraniliprole in protected lettuce (leaf vegetables) from 2006 supervised trials

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg) [c,d]	Ref
Test 01 (Los Palacios y Villafranca, Andalucia, Spain, 2006)	35WG	Lettuce (closed head)/ Iceberg	Lettuce Head	39.53	(-1 h)	0.032	DuPont-18764
				79.07	0 (+1 h)	0.41	
				79.43	1	0.093	
				79.43	7	0.072	
				79.78	14	0.005	
				80.11	28	0.005	
Test 02 (Los Palacios, Andalucia, Spain, 2006)	35WG	Lettuce (closed head)/ Tunice	Lettuce Head	40.60	(-1 h)	0.11	DuPont-18764
				80.83	0 (+1 h)	0.35	
				80.13	1	0.15	
				79.77	7	0.093	
				79.08	14	0.099	
				79.78	28	0.046	
Test 03 (Barbate, Cadiz, Andalucia, Spain, 2006)	35WG	Lettuce (closed head)/ Iceberg	Lettuce Head	66.36	1	0.38	DuPont-18764
Test 04 (Azzano S. Paolo, Lombardia, Italy, 2006)	35WG	Lambs Lettuce / Tropi	Lettuce Leaves	38.47	(-1 h)	3.4	DuPont-18764
				77.66	0 (+2 h)	7.1	
				79.43	1	7.8	
				80.13	7	5.6	
				78.36	14	4.5	
				78.35	29	0.28	
Test 05 (Azzano S. Paolo, Lombardia, Italy,	35WG	Lettuce (closed head)/	Lettuce Head	39.16	(-1 h)	0.57	DuPont-18764
				80.10	0 (+2 h)	1.4	
				78.32	1	1.6	
				79.74	7	1.0	
				79.39	14	0.25	

2006)		Justine		78.68	28	0.005	
Test 06 (Triginto di Mediglia, Lombardia, Italy, 2006)	35WG	Lettuce (open head)/ Fantastic	Lettuce Leaves	79.75	1	1.3	DuPont-18764
Test 07 (Vivy, Pays-de-la-Loire, N. France, 2006)	35WG	Lambs Lettuce / Trophy	Lettuce Leaves	40.50	(-1 h)	1.7	DuPont-18764
				79.90	0 (+4 h)	3.3	
				77.30	1	2.8	
				80.70	7	4.1	
				82.60	14	1.4	
				80.00	28	0.32	
Test 08 (Luce-nay, Rhône-Alpes, S. France, 2006)	35WG	Lettuce (open head) / Dedale	Lettuce Head	39.89	(-1 h)	0.56	DuPont-18764
				80.13	0 (+1 h)	1.7	
				77.30	1	1.4	
				80.13	7	0.91	
				77.30	14	1.1	
				77.30	28	0.77	

Table 215
Residues of chlorantraniliprole in protected lettuce (leaf vegetables) from 2006 supervised trials (continued)

Test Identification (City, State/Region, Country, Year)	EP[a]	Crop/ Variety	Commodity or Matrix	Total Rate (g ai/ha)	DALA[b]/ PHI (days)	Residue ppm (mg/kg) [c,d]	Ref
Test 09 (Pernes les Fontaines, Provence-Alpes-Côte d'Azur, S. France, 2006)	35WG	Lettuce (open head)/ Ki-galie	Lettuce Head	81.55	1	2.0	DuPont-18764
Test 10		Lambs		39.87	(-1 h)	2.1	
				79.74	0 (+1 h)	3.9	
				79.74	1	3.1	

(Venlo, Limburg, The Netherlands, 2006)	35WG	Lettuce / Pulsar	Lettuce Leaves	79.74	7	3.2	DuPont-18764
				81.07	14	2.2	
				79.74	28	0.12	
Test 11 (Murchante, Navarra, Spain, 2006)	35WG	Lettuce (open head)/ Hoja de roble	Lettuce Leaves	39.53	(-1 h)	1.5	DuPont-18764
				78.72	0 (+3 h)	2.2	
				80.48	1	1.8	
				79.07	8	1.7	
				79.43	15	2.3	
				80.10	30	1.1	
Test 12 (Boekend, Limburg, The Netherlands, 2006)	35WG	Lambs Lettuce / Ciriller	Lettuce Leaves	41.20	(-1 h)	0.98	DuPont-18764
				79.74	0 (+1 h)	2.4	
				81.07	1	4.1	
				82.40	7	3.0	
				81.07	14	2.3	
				81.07	28	0.098	
Test 13 (Profitis, Thessaloniki, Greece, 2006)	35WG	Lettuce (open head)/ Simson	Lettuce Leaves	78.69	1	1.8	DuPont-18764
Test 14 (Treviolo, Lombardia, Italy, 2006)	35WG	Lambs Lettuce / Vilmorin	Lettuce Leaves	39.52	(-1 h)	2.5	DuPont-18764
				79.04	0 (+2 h)	5.4	
				80.81	1	8.0	
				78.67	7	3.3	
				77.96	14	2.0	
				80.45	28	0.065	

