REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: 102000012886

Product name(s): Fluopyram + trifloxystrobin SC 500

Active substance(s): (250 + 250 g/L)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Re-Authorisation)

Applicant: Bayer Crop Science Division

Submission date: 30/06/2020

Updated: 07/2021

MS Finalisation date: July 2021 (initial Core Assessment)

March 2022 (final Core Assessment)

Version history

When	What
June 2020	Initial dRR – Bayer
July 2021	Applicant updated dRR. No registration on Golf course use in CZE. Uses 124 removed.
July 2021	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
March 2022	Final report (Core Assessment after the commenting period) Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow, while not agreed use pattern is ~~struck through and shaded~~.

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The product fluopyram + trifloxystrobin SC 500 (250 + 250 g/L) (FLU+TFS SC 500 / Product Code 102000012886) has not been previously evaluated at zonal level. It was not the representative formulation during the renewal of approval of trifloxystrobin. All data and information assessed during the EU re-evaluation of trifloxystrobin is considered EU peer-reviewed data.

Non-renewed substance fluopyram: according to the guidance SANCO/2010/13170 rev. 14, 7 October 2016, for product containing two or more substances, there is no need to evaluate data related to the « non-renewed » substance(s). It is therefore our understanding that only data pertaining to combitox assessment will be taken into consideration.

Reviewer's comments:

Conclusions from the assessment were prepared using grey commenting boxes. Rewording changes or text amendments were done using grey highlights in the text. The parts of the text added by the zRMS reviewer are highlighted in grey, whereas the parts struck off are ~~visibly marked with the grey font~~.

For the current submission in the context of art. 43; Reg. 1107/2009, data for plant protection product FLU+TFS SC 500 / Product Code 102000012886 has been reviewed by the zRMS PL to reflect changes and updates resulting from renewal of the approval of trifloxystrobin as active substance (Trifloxystrobin SANTE/10107/2018; 25 May 2018) in accordance with Regulation (EC) No 1107/2009 (*EFSA (European Food Safety Authority)*.
Product has been previously evaluated in Poland (2014) according to Uniform Principles: Poland Luna Sensation MRiRW nr R-82/2014.
For the renewal process initial dRR has been submitted in 2018, due to category 4 studies, the complete dRR was submitted to Polish authorities on July 27, 2020

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on FLU+TFS SC 500 *

Product name and code	Fluopyram + trifloxystrobin SC 500 (250 + 250 g/L) FLU+TFS SC 500 102000012886
Formulation type	SC (suspension concentrate)
Active substance(s) (incl. content)	Fluopyram + trifloxystrobin SC 500 (250+250 g/L)
Function	Fungicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	Yes. Please refer to Part B0.

* Information on the detailed composition of FLU+TFS SC 500 can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for FLU+TFS SC 500 according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Acute toxicity: Category 4 Effect on or via lactation ~~Acute aquatic toxicity: Category 1~~* ~~Chronic aquatic toxicity: Category 1~~*
Hazard pictograms:	 ~~GHS09~~  GHS07
Signal word:	Warning
Hazard statement(s):	H302 Harmful if swallowed. H362 May cause harm to breast-fed children ~~H410 Very toxic to aquatic life with long lasting effects~~* EUH401 To avoid risks to human health and the environment, comply with the instructions for use. EUH208 contains Trifloxystrobin, 1,2-benzisothiazolin-3-one, reaction mass of 5-chloro-2- methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1). May produce an allergic reaction.
Precautionary statement(s):	P260 Do not breath gas/mist/vapours/spray P263 Avoid contact during pregnancy / while nursing P280 Wear protective gloves~~/protective clothing/eye protection/face protection~~. P308 + P313 If exposed or if you feel unwell: Call a POISON CENTER or doctor/physician. P391 Collect spillage. P501 Dispose of contents/container in accordance with local regulation.
Additional labelling phrases:	None

*Reviewer comment: Following hazard classification entry (H410) are correct and reflects hazard for ecosystems, however in the part B6 of dRR it is not required to add environmetal proposals for classification and labelling, thus this entry has been removed from the table above.

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for FLU+TFS SC 500

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Gloves during mixing and loading and when handling contaminated surfaces during application
Workers	Acceptable	Gloves when handling treated crops for Ornamentals, Strawberry, Nurseries, Flower Bulbs ~~and Golf courses~~
Bystanders	Acceptable	None
Residents	Acceptable	None

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in *Reviewer comment: Following hazard classification entry (H410) are correct and reflects hazard for ecosystems, however in the part B6 of dRR it is not required to add environmetal proposals for classification and labelling, thus this entry has been removed from the table above.
Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in the following table.

Table 6.1-4: Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use-No.*	**Crops and situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ******	**Application**		**Application rate**		**PHI (d)**	**Remarks:** **(e.g. safener/synergist (L/ha))** **critical gap for operator, worker, bystander or resident exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind **(incl. application technique *****)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**Max. application rate kg as/ha** **a) TFS** **b) ~~CCZ~~ FLU**	**Water L/ha** **min / max**			**Operator**	**Worker**	**Bystander**	**Residents**
118	Flower bulbs (BBCH 12-91)	F	Spraying, LCTM	5 ; 5 (7 d)	~~a) 0.3~~ ~~b) 1.5~~ a) 0.075 b) 0.075	150-400	as per growth stage	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874				
~~124~~	~~Golf courses (BBCH 29-33)~~	~~F~~	~~Spraying, LCTM~~	~~2 ; 2 (14 d)~~	~~a) 0.5~~ ~~b) 1.0~~	~~200-600~~	~~as per growth stage~~	~~Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874~~				
138	Grapes (BBCH 15-73)	F	Spraying, LCTM	2 ; 2 (14 d)	~~a) 0.2~~ ~~b) 0.4~~ a) 0.050 b) 0.050	400-1200	14	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874				

1	2	3	4	5	6	7	8	9	10			
Use-No.*	**Crops and situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Application**		**Application rate**		**PHI (d)**	**Remarks:** **(e.g. safener/synergist (L/ha))** **critical gap for operator, worker, bystander or resident exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind **(incl. application technique *****	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**Max. application rate kg as/ha** **a) TFS** **b) ~~CCZ~~ FLU**	**Water L/ha** **min / max**			**Operator**	**Worker**	**Bystander**	**Residents**
141	Hop (BBCH 37-79)	F	Spraying, LCTM	2 ; 2 (14 d)	~~a) 0.6~~ ~~b) 1.2~~ a) 0.150 b) 0.150	2000-3000	14	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874				
169	Nurseries (BBCH 19-89)	F	Spraying, LCTM	2 ; 2 (14 d)	~~a) 0.8~~ ~~b) 0.8~~ a) 0.200 b) 0.200	500-750	as per growth stage	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874				
171	Ornamentals (BBCH 12-91)	F	Spraying, LCTM	1 ; 1 (- d)	~~a) 0.8~~ ~~b) 0.8~~ a) 0.200 b) 0.200	200-1000	as per growth stage	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874				
227	Strawberry (BBCH 60-89)	F	Spraying, LCTM LCHH	2 ; 2 (7 d)	~~a) 0.8~~ ~~b) 1.6~~ a) 0.200 b) 0.200	300-500	1	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874				

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

** 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

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 “Acceptability of exposure assessment”

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

Data gaps

Noticed data gaps are:

- No

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in the Tables below.

Table 6.2-1: Information on active substance fluopyram

Common Name	Fluopyram
CAS-No.	658066-35-4
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: - Code(s) for hazard pictogram(s): - Signal word: -none Hazard statement(s): - Precautionary statement(s): -
Additional C&L proposal	None
Agreed EU endpoints	
AOEL systemic	0.05 mg/kg bw/d
Reference	EFSA Conclusion (EFSA Journal 2013;11(4):3052) Kennel, P. (2005) – Doc M-251136-01-2
Conditions to take into account/critical areas of concern with regard to toxicology	
Review Report/EFSA Conclusion for active substance	None

Table 6.2-2: Information on active substance trifloxystrobin

Common Name	Trifloxystrobin
CAS-No.	141517-21-7
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Skin sensitisation: Category 1 Effects on or via lactation Code(s) for hazard pictogram(s): GHS07 Signal word: Warning Hazard statement(s): H317: May cause an allergic skin reaction. H362: May cause harm to breast-fed children. Precautionary statement(s): P263: Avoid contact during pregnancy P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Additional C&L proposal	None
Agreed EU endpoints	
AOEL systemic	0.06 mg/kg bw/d (based on 2-year rat study[1] with a safety factor of 100, also supported by rat multigeneration study, and corrected for an oral absorption of 60%)
AAOEL	0.3 mg/kg bw (based on rabbit developmental study[2] with a safety factor of 100 and corrected for an oral absorption of 60%)
Reference	EFSA Journal 2017;15(10):4989 Renewal Report for active substance TFS SANTE/10107/2018
Conditions to take into account/critical areas of concern with regard to toxicology	
Review Report/EFSA Conclusion for active substance	EFSA classification proposal (Repro. Cat 2, H361, H362) to be assessed by the Risk Assessment Committee of ECHA: Proposal by rapporteur member state: no classification. Following the EFSA Repro Cat. 2 classification proposal for Trifloxystrobin, according to Regulation EU/2018/1060:

	The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the relevance of metabolites that may occur in groundwater, taking into account any relevant classification for trifloxystrobin in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council, in particular as toxic for reproduction category 2. The applicant shall submit the information requested within one year after the publication, on the website of the European Chemicals Agency (ECHA), of the opinion adopted by the Committee for Risk Assessment of the ECHA in accordance with Article 37(4) of Regulation (EC) No 1272/2008 with respect to trifloxystrobin. Following the ECHA/RAC 50 meeting for trifloxystrobin, the Committee agreed on no classification for effects on sexual function and fertility and developmental toxicity. Regarding effects through or via lactation RAC sup-ported classification of trifloxystrobin as a substance that may cause harm to breast-fed children (Lact.; H362). (ECHA, 15 Nov. 2019).

[1] xxx., 1997; Doc M-040512-02-1 (KCA 5.5/01)
[2] xxx 1994; Doc M-039377-03-1 (KCA 5.6.2/02)

Target specific AOELs for combined non-dietary exposure assessments for Trifloxystrobine		
$AOEL_{Liver}$	0.06 mg/kg bw/day	Liver effects (increased liver weight and hepatocellular hypertrophy) were found in short-term and long-term studies at doses ≥ 30 mg/kg. In addition, in mice at doses ≥ 300 mg/kg single cell necrosis or necrosis of small groups of hepatocytes were observed. The respective AOELliver for Trifloxystrobin is 0.06 mg/kg bw/day and is based on the NOAELliver of 10 mg/kg bw/day applying a safety factor of 100 and adjusted for limited oral absorption of 60%.
$AOEL_{developmental}$	0.3 mg/kg bw/day	In the case of Trifloxystrobin the data from the devel-opmental toxicity studies are not appropriate to derive target specific AOELs (the NOAELs in dams & does are based on unspecific findings like reduced maternal body weight/gain and food intake only). NOAELs in foetuses were ≥ 50 mg/kg bw/day based on unspecific findings in foetuses (enlarged thymus in rats and in-creased incidence of sternebral findings (variations) in rabbits). Consequently, no developmental specific AOEL for TFS should be set. However, according to the EFSA conclusion an AA-OEL is set at 0.3 mg/kg bw/day based on the NOAEL of the developmental toxicity study in rabbits applying a safety factor of 100 and adjusted for limited oral absorption of 60%.

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for FLU+TFS SC 500 is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for FLU+TFS SC 500

Type of test, species, model system (Guideline)	**Result**	**Acceptability**	**Classification (acc. to the criteria in Reg. 1272/2008)**	**Reference**
LD_{50} oral, rat (OECD 423)	$LD_{50\ cut\ off}$ 2000 mg/kg bw	Yes	Acute Tox. 4, H302	xxx
LD_{50} dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	xxx
LC_{50} inhalation, rat (OECD 403)	> 1742 mg/L air	Yes	None	xxx
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None	xxx

Eye irritation, rabbit (OECD 405)	Non-irritant	Yes	None	xxx
Skin sensitisation, (OECD 429, /LLNA)	Non-sensitising	Yes	None	xxx
Supplementary studies for combinations of plant protection products	No data – not required	N/A	N/A	N/A

Table 6.3-2: Additional toxicological information relevant for classification/labelling of FLU+TFS SC 500

	Substance (Concentration in product, % w/w)	**Classification of the substance (acc. to the criteria in Reg. 1272/2008)**	**Reference**	**Classification of product (acc. to the criteria in Reg. 1272/2008)**
Toxicological properties of active substance(s) (relevant for classification of product)	Fluopyram (CAS No. 658066-35-4, 21.37 % (w/w))	Not classified	Reg. 1272/2008	None
	Trifloxystrobin (CAS No. 141517-21-7, 21.37 % (w/w))	Skin Sens. 1, H317 Lact., H362	Reg. 1272/2008	EUH208 H362
Toxicological properties of non-active substance(s) (relevant for classification of product)	1,2-Benzisothiazol-3(2H)-one (CAS No. 2634-33-5, ≥ 0.005 - < 0.05 % (w/w))*	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317	Reg. 1272/2008	EUH208
	reaction mass of 5-chloro-2- methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1) (CAS 55965-84-9, ≥ 0.00015 - < 0.0015 % (w/w))*	Acute Tox. 3, H301 Acute Tox. 2, H310 Acute Tox. 2, H330 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317	Reg. 1272/2008	EUH208
	1,2 Propanediol (CAS 57-55-6, > 1 % (w/w))*	Not classified	Reg. 1272/2008	None
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10 % or > 1 %) as provided in MSDS.

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

6.4.1 Fluopyram

No data/information submitted since only data on the renewed active substance trifloxystrobin will be evaluated by zRMS for the Renewal of Authorisations according to Art. 43 of Reg 1107/2009.

6.4.2 Trifloxystrobin

The following data on metabolites with the potential to reach the groundwater in concentrations above 0.1 µg/L and requiring relevance assessment were submitted. Note that the relevance assessment of the metabolites is reported in Part B.10; the submitted toxicological studies are summarized in this document.

Trifloxystrobin, metabolite CGA 321113

An overview of the results of the accepted toxicological studies for groundwater metabolite CGA 321113 is given in the following table.

Table 6.4-1: Summary of the results of toxicity studies for CGA 321113

Type of test, species (Guideline)	Concentration range tested	Result	Acceptability	Reference*
Bacterial reverse mutation assay, *S. typhimurium* strains: TA1535, TA1537, TA98, TA100, TA102 (OECD 471)	3 – 5000 µg/plate (+/- S9 mix)	Negative (+/- S9 mix)	Yes	Sokolowski (2011) M-406346-01-1*
Mammalian cell gene mutation, Chinese hamster V79 cells (OECD 476)	5 – 320 µg/mL (- S9 mix) 40 – 640 µg/mL (+ S9 mix)	Negative (+/- S9 mix)	Yes	Wollny (2011) M-411413-01-1*
In vitro chromosome aberration, Chinese hamster V79 cells (OECD 473)	40 – 125 µg/mL (- S9 mix) 200 – 400 µg/mL (+ S9 mix)	Positive (+/- S9 mix)	Yes	Hall (2011) M-413745-01-1*
In vivo Micronucleus test, Mouse bone marrow (OECD 474)	500, 1000, 2000 mg/kg bw (oral, gavage)	Negative	Yes	xxx (2013) M-463614-01-1*
In vivo UDS, Rat hepatocytes (OECD 486)	1000 – 2000 mg/kg bw (oral, gavage)	Negative	Yes	Xxx (2013) M-458428-01-1*
In vitro hepatotoxicity and inhibition of mitochondrial respiration, Rat hepatocytes (No guideline study)	Cytotoxicity assessment: Trifloxystrobin: 5 – 100 µM CGA 321113: 5 – 600 µM Mitochondrial respiration: Trifloxystrobin: 10 – 600 nM CGA 321113: 1000 – 30000 nM	CGA 321113 is about 20 times less cytotoxic than TFS. TFS inhibited rat liver mitochondrial respiration *in vitro*, CGA 321113 showed no inhibitory effect	Yes	Bouis (1997) M-039240-01-1*
Interactions with mitochondrial respiration *in vitro*,	TFS: 10 – 600 nM CGA 321113: 5.9 µM CGA 373466: 5.5 µM	Compared to the parent compound TFS, these metabolites are unlikely to	Yes	Freyberger (2002) M-034840-02-1*

Type of test, species (Guideline)	Concentration range tested	Result	Acceptability	Reference*
Rat liver mitochondria (No guideline study)	NOA 413161: 5.8 µM NOA 413163: 5.9 µM	contribute to toxicities mediated by mitochondrial complex III inhibition		
In vitro hepatotoxicity, Rat hepatocytes (No guideline study)	TFS: 1 – 100 µg/mL CGA 321113: 1 – 500 µg/mL CGA 373466: 1 –1000 µg/mL NOA 413161: 1 –1000 µg/mL NOA 413163: 1 –1000 µg/mL	TFS distictly higher hepatotoxic potential than CGA 321113 and CGA 373466. NOA 413161 and NOA 413163 revealed no hepatotoxic potential	Yes	Wasinska-Kempka (2002) M-090653-02-1*

* Study reviewed at EU level for the approval of the active substance

The metabolite CGA 321113, which is also a component of the residue definition, is addressed by the toxicological data package for the parent compound since it accounted for >10% of the systemically available dose in the rat metabolism (ADME) study. Therefore, the toxicity studies performed with the parent compound are sufficient for the toxicity assessment of the metabolite.

In a comparative in-vitro test in rat hepatocytes CGA 321113 caused significantly (900-1000 times) less inhibition of mitochondrial respiration than trifloxystrobin. Since significant inhibition of cellular respiration is likely to have major toxicological consequences for mammals, it is to be expected that CGA 321113 would be less toxic than the parent molecule. CGA 321113 was found to be 10-30 times less hepatotoxic (NOEC 100 µg/mL) than trifloxystrobin (NOEC 3 µg/mL) in rat hepatocytes in-vitro.

In order to fulfil SANCO/221/2000 - rev. 10, 25th February 2003 requirements, the genotoxicity potential of CGA 321113 has been investigated in a battery of *in vitro* and *in vivo* tests. CGA 321113 does not induce mutations in bacteria and in mammalian cell, both with and without metabolic activation. However, CGA 321113 shows a clastogenicity potential in the *in vitro* chromosome aberration assay but this response has not been confirmed in the micronucleus test *in vivo*. Furthermore, the *in vivo* unscheduled DNA synthesis assay also resulted negative.

It can be concluded that the metabolite CGA 321113 is less toxic than the parent compound and overall possesses no genotoxic potential.

Trifloxystrobin, metabolite NOA 413161

An overview of the results of the accepted toxicological studies for groundwater metabolite NOA 413161 is given in the following table.

Table 6.4-2: Summary of the results of toxicity studies for NOA 413161

Type of test, species (Guideline)	Concentration range tested	Result	Acceptability	Reference*
Bacterial reverse mutation assay, *S. typhimurium* strains: TA1535, TA1537, TA98, TA100, TA102 *E.coli* strain: WP2uvrA (OECD 471)	312.5 – 5000 mg/plate (+/- S9 mix)	Negative (+/- S9 mix)	Yes	Deparade (1998) M-054210-01-1*
In vitro mammalian cell gene mutation, Chinese hamster V79 cells (OECD 476)	375 – 3000 mg/mL (+/- S9 mix)	Negative (+/- S9 mix)	Yes	Ogorek (2000) M-054225-01-1*
In vitro mammalian chromosome aberration, Chinese hamster CHO cells (OECD 473)	625 – 2500 µg/mL (+/- S9 mix)	Negative (+/- S9 mix)	Yes	Ogorek (1999) M-054214-01-1*
Acute oral, Rat (OECD 401)	2000 mg/kg bw	LD_{50} > 2000 mg/kg bw	Yes	xxx (1998) M-052694-01-1*
4-week oral (gavage), and 4-week recovery, Rat (96/54/EEC, B.7)	15, 50, 150, 1000 mg/kg bw/d	NOAEL 1000 mg/kg bw/d (NOAEL: 150 (M) NOAEL: 1000 (F) mg/kg bw/d based on increased urobilinogen levels in males see Addendum III to the DAR)	Yes	xxx (2000) M-137124-01-1*
Interactions with mitochondrial respiration *in vitro*, Rat liver mitochondria (No guideline study)	TFS: 10 – 600 nM CGA 321113: 5.9 µM CGA 373466: 5.5 µM NOA 413161: 5.8 µM NOA 413163: 5.9 µM	Compared to the parent compound TFS, these metabolites are unlikely to contribute to toxicities mediated by mitochondrial complex III inhibition	Yes	Freyberger (2002) M-034840-02-1*
In vitro hepatotoxicity, Rat hepatocytes (No guideline study)	TFS: 1-100 µg/mL CGA 321113: 1-500 µg/mL CGA 373466: 1-1000 µg/mL NOA 413161: 1-1000 µg/mL NOA 413163: 1-1000 µg/mL	TFS distictly higher hepatotoxic potential than CGA321113 and CGA 373466. NOA 413161 and NOA 413163 revealed no hepatotoxic potential	Yes	Wasinska-Kempka (2002) M-090653-02-1*

* Study reviewed at EU level for the approval of the active substance

The metabolite NOA 413161 is non-toxic (LD_{50} > 2000 mg/kg bw) after acute oral exposure. There were no indications for a mutagenic or clastogenic effect in the bacterial reverse mutation assay and in mammalian cells *in vitro*.