[a] EP = End-use Product

[b] DALA = Days after last application (Days between last application and sampling)

[c] The designation "nd" is used for treated specimens for which no peak was observed or residue was <LOD (below the limit of detection; <0.004 mg/kg). For calculations, 0.004 mg/kg was used for specimens with no detectable (nd) residues.

[d] Control specimens were collected and analyzed for the target 0 DALA (Tests 1, 2, 4, 5, 7, 8, 10, 11, 12 & 14) and 1 DALA (Tests 3, 6, 9 & 13) sampling dates. No detectable residues, nd, were found in all instances.

Table 216

Summary of residue data from EU protected lettuce field trials with chlorantraniliprole

		Total Applica-		**Residue Levels in ppm (mg/kg)**

Commodity	EP[a]	tion Rate (g ai/ha)	DALA/ PHI (days)	n[b]	Min.[b]	Max.[b]	HAFT[b]	Median[b] (STMdR)	Mean[b] (STMR)	Std. Dev.[b]
Chlorantraniliprole										
Lettuce, excluding Lambs Lettuce	35WG	39.16–40.60	-0[c]	5	0.032	1.5	1.5	0.56	0.55	0.58
		66.36–81.55	0[d]	5	0.35	2.2	2.2	1.4	1.2	0.81
			1	9	0.093	2.0	2.0	1.4	1.2	0.76
			7-8	5	0.072	1.7	1.7	0.91	0.76	0.69
			14-15	5	0.005	2.3	2.3	0.25	0.76	0.97
			28-30	5	0.005	1.1	1.1	0.046	0.39	0.52
Lambs Lettuce	35WG	38.47–41.20	-0[c]	5	0.98	3.4	3.4	2.1	2.1	0.90
		77.30–82.60	0[d]	5	2.4	7.1	7.1	3.9	4.4	1.9
			1	5	2.8	8.0	8.0	4.1	5.2	2.5
			7	5	3.0	5.6	5.6	3.3	3.8	1.1
			14	5	1.4	4.5	4.5	2.2	2.5	1.2
			28-29	5	0.065	0.32	0.32	0.12	0.18	0.12

[a] EP = End-use Product

[b] N = number of individual specimens,
Min = minimum individual specimen residue, Max = maximum individual specimen residue,
HAFT = Highest Average residue from one Field Test; (requested when the raw commodity has associated commercially processed commodities on which tolerances/MRLs could be set),
Median = median of individual specimen residues, Mean = mean of individual specimen residues,
Std Dev = standard deviation of mean

[c] Shortly before the last application

[d] Shortly after the last application

Recovery data: Average recovery data for fortifications run concurrently with the treated samples are given below to demonstrate the validity of the analytical method.

Table 217

Summary of concurrent recoveries of chlorantraniliprole from protected lettuce – DuPont-18764 (2006 season)

Matrix	Fortification level in ppm (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std. dev. (RSD) (% ± % (%))
Chlorantraniliprole				
Lettuce	0.010 0.10 9.0	7 7 2	88, 77, 88, 109, 74, 99, 97 109, 99, 78, 93, 77, 92, 84 99, 86	90 ± 12 (14) 90 ± 12 (13) 92
Overall	-	16	-	90 ± 11 (12)

Statistics were calculated using non-rounded recovery values

RESULTS AND DISCUSSION

The residue studies presented in chlorantraniliprole dossier were carried out in five different EU countries and provide data relevant to conditions in the protected lettuce-growing regions of the EU.

All of the analytical work associated with the studies was performed at Charles River Laboratories, Tranent, EH33 2NE, Scotland in the winter of 2006-7.

In the EU, residues in protected lettuces, excluding lambs lettuce, were less than or equal to 2.3 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in the 9 residue trials conducted in 2006 in which chlorantraniliprole was applied at 79-97% maximum EU recommended rate of 84 g ai/ha/season. Residues on protected lambs lettuce were higher, up to 8.0 mg/kg at 1 DALA or later sampling intervals in the 5 residue trials conducted in 2006 in which chlorantraniliprole was applied at 92-98% maximum EU recommended rate.