In a comparative in-vitro test in rat hepatocytes NOA 413161 caused significantly (900-1000 times) less inhibition of mitochondrial respiration than trifloxystrobin. Since significant inhibition of cellular respiration is likely to have major toxicological consequences for mammals, it is to be expected that NOA 413161 would be less toxic than the parent molecule. NOA 413161 was found to be clearly less hepatotoxic (NOEC >1000 µg/mL) than trifloxystrobin (NOEC 3 µg/mL) in rat hepatocytes in-vitro. Furthermore, the 28-day oral rat study resulted in an about 10 times higher NOAEL than trifloxystrobin.

After four-week oral exposure (gavage) the only treatment-related effect were increased urobilinogen levels in males. The NOAEL established by the study director is 1000 mg/kg bw/day in males/females. However,

during the EU review process a NOAEL of 150 mg/kg bw/day in males and 1000 mg/kg bw/day in females was established.

Overall it can be concluded that the metabolite NOA 413161 is less toxic than the parent compound and possesses no genotoxic potential. ADI of NOA 413161 is set at 0.15 mg/kg bw/day based on the rat 28-day study and an uncertainty factor of 1000.

Trifloxystrobin, metabolite NOA 413163

An overview of the results of the accepted toxicological studies for groundwater metabolite NOA 413163 is given in the following table.

Table 6.4-3: Summary of the results of toxicity studies for NOA 413163

Type of test, species (Guideline)	Concentration range tested	Result	Acceptability	Reference*
Bacterial reverse mutation assay, *S. typhimurium* strains: TA1535, TA1537, TA98, TA100, TA102 *E.coli* strain: WP2uvrA (OECD 471)	312.5 – 5000 mg/plate (+/- S9 mix)	Negative (+/- S9 mix)	Yes	Deparade (1998) M-052705-01-1*
Acute oral, Rat (OECD 401)	2000 mg/kg bw	LD_{50} > 2000 mg/kg bw	Yes	xxx(1998) M-052684-01-1*
Interactions with mitochondrial respiration *in vitro*, Rat liver mitochondria (No guideline study)	TFS: 10 – 600 nM CGA 321113: 5.9 µM CGA 373466: 5.5 µM NOA 413161: 5.8 µM NOA 413163: 5.9 µM	Compared to the parent compound TFS, these metabolites are unlikely to contribute to toxicities mediated by mitochondrial complex III inhibition	Yes	Freyberger (2002) M-034840-02-1*
In vitro hepatotoxicity, Rat hepatocytes (No guideline study)	TFS: 1-100 µg/mL CGA 321113: 1-100 µg/mL CGA 373466: 1-1000 µg/mL NOA 413161: 1-1000 µg/mL NOA 413163: 1-1000 µg/mL	TFS distictly higher hepatotoxic potential than CGA 321113 and CGA 373466. NOA 413161 and NOA 413163 revealed no hepatotoxic potential	Yes	Wasinska-Kempka (2002) M-090653-02-1*
Studies with NOA 413161 / NOA 413163				
In vitro mammalian cell gene mutation test, HPRT, Chinese hamster V79 cells (OECD 476)	600 – 3000 µg/mL (+/- S9 mix)	Negative (+/- S9 mix)	Yes	Herbold (2002) M-069760-01-1*
In vitro mammalian chromosome aberration test, Chinese hamster V79 cells (OECD 473)	625 – 2500 µg/mL (+/- S9 mix)	Negative (+/- S9 mix)	Yes	Herbold (2002) M-069747-01-1*
4-week oral (gavage), and 4-week recovery Rat (OECD 407)	10, 50, 200, 1000 mg/kg bw/day	NOAEL: 1000 mg/kg bw/d (m/f)	Yes	xxx (2003) M-084123-01-1*

* Study reviewed at EU level for the approval of the active substance

The metabolite NOA 413163 is non-toxic (LD_{50} > 2000 mg/kg bw) after acute oral exposure. There were also no indications for a mutagenic effect in the bacterial reverse mutation assay.

In a comparative in-vitro test in rat hepatocytes NOA 413163 caused significantly (900-1000 times) less inhibition of mitochondrial respiration than trifloxystrobin. Since significant inhibition of cellular respiration is likely to have major toxicological consequences for mammals, it is to be expected that NOA 413163 would be less toxic than the parent molecule. NOA 413163 was found to be less (NOEC >1000 µg/mL) hepatotoxic than trifloxystrobin (NOEC 3 µg/mL) in rat hepatocytes in-vitro.

In addition, the mixture of the metabolites NOA 413161 and NOA 413163 (mixture containing 48 % NOA 413161 and 51 % NOA 413163) showed no genotoxic potential in the *in vitro* mammalian cell gene mutation assay and in the *in vitro* mammalian chromosome aberration test.

After four-week oral exposure of 1000 mg/kg bw/day of NOA 413161 / NOA 413163 slight changes of hematological and urinary parameters were observed but these findings were not considered adverse. The NOAEL is 1000 mg/kg bw/day in males/females.

Overall it can be concluded that the metabolite NOA 413163 is less toxic than the parent compound and possesses no genotoxic potential. ADI of NOA 413163 is set at 0.52 mg/kg bw/day based on the rat 28-day study with the mixture of NOA 413161 and NOA 413163 corrected for the content of NOA 413163 in the mixture and an uncertainty factor of 1000.

Trifloxystrobin, metabolite CGA 373466

An overview of the results of the accepted toxicological studies for groundwater metabolite CGA 373466 is given in the following table.

Table 6.4-4: Summary of the results of toxicity studies for CGA 373466

Type of test, species (Guideline)	Concentration range tested	Result	Acceptability	Reference*
Bacterial reverse mutation assay, *S. typhimurium* strains: TA1535, TA1537, TA98, TA100, TA102 *E.coli* strain: WP2uvrA (OECD 471)	312.5 – 5000 mg/plate (+/- S9 mix)	Negative (+/- S9 mix)	Yes	Deparade (1997) M-039119-01-1*
In vitro mammalian cell gene mutation, Chinese hamster V79 cells (OECD 476)	50 - 1200 mg/mL (+/- S9 mix)	Negative (+/- S9 mix)	Yes	Herbold (2002) M-054116-01-1*
In vitro mammalian chromosome aberration, Chinese hamster CHO cells (OECD 473)	125 – 600 µg/mL (+/- S9 mix)	Negative (+/- S9 mix)	Yes	Herbold (2002) M-054928-01-1*
Acute oral, Rat (OECD 401)	2000 mg/kg bw	LD_{50} > 2000 mg/kg bw	Yes	xxx (1997) M-039100-02-1*
4-week oral (dietary), and 4-week recovery, Rat (96/54/EEC, B.7)	0-100-500-2000-8000 ppm (equivalent to 0 - 9.6/11 - 47/61 - 209/236 – 903/928 mg/kg bw/d in males/females)	NOAEL: 2000 ppm (209/236 mg/kg bw/d) based on retarded body weight development, effects on red blood cells, slight liver enzyme	Yes	xxx (2003) M-088404-01-1 (new study submitted for the renewal process but

Type of test, species (Guideline)	Concentration range tested	Result	Acceptability	Reference*
		induction (see MCA, section 5)		not evaluated)
Interactions with mitochondrial respiration *in vitro*, Rat liver mitochondria (No guideline study)	TFS: 10 – 600 nM CGA 321113: 5.9 µM CGA 373466: 5.5 µM NOA 413161: 5.8 µM NOA 413163: 5.9 µM	Compared to the parent compound TFS, these metabolites are unlikely to contribute to toxicities mediated by mitochondrial complex III inhibition	Yes	Freyberger (2002) M-034840-02-1*
In vitro hepatotoxicity, Rat hepatocytes (No guideline study)	TFS: 1-100 µg/mL CGA 321113: 1-500 µg/mL CGA 373466: 1-1000 µg/mL NOA 413161: 1-1000 µg/mL NOA 413163: 1-1000 µg/mL	TFS distictly higher hepatotoxic potential than CGA 321113 and CGA 373466. NOA 413161 and NOA 413163 revealed no hepatotoxic potential	Yes	Wasinska-Kempka (2002) M-090653-02-1*

* indicates that a study was reviewed at EU level

The metabolite CGA 373466 is non-toxic (LD_{50} > 2000 mg/kg bw) after acute oral exposure. There were no indications for a mutagenic or clastogenic effect in the bacterial reverse mutation assay and in mammalian cells *in vitro*.
In a comparative in-vitro test in rat hepatocytes CGA 373466 caused significantly (900-1000 times) less inhibition of mitochondrial respiration than trifloxystrobin. Since significant inhibition of cellular respiration is likely to have major toxicological consequences for mammals, it is to be expected that CGA 373466 would be significantly less toxic than the parent molecule. CGA 373466 was found to be less hepatotoxic (NOEC >100 µg/mL) than trifloxystrobin (NOEC 3 µg/mL) in rat hepatocytes in-vitro.

After four week oral exposure (diet) treatment-related effects were retarded body weight development, effects on red blood cells and slight liver enzyme induction. A NOAEL can be established at 2000 ppm (209/236 mg/kg bw/day in males/females).

Overall it can be concluded that the metabolite CGA 373466 is less toxic than the parent compound and possesses no genotoxic potential. ADI of CGA 373466 is set at 0.2 mg/kg bw/day based on the rat 28-day study and an uncertainty factor of 1000.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in FLU+TFS SC 500 are presented in the following table. Proposed dermal absorption rates for trifloxystrobin and fluopyram are based on dermal absorption studies performed on a previous specification version of FLU+TFS SC 500. The equivalence of composition is demonstrated in a bridging statement (Vinck K. and Immink H., 2020) found in the confidential Part C of the draft Registration Report.

Table 6.5-1: Dermal absorption rates for active substances in FLU+TFS SC 500

	Fluopyram	
	Value	**Reference**
Concentrate	0.083 %	New study reported in Appendix 2
Dilution (1 in 1250)	5.9 %	New study reported in Appendix 2
Dilution (1 in 7600)	18 %	New study reported in Appendix 2
	Trifloxystrobin	
	Value	**Reference**
Concentrate	0.14 %	New study reported in Appendix 2
Dilution (1 in 1250)	0.95 %	New study reported in Appendix 2
Dilution (1 in 7600)	16 %	New study reported in Appendix 2

6.5.1 Justification for proposed values - Fluopyram

Data on dermal absorption for fluopyram in product FLU+TFS SC 500 is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) are presented in the following table.

Default dermal absorption rates for Fluopyram

Proposed dermal absorption rates for fluopyram are based on dermal absorption studies on a formulation identical to FLU+TFS SC 500[#]. The study results are summarized in the following table. Full summaries of studies on the dermal absorption of active substance/formulation that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2. / The results of the experiments with product code/name are not applicable for the risk assessment of the present application.