All 14 sets of data show an overall consistent residue profile when chlorantraniliprole is applied in accordance with GAP.

Dissipation half-lives for chlorantraniliprole in protected lettuce, including lambs lettuce, following applications of Chlorantraniliprole 35WG were 5, 12, 6, 3, 8, 30, 6, 40, 6, and 4 days, for DuPont-18764, trials 1, 2, 4, 5, 7,

8, 10, 11, 12, and 14, respectively. The calculated average half-lives for chlorantraniliprole in open-head lettuce

(2 trials), closed-head lettuce (3 trials), and lambs lettuce (5 trials) were 35, 7, and 6 days, respectively.

Recovery values for fresh control fortification run concurrently with treated samples in all the trials were within 74-109% (n = 16) for protected lettuce. Approximately 75% or more of the recoveries were within 70–110% and the relative standard deviations were <20% for all trials. Therefore, the analytical methods used performed well for the determination of chlorantraniliprole in treated crops.

CONCLUSION – EU PROTECTED LETTUCE TRIALS

Overall consistent residue behaviour of chlorantraniliprole on protected lettuce, including lambs lettuce, was found for one season of study in the EU, for application and sampling conducted according to GAP. Residues in protected lettuces, excluding lambs lettuce, were less than or equal to 2.3 mg/kg at 1 DALA, the target PHI, or later sampling intervals, in the 9 residue trials in which chlorantraniliprole was applied. Residues on protected lambs lettuce were higher, up to 8.0 mg/kg at 1 DALA or later sampling intervals in the 5 residue trials in which chlorantraniliprole was applied. Dissipation half-lives for chlorantraniliprole in protected lettuce, including lambs lettuce, were 5, 12, 6, 3, 8, 30, 6, 40, 6, and 4 days.

The data generated from all 2006 lettuce trials will be considered as two separate EU lettuce residue populations, protected lettuce excluding lambs lettuce and protected lambs lettuce, for further residue population comparison.

A 2.2.2.2.10 PLUM

Table B.7.6.1: Residue Trial Results For Plums

Residue trial number	Crop	Country and year	Application rate (g as/ha)	Growth stage at last treatment	DALA	Application No.	Residues found (mg/kg)	Remarks
Test 1	Plum	Great Holland, Essex, UK. 2007 EU Northern Zone	2 x 49.94 (Foliar application)	BBCH 81-89	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.081	The study was carried out to GLP. Samples were analysed by LC-MS/MS to determine residues of chlorantraniliprole {analytical method no. 0673, see DuPont-13294 and DuPont-13295}. The LOQ was 0.01 mg/kg and the LOD was 0.004 mg/kg. Chlorantraniliprole was formulated as Chlorantraniliprole 20SC, a suspension concentrate which nominally contained 200 g ai/l.
Test 2	Plum	Bessanay, 69690, Rhone-Alps, South France 2007 EU Southern Zone	2 x 58.86 (Foliar application)	BBCH 89	-0 0.04	2	**Chlorantraniliprole:** -0 DALA Mature fruit flesh: 0.036 0.04 DALA Mature fruit flesh: 0.071	
			1 x 59.88 + 1 x 59.67 (Foliar application)	BBCH 87-89	7	2	**Chlorantraniliprole:** 7 DALA Mature fruit flesh: 0.048	
			1 x 60.08 + 1 x 59.47	BBCH 85-87	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.056	