Table 6.5-2: Summary of the results of submitted dermal absorption studies for Fluopyram

Test	**Concentrate**	**Spray dilution (dilution factor)**	**Formulation in study**	**Acceptability of study**	**Justification provided on representativity of study formulation for current product**	**Acceptability of justification**	**Reference**
In vitro (Human)	0.083%	5.9% (1 in 1250) 18% (1 in 7600)	FLU+TFS SC 500	Yes, endpoint can be used for current product	Not required	N/A	Bernal, J. 2014.

* indicates that a study was reviewed at EU level

[#] **Reviewer comment:**
Detailed bridging assessment provided in the Part C (Vinck, K.; Immink, H.; 2020) has been considered as sufficient to conclude applicability of submitted dermal absorption studies for the current registration process and the dermal absorption values for fluopyram and trifloxystrobin can be used when moving from the formulation specification 10200002886-04 to specification 10200002886-05. This assessment aims to demonstrate that dermal absorption studies prepared for the formulation coded 102000012886-04 are also usable without further testing for the formulation coded 102000012886-05. In accordance with the EFSA guidance on dermal absorption 2017 (*EFSA (European Food Safety Authority), 2017. Guidance on dermal absorption. EFSA Journal 2017; 15(6): 4873*).

6.5.2 Justification for proposed values - Trifloxystrobin

Data on dermal absorption for trifloxystrobin in FLU+TFS SC 500 is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) are presented in the

following table.

Default dermal absorption rates for Trifloxystrobin

Proposed dermal absorption rates for trifloxystrobin are based on dermal absorption studies on a formulation identical to FLU+TFS SC 500[#]. The study results are summarized in the following table. Full summaries of studies on the dermal absorption of active substance/formulation that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2. / The results of the experiments with product code/name are not applicable for the risk assessment of the present application.

Table 6.5-3: Summary of the results of submitted dermal absorption studies for Trifloxystrobin

Test	Concentrate	Spray dilution (dilution factor)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference
In vitro (Human)	0.14%	0.95% (1 in 1250) 16% (1 in 7600)	FLU+TFS SC 500	Yes, endpoint can be used for current product	Not required	N/A	Odin-Feurtet, M. 2014.

* indicates that a study was reviewed at EU level

[#]**Reviewer comment:**
Detailed bridging assessment provided in the Part C (Vinck, K.; Immink, H.; 2020) has been considered as sufficient to conclude applicability of submitted dermal absorption studies for the current registration process and the dermal absorption values for fluopyram and trifloxystrobin can be used when moving from the formulation specification 10200002886-04 to specification 10200002886-05. This assessment aims to demonstrate that dermal absorption studies prepared for the formulation coded 102000012886-04 are also usable without further testing for the formulation coded 102000012886-05. In accordance with the EFSA guidance on dermal absorption 2017 (*EFSA (European Food Safety Authority), 2017. Guidance on dermal absorption. EFSA Journal 2017; 15(6): 4873*).

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product	FLU+TFS SC 500 (250+250)						
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.						
Active substance(s) (incl. content)	**Substance Concentration** [g/L or g/kg]	**$AOEL_{systemic}$ (RVNAS)** [mg/kg bw/d]	**AAOEL (RVAAS)** [mg/kg bw/d]	**Inhalation absorption [%]**	**Oral absorption [%]**	**Dermal absorption***	
						Concentrate **[%]**	Dilution **[%]**
Fluopyram (FLU)	250	0.05	-	100	100	0.083	18
Trifloxystrobin (TFS)	250	0.06	0.3	100	100	0.14	16

**For more information please refer to chapter 6.5*

6.6.1 Selection of critical use(s) and justification

The critical GAP(s) used for the exposure assessment of the plant protection product are shown in Table 6.1-4. A list of all intended uses within the zone/ EU is given in Part B, Section 0.

Justification

Operator
As critical use Flower bulbs (118), ~~Golf courses (124),~~ Grapes (138), Hops (141), Ornamentals (171) and Strawberry (227) are used for calculations.
These uses cover the highest application rates as worst-case scenarios.
Use Strawberry (227) is used for calculation of tractor-mounted and hand-held application techniques.
As use for the upward application scenario Grapes (138) and Hops (141) are presented.

Worker
As critical use Flower bulbs (118), ~~Golf courses (124),~~ Grapes (138), Hops (141), Ornamentals (169 and 171) and Strawberry (227) are used for calculations.
Use Strawberry (227) covers 2 applications for low crops with tractor-mounted and hand-held techniques as worst-case scenario.
The use Ornamentals (169 and 171) is presented to cover the lowest water volume and highest application number for low crops.
As use for the upward application scenario Grapes (138) and Hops (141) are presented.

Bystander/Resident
As critical use Flower bulbs (118), ~~Golf courses (124),~~ Grapes (138), Hops (141), Ornamentals (169) and Strawberry (227) are used for calculations.
Use Strawberry (227) is presented to cover the lowest water volume as worst case. In addition, the use Ornamentals (169) is presented to cover the lowest water volume with 2 applications for low crops.
As critical use the for upward application scenario Grapes (138) and Hops (141) are presented.

6.6.2 Operator exposure (KCP 7.2.1)

Reviewer comment	NDE calculation, provided by the APPL has been aaccdpted by the ZRMS as sufficient to risk assessment.

No acute non-dietary risk assessment for fluopyram is included in this submission. Lack of scientific guidance or methodology is an acceptable reason for waiving according to Guidance of the European Commission[1]. The absence of such guidance on derivation of an appropriate reference dose ("AAOEL") was recognized by

- the European Food Safety Authority[2], and
- the European Commission Standing Committee[3].

Therefore, this waiver is presented in line with the Guidance of the European Commission.

This applies for the same degree with regard to acute operator exposure estimates.

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for the estimation of operator exposure to the active substance(s) during application of FLU+TFS SC 500 (250+250) according to the critical use(s) is presented in the following table. Detailed calculations are presented in Appendix 3.

[1] Guidance Document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013. SANCO/10181/2013, May 2013
[2] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874
[3] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. SANTE-10832-2015

Table 6.6-2: Exposure models for intended uses

Critical use(s)	0.2 L / kg product/ha for Grapes 0.8 L / kg product/ha for Low berries and other small fruits 0.6 L / kg product/ha for Hops 0.3 L / kg product/ha for Root and tuber vegetables 0.8 L / kg product/ha for Ornamentals ~~0.5 L / kg product/ha for Golf course, turf or other sports lawns~~
Model(s)	*Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874*

The outcome of the estimation is presented in the following table(s).

Table 6.6-3: Estimated operator exposure, Fluopyram, Grapes

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Upward spraying, Vehicle-mounted Application rate: 0.05 kg a.s./ha			
EFSA Operator Model (75^{th} quantile regression)	no PPE[2]	0.00681	13.6
	with PPE[3]	0.00273	5.46

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-4: Estimated operator exposure, Fluopyram, Low berries and other small fruits

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Downward spraying, Vehicle-mounted Application rate: 0.2 kg a.s./ha			
EFSA Operator Model (75^{th} quantile regression)	no PPE[2]	0.00522	10.4
	with PPE[3]	0.000819	1.64

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-5: Estimated operator exposure, Fluopyram, Low berries and other small fruits

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Downward spraying, Manual-Hand held Application rate: 0.2 kg a.s./ha			
EFSA Operator Model (75^{th} quantile regression)	no PPE[2]	0.0319	63.9
	with PPE[3]	0.0273	54.5

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-6: Estimated operator exposure, Fluopyram, Low berries and other small fruits

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Downward spraying, Manual-Knapsack Application rate: 0.2 kg a.s./ha			
EFSA Operator Model (75^{th} quantile regression)	no PPE[2]	0.0324	64.7
	with PPE[3]	0.0276	55.2

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-7: Estimated operator exposure, Fluopyram, Hops

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Upward spraying, Vehicle-mounted Application rate: 0.15 kg a.s./ha			
EFSA Operator Model (75^{th} quantile regression)	no PPE[2]	0.0181	36.1
	with PPE[3]	0.0073	14.6

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-8: Estimated operator exposure, Fluopyram, Root and tuber vegetables

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Downward spraying, Vehicle-mounted Application rate: 0.075 kg a.s./ha			
EFSA Operator Model (75^{th} quantile regression)	no PPE[2]	0.00205	4.11
	with PPE[3]	0.00046	0.92

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-9: Estimated operator exposure, Fluopyram, Ornamentals

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Downward spraying, Vehicle-mounted Application rate: 0.2 kg a.s./ha			
EFSA Operator Model (75^{th} quantile regression)	no PPE[2]	0.0103	20.6
	with PPE[3]	0.000546	1.09

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

~~**Table 6.6-10: Estimated operator exposure, Fluopyram, Golf course, turf or other sports lawns**~~

~~Model data~~	~~Level of PPE~~	~~Total absorbed dose (mg/kg/day)~~	~~% of systemic AOEL[1] (RVNAS)~~
~~Outdoor, Downward spraying, Vehicle-mounted Application rate: 0.125 kg a.s./ha~~			
~~**EFSA Operator Model** (75^{th} quantile regression)~~	~~no PPE[2]~~	~~0.00333~~	~~6.66~~
	~~with PPE[3]~~	~~0.000617~~	~~1.23~~

~~[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day~~
~~[2] no PPE: Work wear - arms, body and legs covered~~
~~[3] with PPE: Covered body and gloves.~~

Table 6.6-11: Estimated operator exposure, Trifloxystrobin, Grapes

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Upward spraying, Vehicle-mounted Application rate: 0.05 kg a.s./ha			
EFSA Operator Model (75^{th} quantile regression)	no PPE[2]	0.00617	10.3
	with PPE[3]	0.00251	4.19

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-12: Estimated acute operator exposure, Trifloxystrobin, Grapes

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL[1] (RVAAS)
Outdoor, Upward spraying, Vehicle-mounted Application rate: 0.05 kg a.s./ha			
EFSA Operator Model (95th quantile regression)	no PPE[2]	0.0195	6.5
	with PPE[3]	0.0122	4.06

[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-13: Estimated operator exposure, Trifloxystrobin, Low berries and other small fruits

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Downward spraying, Vehicle-mounted Application rate: 0.2 kg a.s./ha			
EFSA Operator Model (75th quantile regression)	no PPE[2]	0.00498	8.3
	with PPE[3]	0.000757	1.26

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-14: Estimated acute operator exposure, Trifloxystrobin, Low berries and other small fruits

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL[1] (RVAAS)
Outdoor, Downward spraying, Vehicle-mounted Application rate: 0.2 kg a.s./ha			
EFSA Operator Model (95th quantile regression)	no PPE[2]	0.0367	12.2
	with PPE[3]	0.0129	4.31

[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-15: Estimated operator exposure, Trifloxystrobin, Low berries and other small fruits

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Downward spraying, Manual-Hand held Application rate: 0.2 kg a.s./ha			
EFSA Operator Model (75th quantile regression)	no PPE[2]	0.0285	47.5
	with PPE[3]	0.0243	40.5

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-16: Estimated acute operator exposure, Trifloxystrobin, Low berries and other small fruits