			(Foliar application)					Each test site had one control plot and one treated plots. Applications were applied as foliar broadcast sprays to each treated plot. Two applications of the test sub-stance were made at 10 day inter-vals. Specimens were non-systematically collected, starting with the control plot and ending with the treated plot. Samples from this study were stored up to 7 months from the date of sampling to analysis. Samples were stored frozen at -18°C. Storage stability was assessed in a separate study, DuPont-12985. No residues of chlorantraniliprole above the LOD were found in un-treated samples.
			1 x 59.88 + 1 x 60.08 (Foliar application)	BBCH 75	28	2	**Chlorantraniliprole:** 28 DALA Mature fruit flesh: 0.027	
Test 3	Plum	Molembaix, Hainaut, Belgium. 2007 EU Northern Zone	2 x 49.94 (Foliar application)	BBCH 85-87	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.038	
Test 4	Plum	Blumberg, Brandenburg, Germany 2007 EU Northern Zone	1 x 47.60 + 1 x 47.82 (Foliar application)	BBCH 89	-0 0.08	2	**Chlorantraniliprole:** -0 DALA Mature fruit flesh: 0.011 0.08 DALA Mature fruit flesh: 0.006	
Residue trial number	**Crop**	**Country and year**	**Application rate (g as/ha)**	**Growth stage at last treatment**	**DALA**	**Application No.**	**Residues found (mg/kg)**	**Remarks**
			1 x 48.65 + 1 x 48.82 (Foliar application)	BBCH 85	7	2	**Chlorantraniliprole:** 7 DALA Mature fruit flesh: 0.009	
			1 x 47.76 + 1 x 49.98 (Foliar application)	BBCH 81	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.009	
			1 x 52.31 + 1 x 48.10 (Foliar application)	BBCH 75	28	2	**Chlorantraniliprole:** 28 DALA Mature fruit flesh: 0.006	
Test 5	Plum	Galatades, Pella, Central Macedonia, Greece. 2007 EU Southern Zone	1 x 60.01 + 1 x 59.95 (Foliar application)	BBCH 79-85	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.020	
Test 6	Plum	Obernai, Alsace, Northern France. 2007	1 x 59.67 + 1 x 60.49	BBCH 89	-0 0.04	2	**Chlorantraniliprole:** -0 DALA Mature fruit flesh: 0.030 0.04 DALA Mature fruit flesh: 0.066	

		EU Northern Zone	(Foliar application)					
			1 x 60.08 + 1 x 60.49 (Foliar application)	BBCH 85-87	7	2	**Chlorantraniliprole:** 7 DALA Mature fruit flesh: 0.042	
			1 x 59.88 + 1 x 59.47 (Foliar application)	BBCH 85-87	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.063	
			1 x 59.88 + 1 x 60.08 (Foliar application)	BBCH 75	28	2	**Chlorantraniliprole:** 28 DALA Mature fruit flesh: 0.033	

Residue trial number	Crop	Country and year	Application rate (g as/ha)	Growth stage at last treatment	DALA	Application No.	Residues found (mg/kg)	Remarks
Test 7	Plum	Alcarras, Lleida, Catalunya, Spain. 2007 EU Southern Zone	1 x 39.38 + 1 x 60.28 (Foliar application)	BBCH 78	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.014	
Test 8	Plum	Royston, Hertford-shire, UK. 2008 EU Northern Zone	2 x 49.92 (Foliar application)	BBCH 87-89	-0 0.08	2	**Chlorantraniliprole:** -0 DALA Mature fruit flesh: 0.009 0.08 DALA Mature fruit flesh: 0.033	
			2 x 49.54 (Foliar application)	BBCH 85	7	2	**Chlorantraniliprole:** 7 DALA Mature fruit flesh: 0.047	
			1 x 49.92 + 1 x 49.54 (Foliar application)	BBCH 79-81	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.026	
			1 x 49.73 + 1 x 49.92 (Foliar application)	BBCH 79-81	28	2	**Chlorantraniliprole:** 28 DALA Mature fruit flesh: 0.016	
Test 9	Plum	Obernai, 67210, Alsace, France. 2008 EU Northern Zone	1 x 48.58 + 1 x 47.81 (Foliar application)	BBCH 89	-0 0.04	2	**Chlorantraniliprole:** -0 DALA Mature fruit flesh: 0.041 0.04 DALA Mature fruit flesh: 0.094	
			1 x 48.00 + 1 x 47.81 (Foliar application)	BBCH 85	7	2	**Chlorantraniliprole:** 7 DALA Mature fruit flesh: 0.054	
			1 x 48.38 + 1 x 48.38 (Foliar application)	BBCH 81	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.034	
			1 x 48.19 + 1 x 48.00 (Foliar application)	BBCH 81	29	2	**Chlorantraniliprole:** 29 DALA Mature fruit flesh: 0.017	

Residue trial number	Crop	Country and year	Application rate (g as/ha)	Growth stage at last treatment	DALA	Application No.	Residues found (mg/kg)	Remarks
Test 10	Plum	Blumberg, Brandenburg, Germany. 2008 EU Northern Zone	1 x 47.33 + 1 x 49.30 (Foliar application)	BBCH 89	-0 0.08	2	**Chlorantraniliprole:** -0 DALA Mature fruit flesh: ND 0.08 DALA Mature fruit flesh: 0.007	
			1 x 48.36 + 1 x 49.46 (Foliar application)	BBCH 85	7	2	**Chlorantraniliprole:** 7 DALA Mature fruit flesh: 0.006	
			1 x 47.57 + 1 x 48.91 (Foliar application)	BBCH 81-85	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.005	
			1 x 49.30 + 1 x 49.46 (Foliar application)	BBCH 81	28	2	**Chlorantraniliprole:** 28 DALA Mature fruit flesh: ND	
Test 11	Plum	Volpedo, Piemonte, Italy. 2008 EU Southern Zone	1 x 60.69 + 1 x 60.08 (Foliar application)	BBCH 89	-0 0.04	2	**Chlorantraniliprole:** -0 DALA Mature fruit flesh: 0.008 0.04 DALA Mature fruit flesh: 0.017	
			1 x 61.30 + 1 x 59.88 (Foliar application)	BBCH 86	7	2	**Chlorantraniliprole:** 7 DALA Mature fruit flesh: 0.009	
			1 x 60.28 + 1 x 59.88 (Foliar application)	BBCH 83	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.021	
			1 x 59.27 + 1 x 60.69 (Foliar application)	BBCH 76	28	2	**Chlorantraniliprole:** 28 DALA Mature fruit flesh: 0.019	
Test 12	Plum	Bessenay, Rhone Alpes, France. 2008	1 x 58.18 + 1 x 58.75 (Foliar application)	BBCH 89	-0 0.08	2	**Chlorantraniliprole:** -0 DALA Mature fruit flesh: 0.044 0.08 DALA Mature fruit flesh: 0.066	

Residue trial number	Crop	Country and year	Application rate (g as/ha)	Growth stage at last treatment	DALA	Application No.	Residues found (mg/kg)	Remarks
		EU Northern Zone	1 x 58.94 + 1 x 57.98 (Foliar application)	BBCH 83-85	7	2	**Chlorantraniliprole:** 7 DALA Mature fruit flesh: 0.048	
			1 x 57.22 + 1 x 57.79 (Foliar application)	BBCH 83	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.034	
			1 x 57.22 + 1 x 57.02 (Foliar application)	BBCH 81	28	2	**Chlorantraniliprole:** 28 DALA Mature fruit flesh: 0.016	
Test 13	Plum	Agard, Fejer County, H-2484, Hungary. 2008 EU Northern Zone	1 x 48.38 + 1 x 48.58 (Foliar application)	BBCH 84	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.010	
Test 14	Plum	DR Dodewaard, Gelderland, NL-6669, Netherlands. 2008 EU Northern Zone	1 x 40.00 + 1 x 40.00 (Foliar application)	BBCH 83	14	2	**Chlorantraniliprole:** 14 DALA Mature fruit flesh: 0.006	

Data from the above trials was taken from residues report: "Magnitude and decline of chlorantraniliprole residues in plums (stone fruit) following foliar applications of DPX-E2Y45 20SC [200 g as/l (w/v); 18.5% (w/w)] – Northern and Southern Europe, 2007 and 2008", Foster, Andrew C., Cairns, Scott D. report number: DuPont-21714, Charles River Laboratories Project Number 691193, 31st July 2009.

ND = non detectable – a result <LOD of 0.004mg/kg.

Discussion:
The submitted GAP for stone fruit (peaches and apricots, plums) is 2 applications at 60 g as/ha, with a total maximum dose for the season of 120 g as/ha, the minimum recommended application rate is 32 g/ai/ha/appl (64 g/ai/ha/season) (see Table 7, DuPont-18272, Revision No.1, Supplement No. 2). The PHI is 14 days. The above residue trials are acceptable.

Results:
NEU:
0.081, 0.038, 0.009, 0.063, 0.026, 0.034, 0.005, 0.034, 0.010, 0.006 mg/kg