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL[1] (RVAAS)
Outdoor, Downward spraying, Manual-Hand held Application rate: 0.2 kg a.s./ha			
EFSA Operator Model (95th quantile regression)	no PPE[2]	0.18	59.9
	with PPE[3]	0.168	56.1

[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-17: Estimated operator exposure, Trifloxystrobin, Low berries and other small fruits

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Downward spraying, Manual-Knapsack Application rate: 0.2 kg a.s./ha			
EFSA Operator Model (75th quantile regression)	no PPE[2]	0.029	48.3
	with PPE[3]	0.0246	41.1

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-18: Estimated acute operator exposure, Trifloxystrobin, Low berries and other small fruits

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL[1] (RVAAS)
Outdoor, Downward spraying, Manual-Knapsack Application rate: 0.2 kg a.s./ha			
EFSA Operator Model (95^{th} quantile regression)	no PPE[2]	0.18	60
	with PPE[3]	0.168	56.1

[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-19: Estimated operator exposure, Trifloxystrobin, Hops

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Upward spraying, Vehicle-mounted Application rate: 0.15 kg a.s./ha			
EFSA Operator Model (75^{th} quantile regression)	no PPE[2]	0.0163	27.2
	with PPE[3]	0.00664	11.1

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-20: Estimated acute operator exposure, Trifloxystrobin, Hops

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL[1] (RVAAS)
Outdoor, Upward spraying, Vehicle-mounted Application rate: 0.15 kg a.s./ha			
EFSA Operator Model (95^{th} quantile regression)	no PPE[2]	0.0574	19.1
	with PPE[3]	0.0356	11.9

[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-21: Estimated operator exposure, Trifloxystrobin, Root and tuber vegetables

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Downward spraying, Vehicle-mounted Application rate: 0.075 kg a.s./ha			
EFSA Operator Model (75^{th} quantile regression)	no PPE[2]	0.00199	3.32
	with PPE[3]	0.000427	0.711

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-22: Estimated acute operator exposure, Trifloxystrobin, Root and tuber vegetables

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL[1] (RVAAS)
Outdoor, Downward spraying, Vehicle-mounted Application rate: 0.075 kg a.s./ha			
EFSA Operator Model (95^{th} quantile regression)	no PPE[2]	0.0181	6.02
	with PPE[3]	0.0112	3.73

[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-23: Estimated operator exposure, Trifloxystrobin, Ornamentals

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
Outdoor, Downward spraying, Vehicle-mounted Application rate: 0.2 kg a.s./ha			
EFSA Operator Model (75^{th} quantile regression)	no PPE[2]	0.00926	15.4
	with PPE[3]	0.00051	0.849

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

Table 6.6-24: Estimated acute operator exposure, Trifloxystrobin, Ornamentals

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL[1] (RVAAS)
Outdoor, Downward spraying, Vehicle-mounted Application rate: 0.2 kg a.s./ha			
EFSA Operator Model (95th quantile regression)	no PPE[2]	0.0198	6.61
	with PPE[3]	0.00259	0.863

[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day
[2] no PPE: Work wear - arms, body and legs covered
[3] with PPE: Covered body and gloves.

~~**Table 6.6-25: Estimated operator exposure, Trifloxystrobin, Golf course, turf or other sports lawns**~~

~~Model data~~	~~Level of PPE~~	~~Total absorbed dose (mg/kg/day)~~	~~% of systemic AOEL[1] (RVNAS)~~
~~Outdoor, Downward spraying, Vehicle-mounted Application rate: 0.125 kg a.s./ha~~			
~~**EFSA Operator Model** (75th quantile regression)~~	~~no PPE[2]~~	~~0.0032~~	~~5.33~~
	~~with PPE[3]~~	~~0.000572~~	~~0.953~~

~~[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day~~
~~[2] no PPE: Work wear – arms, body and legs covered~~
~~[3] with PPE: Covered body and gloves.~~

~~**Table 6.6-26: Estimated acute operator exposure, Trifloxystrobin, Golf course, turf or other sports lawns**~~

~~Model data~~	~~Level of PPE~~	~~Total absorbed dose (mg/kg/day)~~	~~% of systemic AAOEL[1] (RVAAS)~~
~~Outdoor, Downward spraying, Vehicle-mounted Application rate: 0.125 kg a.s./ha~~			
~~**EFSA Operator Model** (95th quantile regression)~~	~~no PPE[2]~~	~~0.0261~~	~~8.7~~
	~~with PPE[3]~~	~~0.012~~	~~4.01~~

~~[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day~~
~~[2] no PPE: Work wear – arms, body and legs covered~~
~~[3] with PPE: Covered body and gloves.~~

6.6.3 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the Acceptable Operator Exposure Level (AOEL/RVNAS) as well as the Acute Acceptable Operator Exposure Level (AAOEL/RVAAS) will not be exceeded under conditions of intended uses and considering above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was

therefore not performed.

6.6.4 Worker exposure (KCP 7.2.3)

6.6.4.1 Estimation of worker exposure

A summary of the exposure models used for the estimation of worker exposure with default DFR (= 3 µg/cm²) to the active substance(s) after entry into a previously treated area or handling a crop treated with FLU+TFS SC 500 is presented in the following table. Detailed calculations are presented in Appendix 3.

Table 6.6-27: Exposure models for intended uses

Critical use(s)	0.2 L / kg product/ha for Grapes 0.8 L / kg product/ha for Low berries and other small fruits 0.6 L / kg product/ha for Hops 0.3 L / kg product/ha for Root and tuber vegetables 0.8 L / kg product/ha for Ornamentals ~~0.5 L / kg product/ha for Golf course, turf or other sports lawns~~
Model	*Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874*

The following table shows the crop groups with their respective transfer coefficients (TC) and task duration relevant for the estimation of worker exposure after the intended use of FLU+TFS SC 500. Worker exposures for all intended uses within the zone/ EU given in Part B, Section 0 are covered by that.

Table 6.6-28: Relevant parameters used for the worker exposure assessment

Crop / Crop Group	**Nº of applications**	**Max. application rate kg as/ha** **a) TFS** **b) FLU**	**Interval** (Days)	**TC**[1] (cm²/hour)	**Task Duration** (hours)
Grapes	2	a) 0.050 b) 0.050	14	10100[2]	8
Low berries and other small fruits	2	a) 0.200 b) 0.200	7	750[3]	8
Hops	2	a) 0.150 b) 0.150	14	1400[2]	2
Root and tuber vegetables	5	a) 0.200 b) 0.200	7	1400[2]	2
Ornamentals	1	a) 0.200 b) 0.200	365	1400[3]	8
~~Golf course, turf or other sports lawns~~	~~2~~		~~14~~	~~580[3]~~	~~8~~

[1] TC = transfer coefficients
[2] TC assuming arms, body and legs covered.
[3] TC assuming hands, arms, body and legs covered.

The outcome of the estimation is presented in the following tables.

Table 6.6-29: Estimated worker exposure for re-entry in Grapes

Active substance	Application rate (kg a.s./ha)	Total absorbed dose[2] (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
FLU	0.05	0.0627	125
TFS		0.0557	92.8

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
TFS: 0.06 mg/kg bw/day

[2] Assuming arms, body and legs covered (workwear, bare hands)

Table 6.6-30: Estimated worker exposure for re-entry in Low berries and other small fruits

Active substance	Application rate (kg a.s./ha)	Total absorbed dose[2] (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
FLU	0.2	0.0799	160
TFS		0.0711	118

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
TFS: 0.06 mg/kg bw/day

[2] Assuming arms, body and legs covered (workwear with gloves)

~~Table 6.6-31: Estimated worker exposure for re-entry in Hops~~

~~Active substance~~	~~Application rate (kg a.s./ha)~~	~~Total absorbed dose[2] (mg/kg/day)~~	~~% of systemic AOEL[1] (RVNAS)~~
~~FLU~~	~~0.15~~	~~0.00652~~	~~13~~
~~TFS~~		~~0.00579~~	~~9.65~~

~~[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day~~
~~TFS: 0.06 mg/kg bw/day~~
~~[2] Assuming arms, body and legs covered (workwear, bare hands)~~

Table 6.6-32: Estimated worker exposure for re-entry in Root and tuber vegetables

Active substance	Application rate (kg a.s./ha)	Total absorbed dose[2] (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
FLU	0.075	0.00702	14
TFS		0.00624	10.4

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
TFS: 0.06 mg/kg bw/day

[2] Assuming arms, body and legs covered (workwear, bare hands)

Table 6.6-33: Estimated worker exposure for re-entry in Ornamentals

Active substance	Application rate (kg a.s./ha)	Total absorbed dose[2] (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
FLU	0.2	0.072	144
TFS		0.064	107

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
TFS: 0.06 mg/kg bw/day

[2] Assuming arms, body and legs covered (workwear with gloves)

Table 6.6-34: Estimated worker exposure for re-entry in Ornamentals

Active substance	Application rate (kg a.s./ha)	Total absorbed dose[2] (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
FLU	0.2	0.124	248
TFS		0.11	184

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
TFS: 0.06 mg/kg bw/day

[2] Assuming arms, body and legs covered (workwear with gloves)

~~**Table 6.6-35: Estimated worker exposure for re-entry in Golf course, turf or other sports lawns**~~

~~Active substance~~	~~Application rate (kg a.s./ha)~~	~~Total absorbed dose[2] (mg/kg/day)~~	~~% of systemic AOEL[1] (RVNAS)~~
~~FLU~~	~~0.125~~	~~0.009~~	~~18~~
~~TFS~~		~~0.008~~	~~13.3~~

~~[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day~~
~~TFS: 0.06 mg/kg bw/day~~

~~[2] Assuming arms, body and legs covered (workwear with gloves)~~

6.6.5 Refinement of generic DFR value (KCP 7.2)

Reviewer comment	Refinement regarding DFR value, provided by the APPL has been aaccdpted by the ZRMS for the risk assessmet purpose.

A summary of the exposure models used for the estimation of worker exposure with measured DFR (default DFR: 3 µg/cm²) if available to the active substance(s) after entry into a previously treated area or handling a crop treated with FLU+TFS SC 500 is presented in the following table. Detailed calculations are presented in Appendix 3.

Table 6.6-36: Exposure models for intended uses

Critical use(s)	0.2 L / kg product/ha for Grapes 0.8 L / kg product/ha for Low berries and other small fruits 0.8 L / kg product/ha for Ornamentals
Model	*Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874*

The following table shows the parameters of the used DFR studies. Worker exposures for all intended uses within the zone/ EU given in Part B, Section 0 are covered by that.

Table 6.6-37: Relevant parameters used for the worker exposure assessment

Active substance	**Crop / Crop Group**	**Application rate (kg a.s./ha)**	**Nº of applications**	**Interval** (Days)	**TC[1]** (cm²/hour)	**Task Duration** (hours)	**Measured DFR** (µg/cm²/kg a.s./ha)
FLU	Grapes	0.05	2	14	10100[2]	8	2.24
TFS	Grapes	0.05	2	14	10100[2]	8	1.93
FLU	Low berries and other small fruits	0.2	2	7	750[3]	8	7.3
TFS	Low berries and other small fruits	0.2	2	7	750[3]	8	3.29
FLU	Ornamentals	0.2	1	365	1400[3]	8	2.885
TFS	Ornamentals	0.2	1	365	1400[3]	8	2.285
FLU	Ornamentals	0.2	2	14	1400[3]	8	2.885
TFS	Ornamentals	0.2	2	14	1400[3]	8	2.285

[1] TC = transfer coefficients
[2] TC assuming arms, body and legs covered.
[3] TC assuming hands, arms, body and legs covered.

The outcome of the estimation is presented in the following tables.

Table 6.6-38: Estimated worker exposure for re-entry in Grapes

Active substance	Application rate (kg a.s./ha)	DFR (µg/cm²/kg a.s./ha)	Total absorbed dose[2] (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
FLU	0.05	3[3]	0.0627	125
		2.24[4]	0.0271	54.3
TFS		3[3]	0.0557	92.8
		1.93[4]	0.0208	34.7

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
TFS: 0.06 mg/kg bw/day
[2] Assuming arms, body and legs covered (workwear, bare hands)
[3] Calculation with default DFR according to model.
[4] Calculation with measured DFR assuming highest DFR after maximum number of applications

Table 6.6-39: Estimated worker exposure for re-entry in Low berries and other small fruits

Active substance	Application rate (kg a.s./ha)	DFR (µg/cm²/kg a.s./ha)	Total absorbed dose[2] (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
FLU	0.2	3[3]	0.0799	160
		7.3[4]	0.0263	52.6
TFS		3[3]	0.0711	118
		3.29[4]	0.0105	17.5

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
TFS: 0.06 mg/kg bw/day
[2] Assuming arms, body and legs covered (workwear with gloves)
[3] Calculation with default DFR according to model
[4] Calculation with measured DFR assuming highest DFR after maximum number of applications

Table 6.6-40: Estimated worker exposure for re-entry in Ornamentals

Active substance	Application rate (kg a.s./ha)	DFR (µg/cm²/kg a.s./ha)	Total absorbed dose[2] (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
FLU	0.2	3[3]	0.072	144
		2.885[4]	0.0194	38.8
TFS		3[3]	0.064	107
		2.285[4]	0.0136	22.7

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
TFS: 0.06 mg/kg bw/day
[2] Assuming arms, body and legs covered (workwear with gloves)
[3] Calculation with default DFR according to model
[4] Calculation with measured DFR assuming highest DFR after maximum number of applications

Table 6.6-41: Estimated worker exposure for re-entry in Ornamentals

Active substance	Application rate (kg a.s./ha)	DFR (µg/cm²/kg a.s./ha)	Total absorbed dose[2] (mg/kg/day)	% of systemic AOEL[1] (RVNAS)
FLU	0.2	3[3]	0.124	248
		2.885[4]	0.0194	38.8
TFS		3[3]	0.11	184
		2.285[4]	0.0136	22.7

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
TFS: 0.06 mg/kg bw/day

[2] Assuming arms, body and legs covered (workwear with gloves)

[3] Calculation with default DFR according to model

[4] Calculation with measured DFR assuming highest DFR after maximum number of applications

6.6.5.1 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the Acceptable Operator Exposure Level (AOEL/RVNAS) will not be exceeded under conditions of intended uses a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.6 Bystander and resident exposure (KCP 7.2.2)

According to EFSA longer term exposure of bystanders is covered by the resident scenario.

6.6.6.1 Estimation of bystander and resident exposure (acute & long term exposure)

A summary of the exposure models used for the estimation of resident exposure to the active substance(s) during application of FLU+TFS SC 500 according to the critical use(s) is presented in the following table. Detailed calculations are presented in Appendix 3.

Table 6.6-42: Exposure models for intended uses

Critical use(s)	0.2 L / kg product/ha for Grapes 0.8 L / kg product/ha for Low berries and other small fruits 0.6 L / kg product/ha for Hops 0.3 L / kg product/ha for Root and tuber vegetables 0.8 L / kg product/ha for Ornamentals ~~0.5 L / kg product/ha for Golf course, turf or other sports lawns~~
Model	*Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874*

Regarding the resident exposure to direct drift, exposure calculations are performed for ground boom sprayer (for low crops) and broadcast air assisted applications (for high crops) separately, when relevant. The outcome of the estimation is presented in the following table(s).

Table 6.6-43: Estimated resident exposure, Fluopyram, Grapes

	Adult[2]			Child[2]		
Outdoor, Upward spraying, Vehicle-mounted Application rate: 2 x 0.05 kg a.s./ha, 14 days interval, Minimum water volume: 400 L/ha						
Routes of exposure	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**
Spray drift[3]	0.00174	3.47	0.00114	0.00314	6.27	0.00206
Vapour	0.00023	0.46	0.00023	0.00107	2.14	0.00107
Surface deposits	5.79E-05	0.116	4.38E-05	0.000162	0.324	0.000123
Entry into treated crops[4]	0.00145	2.91	0.00116	0.00262	5.24	0.00209
Sum of all pathways: default DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00257 (5.14%)			0.00534 (10.7%)
Entry into treated crops[5]	0.00063	1.26	0.000502	0.00113	2.27	0.000904
Sum of all pathways: measured DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00189 (3.79%)			0.00411 (8.22%)

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 5 m distance
[4] Default DFR = 3
[5] Measured DFR = 2.24

Table 6.6-44: Estimated resident exposure, Fluopyram, Low berries and other small fruits

	Adult[2]			Child[2]		
Outdoor, Downward spraying, Vehicle-mounted Application rate: 2 x 0.2 kg a.s./ha, 7 days interval, Minimum water volume: 300 L/ha						
Routes of exposure	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**
Spray drift[3]	0.000772	1.54	0.000367	0.00323	6.46	0.00178
Vapour	0.00023	0.46	0.00023	0.00107	2.14	0.00107
Surface deposits	0.000454	0.908	0.000332	0.00127	2.54	0.00093
Entry into treated crops[4]	0.00625	12.5	0.00498	0.0112	22.5	0.00896
Sum of all pathways: default DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00591 (11.8%)			0.0127 (25.5%)
Entry into treated crops[5]	0.00821	16.4	0.00655	0.0148	29.6	0.0118
Sum of all pathways: measured DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00732 (14.6%)			0.0151 (30.3%)

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 2-3 m distance
[4] Default DFR = 3
[5] Measured DFR = 7.3

Table 6.6-45: Estimated resident exposure, Fluopyram, Hops

	Adult[2]			Child[2]		
Outdoor, Upward spraying, Vehicle-mounted Application rate: 2 x 0.15 kg a.s./ha, 14 days interval, Minimum water volume: 2000 L/ha						
Routes of exposure	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**
Spray drift[3]	0.00104	2.08	0.000681	0.00188	3.76	0.00124
Vapour	0.00023	0.46	0.00023	0.00107	2.14	0.00107
Surface deposits	0.000485	0.97	0.000335	0.00136	2.72	0.000937
Entry into treated crops[4]	0.00436	8.73	0.00348	0.00785	15.7	0.00626
Sum of all pathways: default DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00472 (9.45%)			0.00951 (19%)

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 5 m distance
[4] Default DFR = 3
[5] Measured DFR = -

Table 6.6-46: Estimated resident exposure, Fluopyram, Root and tuber vegetables

	Adult[2]			Child[2]		
Outdoor, Downward spraying, Vehicle-mounted Application rate: 5 x 0.075 kg a.s./ha, 7 days interval, Minimum water volume: 150 L/ha						
Routes of exposure	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**
Spray drift[3]	0.000579	1.16	0.000275	0.00242	4.85	0.00134
Vapour	0.00023	0.46	0.00023	0.00107	2.14	0.00107
Surface deposits	0.000342	0.683	0.00025	0.000956	1.91	0.0007
Entry into treated crops[4]	0.0047	9.4	0.00375	0.00846	16.9	0.00675
Sum of all pathways: default DFR [mg/kg bw/day] of AOEL (RVNAS)			0.0045 (9.01%)			0.00985 (19.7%)

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 2-3 m distance
[4] Default DFR = 3
[5] Measured DFR = -

Table 6.6-47: Estimated resident exposure, Fluopyram, Ornamentals

	Adult[2]			Child[2]		
Outdoor, Downward spraying, Vehicle-mounted Application rate: 1 x 0.2 kg a.s./ha, 365 days interval, Minimum water volume: 200 L/ha						
Routes of exposure	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**
Spray drift[3]	0.00116	2.32	0.000551	0.00485	9.7	0.00267
Vapour	0.00023	0.46	0.00023	0.00107	2.14	0.00107
Surface deposits	0.000245	0.491	0.00018	0.000687	1.37	0.000503
Entry into treated crops[4]	0.00338	6.75	0.00269	0.00608	12.2	0.00484
Sum of all pathways: default DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00365 (7.3%)			0.00909 (18.2%)
Entry into treated crops[5]	0.00325	6.49	0.00259	0.00584	11.7	0.00466
Sum of all pathways: measured DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00355 (7.1%)			0.0089 (17.8%)

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 2-3 m distance
[4] Default DFR = 3
[5] Measured DFR = 2.885

Table 6.6-48: Estimated resident exposure, Fluopyram, Ornamentals

	Adult[2]			Child[2]		
Outdoor, Downward spraying, Vehicle-mounted Application rate: 2 x 0.2 kg a.s./ha, 14 days interval, Minimum water volume: 500 L/ha						
Routes of exposure	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**
Spray drift[3]	0.000463	0.926	0.00022	0.00194	3.88	0.00107
Vapour	0.00023	0.46	0.00023	0.00107	2.14	0.00107
Surface deposits	0.000423	0.846	0.00031	0.00118	2.37	0.000866
Entry into treated crops[4]	0.00582	11.6	0.00464	0.0105	20.9	0.00835
Sum of all pathways: default DFR [mg/kg bw/day] of AOEL (RVNAS)			0.0054 (10.8%)			0.0114 (22.7%)
Entry into treated crops[5]	0.00325	6.49	0.00259	0.00584	11.7	0.00466
Sum of all pathways: measured DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00322 (6.44%)			0.0073 (14.6%)

[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 2-3 m distance
[4] Default DFR = 3
[5] Measured DFR = 2.885

~~**Table 6.6-49: Estimated resident exposure, Fluopyram, Golf course, turf or other sports lawns**~~