SEU
0.056, 0.020, 0.014, 0.021 mg/kg

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Chlorantraniliprole

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	1.56	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2013	Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
	2%	NL toddler	38.56	0.9%	Spinaches	0.3%	Escaroles/broad-leaved endives	0.3%	Apples		
	1%	DE child	20.88	0.3%	Apples	0.3%	Spinaches	0.1%	Lettuces		
	1%	SE general	20.72	0.5%	Lettuces	0.3%	Chinese cabbages/pe-tsai	0.1%	Kales		
	1%	NL child	19.87	0.3%	Spinaches	0.2%	Kales	0.1%	Apples		
	1%	GEMS/Food G10	19.61	0.4%	Lettuces	0.2%	Chinese cabbages/pe-tsai	0.1%	Cress and other sprouts and shoo		
	1%	IT adult	19.03	0.5%	Lettuces	0.2%	Other lettuce and other salad plants	0.1%	Spinaches		
	1%	ES adult	16.76	0.7%	Lettuces	0.1%	Chards/beet leaves	0.1%	Spinaches		
	1%	GEMS/Food G08	15.95	0.3%	Lettuces	0.1%	Lamb's lettuce/corn salads	0.1%	Watercress		
	1.0%	GEMS/Food G06	15.45	0.1%	Tomatoes	0.1%	Lettuces	0.1%	Kales		
	1.0%	PT general	15.02	0.5%	Kales	0.2%	Wine grapes	0.1%	Lettuces		
	1.0%	ES child	15.01	0.5%	Lettuces	0.1%	Spinaches	0.1%	Chards/beet leaves		
	1.0%	IT toddler	14.95	0.4%	Lettuces	0.1%	Other lettuce and other salad plants	0.1%	Chards/beet leaves		
	0.9%	GEMS/Food G07	14.53	0.3%	Lettuces	0.1%	Wine grapes	0.1%	Rapeseeds/canola seeds		
	0.9%	IE adult	14.39	0.2%	Other leafy brassica	0.2%	Spinaches	0.1%	Lettuces		
	0.9%	NL general	14.01	0.2%	Spinaches	0.2%	Kales	0.1%	Escaroles/broad-leaved endives		
	0.8%	GEMS/Food G15	12.10	0.1%	Lettuces	0.1%	Head cabbages	0.1%	Sunflower seeds		
	0.8%	GEMS/Food G11	12.06	0.1%	Spinaches	0.1%	Lamb's lettuce/corn salads	0.1%	Lettuces		
	0.7%	FR child 3 15 yr	10.25	0.1%	Other lettuce and other salad plants	0.1%	Spinaches	0.1%	Milk: Cattle		
	0.6%	RO general	10.07	0.2%	Head cabbages	0.1%	Wine grapes	0.1%	Sunflower seeds		
	0.6%	FR toddler 2 3 yr	9.74	0.2%	Spinaches	0.1%	Milk: Cattle	0.1%	Apples		
	0.6%	DE women 14-50 yr	9.46	0.1%	Lettuces	0.1%	Apples	0.1%	Spinaches		
	0.6%	FR adult	9.39	0.2%	Other lettuce and other salad plants	0.1%	Wine grapes	0.1%	Spinaches		
	0.6%	DE general	8.92	0.1%	Lettuces	0.1%	Apples	0.1%	Spinaches		
	0.6%	FR infant	8.84	0.3%	Spinaches	0.1%	Milk: Cattle	0.0%	Apples		
	0.5%	DK child	7.12	0.2%	Lettuces	0.1%	Apples	0.0%	Milk: Cattle		
	0.4%	UK vegetarian	6.33	0.2%	Lettuces	0.1%	Wine grapes	0.0%	Spinaches		
	0.3%	DK adult	5.34	0.1%	Lettuces	0.1%	Wine grapes	0.0%	Apples		
	0.3%	FI 6 yr	5.22	0.1%	Lettuces	0.1%	Spinaches	0.0%	Chinese cabbages/pe-tsai		
	0.3%	UK adult	5.13	0.2%	Lettuces	0.1%	Wine grapes	0.0%	Spinaches		
	0.3%	FI adult	5.02	0.2%	Lettuces	0.0%	Chinese cabbages/pe-tsai	0.0%	Tomatoes		
	0.3%	FI 3 yr	4.89	0.1%	Spinaches	0.0%	Lettuces	0.0%	Chinese cabbages/pe-tsai		
	0.3%	UK infant	4.38	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Eggs: Chicken		
	0.3%	UK toddler	4.35	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Spinaches		
	0.3%	PL general	4.24	0.1%	Apples	0.0%	Head cabbages	0.0%	Tomatoes		
	0.3%	LT adult	4.02	0.1%	Lettuces	0.1%	Head cabbages	0.0%	Apples		
	0.1%	IE child	0.97	0.0%	Milk: Cattle	0.0%	Lettuces	0.0%	Apples		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Chlorantraniliprole is unlikely to present a public health concern.

A 3.2 IEDI calculations

Not necessary

A 3.3 IESTI calculations - Raw commodities

Not relevant

Appendix 4 Additional information provided by the applicant