	~~**Adult**[2]~~			~~**Child**[2]~~		
~~Outdoor, Downward spraying, Vehicle-mounted Application rate: 2 x 0.125 kg a.s./ha, 14 days interval, Minimum water volume: 200 L/ha~~						
~~**Routes of exposure**~~	~~**75th centile (mg/kg bw/day)**~~	~~**in % of AOEL[1] (RVNAS)**~~	~~**Mean (mg/kg bw/day)**~~	~~**75th centile (mg/kg bw/day)**~~	~~**in % of AOEL[1] (RVNAS)**~~	~~**Mean (mg/kg bw/day)**~~
~~Spray drift[3]~~	~~0.000724~~	~~1.45~~	~~0.000344~~	~~0.00303~~	~~6.06~~	~~0.00167~~
~~Vapour~~	~~0.00023~~	~~0.46~~	~~0.00023~~	~~0.00107~~	~~2.14~~	~~0.00107~~
~~Surface deposits~~	~~0.000264~~	~~0.528~~	~~0.000193~~	~~0.00074~~	~~1.48~~	~~0.000542~~
~~Entry into treated crops[4]~~	~~0.00059~~	~~1.18~~	~~0.00059~~	~~0.00259~~	~~5.19~~	~~0.00126~~
~~**Sum of all pathways:** default DFR [mg/kg bw/day] of AOEL (RVNAS)~~			~~0.00136 (2.71%)~~			~~0.00454 (9.09%)~~

~~[1] AOEL (RVNAS) of FLU: 0.05 mg/kg bw/day~~
~~[2] Considered bodyweight: adult = 60 kg, child = 10 kg~~
~~[3] Exposure at 2-3 m distance~~
~~[4] Default DFR = 3~~
~~[5] Measured DFR = –~~

Table 6.6-50: Estimated bystander exposure, Trifloxystrobin, Grapes

	Adult[2]		**Child[2]**	
Outdoor, Upward spraying, Vehicle-mounted Application rate: 2 x 0.05 kg a.s./ha, 14 days interval, Minimum water volume: 400 L/ha				
Routes of exposure	**95th centile (mg/kg bw/day)**	**in % of AAOEL[1] (RVAAS)**	**95th centile (mg/kg bw/day)**	**in % of AAOEL[1] (RVAAS)**
Spray drift[3]	0.00354	1.18	0.00639	2.13
Vapour	0.00023	0.0767	0.00107	0.357
Surface deposits	0.000121	0.0402	0.000338	0.113
Entry into treated crops[4]	0.00129	0.431	0.00233	0.776
Entry into treated crops[5]	0.000483	0.161	0.000869	0.29

[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 5 m distance
[4] Default DFR = 3
[5] Measured DFR = 1.93

Table 6.6-51: Estimated resident exposure, Trifloxystrobin, Grapes

	Adult[2]			Child[2]		
Outdoor, Upward spraying, Vehicle-mounted Application rate: 2 x 0.05 kg a.s./ha, 14 days interval, Minimum water volume: 400 L/ha						
Routes of exposure	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**
Spray drift[3]	0.00154	2.57	0.00101	0.00279	4.65	0.00184
Vapour	0.00023	0.383	0.00023	0.00107	1.78	0.00107
Surface deposits	5.15E-05	0.0858	3.89E-05	0.000148	0.247	0.000112
Entry into treated crops[4]	0.00129	2.15	0.00103	0.00233	3.88	0.00186
Sum of all pathways: default DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00231 (3.85%)			0.00487 (8.12%)
Entry into treated crops[5]	0.000483	0.804	0.000385	0.000869	1.45	0.000692
Sum of all pathways: measured DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00165 (2.74%)			0.00366 (6.11%)

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 5 m distance
[4] Default DFR = 3
[5] Measured DFR = 1.93

Table 6.6-52: Estimated bystander exposure, Trifloxystrobin, Low berries and other small fruits

	Adult[2]		Child[2]	
Outdoor, Downward spraying, Vehicle-mounted Application rate: 2 x 0.2 kg a.s./ha, 7 days interval, Minimum water volume: 300 L/ha				
Routes of exposure	**95th centile (mg/kg bw/day)**	**in % of AAOEL[1] (RVAAS)**	**95th centile (mg/kg bw/day)**	**in % of AAOEL[1] (RVAAS)**
Spray drift[3]	0.00177	0.59	0.00655	2.18
Vapour	0.00023	0.0767	0.00107	0.357
Surface deposits	0.00122	0.406	0.0034	1.13
Entry into treated crops[4]	0.00555	1.85	0.00999	3.33
Entry into treated crops[5]	0.00329	1.1	0.00592	1.97

[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 2-3 m distance
[4] Default DFR = 3
[5] Measured DFR = 3.29

Table 6.6-53: Estimated resident exposure, Trifloxystrobin, Low berries and other small fruits

	Adult[2]			Child[2]		
Outdoor, Downward spraying, Vehicle-mounted Application rate: 2 x 0.2 kg a.s./ha, 7 days interval, Minimum water volume: 300 L/ha						
Routes of exposure	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**
Spray drift[3]	0.000686	1.14	0.000326	0.00287	4.79	0.00159
Vapour	0.00023	0.383	0.00023	0.00107	1.78	0.00107
Surface deposits	0.000403	0.672	0.000295	0.00116	1.94	0.000851
Entry into treated crops[4]	0.00555	9.25	0.00443	0.00999	16.7	0.00797
Sum of all pathways: default DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00528 (8.8%)			0.0115 (19.1%)
Entry into treated crops[5]	0.00329	5.48	0.00262	0.00592	9.87	0.00472
Sum of all pathways: measured DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00334 (5.57%)			0.00784 (13.1%)

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 2-3 m distance
[4] Default DFR = 3
[5] Measured DFR = 3.29

Table 6.6-54: Estimated bystander exposure, Trifloxystrobin, Hops

	Adult[2]		Child[2]	
Outdoor, Upward spraying, Vehicle-mounted Application rate: 2 x 0.15 kg a.s./ha, 14 days interval, Minimum water volume: 2000 L/ha				
Routes of exposure	**95th centile (mg/kg bw/day)**	**in % of AAOEL[1] (RVAAS)**	**95th centile (mg/kg bw/day)**	**in % of AAOEL[1] (RVAAS)**
Spray drift[3]	0.00212	0.707	0.00383	1.28
Vapour	0.00023	0.0767	0.00107	0.357
Surface deposits	0.00116	0.386	0.00324	1.08
Entry into treated crops[4]	0.00388	1.29	0.00698	2.33

[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 5 m distance
[4] Default DFR = 3
[5] Measured DFR = -

Table 6.6-55: Estimated resident exposure, Trifloxystrobin, Hops

	Adult[2]			Child[2]		
Outdoor, Upward spraying, Vehicle-mounted Application rate: 2 x 0.15 kg a.s./ha, 14 days interval, Minimum water volume: 2000 L/ha						
Routes of exposure	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**
Spray drift[3]	0.000926	1.54	0.000606	0.00167	2.79	0.0011
Vapour	0.00023	0.383	0.00023	0.00107	1.78	0.00107
Surface deposits	0.000431	0.719	0.000297	0.00124	2.07	0.000857
Entry into treated crops[4]	0.00388	6.46	0.00309	0.00698	11.6	0.00557
Sum of all pathways: default DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00423 (7.04%)			0.0086 (14.3%)

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 5 m distance
[4] Default DFR = 3
[5] Measured DFR = -

Table 6.6-56: Estimated bystander exposure, Trifloxystrobin, Root and tuber vegetables

	Adult[2]		Child[2]	
Outdoor, Downward spraying, Vehicle-mounted Application rate: 5 x 0.075 kg a.s./ha, 7 days interval, Minimum water volume: 150 L/ha				
Routes of exposure	**95th centile (mg/kg bw/day)**	**in % of AAOEL[1] (RVAAS)**	**95th centile (mg/kg bw/day)**	**in % of AAOEL[1] (RVAAS)**
Spray drift[3]	0.00133	0.442	0.00491	1.64
Vapour	0.00023	0.0767	0.00107	0.357
Surface deposits	0.000915	0.305	0.00256	0.854
Entry into treated crops[4]	0.00418	1.39	0.00752	2.51

[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 2-3 m distance
[4] Default DFR = 3
[5] Measured DFR = -

Table 6.6-57: Estimated resident exposure, Trifloxystrobin, Root and tuber vegetables

	Adult[2]			Child[2]		
Outdoor, Downward spraying, Vehicle-mounted Application rate: 5 x 0.075 kg a.s./ha, 7 days interval, Minimum water volume: 150 L/ha						
Routes of exposure	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**
Spray drift[3]	0.000515	0.858	0.000245	0.00216	3.59	0.00119
Vapour	0.00023	0.383	0.00023	0.00107	1.78	0.00107
Surface deposits	0.000304	0.506	0.000222	0.000875	1.46	0.000641
Entry into treated crops[4]	0.00418	6.96	0.00333	0.00752	12.5	0.006
Sum of all pathways: default DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00403 (6.71%)			0.0089 (14.8%)

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 2-3 m distance
[4] Default DFR = 3
[5] Measured DFR = -

Table 6.6-58: Estimated bystander exposure, Trifloxystrobin, Ornamentals

	Adult[2]		Child[2]	
Outdoor, Downward spraying, Vehicle-mounted Application rate: 1 x 0.2 kg a.s./ha, 365 days interval, Minimum water volume: 200 L/ha				
Routes of exposure	**95th centile (mg/kg bw/day)**	**in % of AAOEL[1] (RVAAS)**	**95th centile (mg/kg bw/day)**	**in % of AAOEL[1] (RVAAS)**
Spray drift[3]	0.00265	0.885	0.00982	3.27
Vapour	0.00023	0.0767	0.00107	0.357
Surface deposits	0.000657	0.219	0.00184	0.613
Entry into treated crops[4]	0.003	1	0.0054	1.8
Entry into treated crops[5]	0.00229	0.762	0.00411	1.37

[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 2-3 m distance
[4] Default DFR = 3
[5] Measured DFR = 2.285

Table 6.6-59: Estimated resident exposure, Trifloxystrobin, Ornamentals

	Adult[2]			Child[2]		
Outdoor, Downward spraying, Vehicle-mounted Application rate: 1 x 0.2 kg a.s./ha, 365 days interval, Minimum water volume: 200 L/ha						
Routes of exposure	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**
Spray drift[3]	0.00103	1.72	0.00049	0.00431	7.19	0.00238
Vapour	0.00023	0.383	0.00023	0.00107	1.78	0.00107
Surface deposits	0.000218	0.363	0.00016	0.000628	1.05	0.00046
Entry into treated crops[4]	0.003	5	0.00239	0.0054	9	0.00431
Sum of all pathways: default DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00327 (5.45%)			0.00821 (13.7%)
Entry into treated crops[5]	0.00229	3.81	0.00182	0.00411	6.86	0.00328
Sum of all pathways: measured DFR [mg/kg bw/day] of AOEL (RVNAS)			0.0027 (4.5%)			0.00719 (12%)

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 2-3 m distance
[4] Default DFR = 3
[5] Measured DFR = 2.285

Table 6.6-60: Estimated bystander exposure, Trifloxystrobin, Ornamentals

	Adult[2]		Child[2]	
Outdoor, Downward spraying, Vehicle-mounted Application rate: 2 x 0.2 kg a.s./ha, 14 days interval, Minimum water volume: 500 L/ha				
Routes of exposure	**95th centile (mg/kg bw/day)**	**in % of AAOEL[1] (RVAAS)**	**95th centile (mg/kg bw/day)**	**in % of AAOEL[1] (RVAAS)**
Spray drift[3]	0.00106	0.354	0.00393	1.31
Vapour	0.00023	0.0767	0.00107	0.357
Surface deposits	0.00113	0.378	0.00317	1.06
Entry into treated crops[4]	0.00517	1.72	0.00931	3.1
Entry into treated crops[5]	0.00229	0.762	0.00411	1.37

[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 2-3 m distance
[4] Default DFR = 3
[5] Measured DFR = 2.285

Table 6.6-61: Estimated resident exposure, Trifloxystrobin, Ornamentals

	Adult[2]			Child[2]		
Outdoor, Downward spraying, Vehicle-mounted Application rate: 2 x 0.2 kg a.s./ha, 14 days interval, Minimum water volume: 500 L/ha						
Routes of exposure	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**
Spray drift[3]	0.000412	0.686	0.000196	0.00172	2.87	0.000951
Vapour	0.00023	0.383	0.00023	0.00107	1.78	0.00107
Surface deposits	0.000376	0.626	0.000275	0.00108	1.8	0.000793
Entry into treated crops[4]	0.00517	8.62	0.00412	0.00931	15.5	0.00742
Sum of all pathways: default DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00482 (8.04%)			0.0102 (17.1%)
Entry into treated crops[5]	0.00229	3.81	0.00182	0.00411	6.86	0.00328
Sum of all pathways: measured DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00241 (4.01%)			0.00576 (9.6%)

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 2-3 m distance
[4] Default DFR = 3
[5] Measured DFR = 2.285

~~**Table 6.6-62: Estimated bystander exposure, Trifloxystrobin, Golf course, turf or other sports lawns**~~

	~~Adult[2]~~		~~Child[2]~~	
~~Outdoor, Downward spraying, Vehicle-mounted Application rate: 2 x 0.125 kg a.s./ha, 14 days interval, Minimum water volume: 200 L/ha~~				
~~**Routes of exposure**~~	~~**95th centile (mg/kg bw/day)**~~	~~**in % of AAOEL[1] (RVAAS)**~~	~~**95th centile (mg/kg bw/day)**~~	~~**in % of AAOEL[1] (RVAAS)**~~
~~Spray drift[3]~~	~~0.00166~~	~~0.553~~	~~0.00614~~	~~2.05~~
~~Vapour~~	~~0.00023~~	~~0.0767~~	~~0.00107~~	~~0.357~~
~~Surface deposits~~	~~0.000708~~	~~0.236~~	~~0.00198~~	~~0.661~~
~~Entry into treated crops[4]~~	~~0.00104~~	~~0.347~~	~~0.00386~~	~~1.29~~

~~[1] AAOEL (RVAAS) of TFS: 0.3 mg/kg bw/day~~
~~[2] Considered bodyweight: adult = 60 kg, child = 10 kg~~
~~[3] Exposure at 2-3 m distance~~
~~[4] Default DFR = 3~~
~~[5] Measured DFR = –~~

Table 6.6-63: Estimated resident exposure, Trifloxystrobin, Golf course, turf or other sports lawns

	Adult[2]			Child[2]		
Outdoor, Downward spraying, Vehicle-mounted Application rate: 2 x 0.125 kg a.s./ha, 14 days interval, Minimum water volume: 200 L/ha						
Routes of exposure	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**	**75th centile (mg/kg bw/day)**	**in % of AOEL[1] (RVNAS)**	**Mean (mg/kg bw/day)**
Spray drift[3]	0.000643	1.07	0.000306	0.0027	4.49	0.00149
Vapour	0.00023	0.383	0.00023	0.00107	1.78	0.00107
Surface deposits	0.000235	0.391	0.000172	0.000677	1.13	0.000496
Entry into treated crops[4]	0.000524	0.874	0.000524	0.00245	4.09	0.00112
Sum of all pathways: default DFR [mg/kg bw/day] of AOEL (RVNAS)			0.00123 (2.05%)			0.00417 (6.95%)

[1] AOEL (RVNAS) of TFS: 0.06 mg/kg bw/day
[2] Considered bodyweight: adult = 60 kg, child = 10 kg
[3] Exposure at 2-3 m distance
[4] Default DFR = 3
[5] Measured DFR = –

6.6.6.2 Measurement of bystander and/or resident exposure

Since the bystander/resident exposure estimations carried out indicated that the Acceptable Operator Exposure Level (AOEL/RVNAS) as well as the Acute Acceptable Operator Exposure Level (AAOEL/RVAAS) will not be exceeded under conditions of intended uses a study to provide measurements of bystander/resident exposure to spray drift, vapour, surface deposits or entry into treated crops was not necessary and was therefore not performed.

6.6.7 Combined exposure

The product is a mixture of 2 active substances. Therefore, a combined exposure assessment is provided.

6.6.7.1 Exposure Assessment of the active substances (Fluopyram, Trifloxystrobin) in FLU+TFS SC 500

Reviewer comment	Assessment reflecting combined exposure, provided by the APPL has been aaccdpted by the ZRMS.

Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL/RVNAS and AAOEL/RVAAS. This is equivalent to the predicted exposure as % of systemic AOEL/RVNAS and AAOEL/RVAAS to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-64: Risk assessment from combined exposure for Operators with PPE

Application scenario	Active Substance	Estimated exposure / AOEL (RVNAS) (HQ)[2]	Estimated exposure / AAOEL (RVAAS) (HQ)[3]
Grapes	Fluopyram	0.136	-
	Trifloxystrobin	0.103	0.065
	Cumulative risk Operators (HI)[1]	**0.239**	**0.065**
Low berries and other small fruits Low crop tractor-mounted	Fluopyram	0.104	-
	Trifloxystrobin	0.083	0.122
	Cumulative risk Operators (HI)[1]	**0.187**	**0.122**
Low berries and other small fruits, Low crop hand-held manual	Fluopyram	0.545	-
	Trifloxystrobin	0.405	0.599
	Cumulative risk Operators (HI)[1]	**0.95**	**0.599**
Low berries and other small fruits, Low crop hand-held manual-Knapsack	Fluopyram	0.552	-
	Trifloxystrobin	0.411	0.6
	Cumulative risk Operators (HI)[1]	**0.963**	**0.6**
Hops	Fluopyram	0.361	-
	Trifloxystrobin	0.272	0.191
	Cumulative risk Operators (HI)[1]	**0.633**	**0.191**
Root and tuber vegetables	Fluopyram	0.0411	-
	Trifloxystrobin	0.0332	0.0602
	Cumulative risk Operators (HI)[1]	**0.0743**	**0.0602**
Ornamentals	Fluopyram	0.206	-
	Trifloxystrobin	0.154	0.0661
	Cumulative risk Operators (HI)[1]	**0.36**	**0.0661**
~~*Golf course, turf or other sports lawns*~~	~~Fluopyram~~	~~0.0666~~	~~-~~
	~~Trifloxystrobin~~	~~0.0533~~	~~0.087~~
	~~**Cumulative risk Operators (HI)[1]**~~	~~**0.12**~~	~~**0.087**~~

[1] HI = Hazard Index
[2] HQ = Hazard Quotient, 75th percentile
[3] HQ = Hazard Quotient, 95th percentile

Table 6.6-65: Risk assessment from combined exposure for Workers

Application scenario	Active Substance	Estimated exposure / AOEL (RVNAS) (HQ)[2]	Measured DFR[3]
Grapes	Fluopyram	1.25	0.543
	Trifloxystrobin	0.92	0.347
	Cumulative risk Workers (HI)[1]	**2.17**	**0.89**
Low berries and other small fruits Low crop tractor-mounted	Fluopyram	0.4	0.526
	Trifloxystrobin	0.296	0.175
	Cumulative risk Workers (HI)[1]	**0.696**	**0.701**
Low berries and other small fruits, Low crop hand-held manual	Fluopyram	0.4	0.526
	Trifloxystrobin	0.296	0.175
	Cumulative risk Workers (HI)[1]	**0.696**	**0.701**
Low berries and other small fruits, Low crop hand-held manual-Knapsack	Fluopyram	0.4	0.526
	Trifloxystrobin	0.296	0.175
	Cumulative risk Workers (HI)[1]	**0.696**	**0.701**
Hops	Fluopyram	0.13	-
	Trifloxystrobin	0.0965	-
	Cumulative risk Workers (HI)[1]	**0.227**	**-**
Root and tuber vegetables	Fluopyram	0.14	-
	Trifloxystrobin	0.104	-
	Cumulative risk Workers (HI)[1]	**0.244**	**-**
Ornamentals	Fluopyram	1.44	0.388
	Trifloxystrobin	1.07	0.227
	Cumulative risk Workers (HI)[1]	**2.51**	**0.615**
Ornamentals	Fluopyram	2.48	0.388
	Trifloxystrobin	1.84	0.227
	Cumulative risk Workers (HI)[1]	**4.32**	**0.615**
~~*Golf course, turf or other sports lawns*~~	~~Fluopyram~~	~~0.18~~	~~-~~
	~~Trifloxystrobin~~	~~0.133~~	~~-~~
	~~**Cumulative risk Workers (HI)[1]**~~	~~**0.313**~~	~~-~~

[1] HI = Hazard Index
[2] HQ = Hazard Quotient
[3] Hazard Quotient, for addition the value of the default DFR is used, when measured DFR not available

Table 6.6-66: Risk assessment from combined exposure for Bystander

Application scenario	Active Substance	Estimated exposure / AOEL (RVNAS) (HQ)[3]	Measured DFR
Adult[1] Grapes	Fluopyram	-	-
	Trifloxystrobin	0.0172	0.00146
	Cumulative risk Bystander – Adult (HI)[2]	**0.0172**	**0.00146**
Child[1] Grapes	Fluopyram	-	-
	Trifloxystrobin	0.0338	0.0289
	Cumulative risk Bystander – Child (HI)[2]	**0.0338**	**0.0289**
Adult[1] Low berries and other small fruits	Fluopyram	-	-
	Trifloxystrobin	0.0292	0.0217
	Cumulative risk Bystander – Adult (HI)[2]	**0.0292**	**0.0217**
Child[1] Low berries and other small fruits	Fluopyram	-	-
	Trifloxystrobin	0.07	0.0565
	Cumulative risk Bystander – Child (HI)[2]	**0.07**	**0.0565**
Adult[1] Hops	Fluopyram	-	-
	Trifloxystrobin	0.0246	-
	Cumulative risk Bystander – Adult (HI)[2]	**0.0246**	**-**
Child[1] Hops	Fluopyram	-	-
	Trifloxystrobin	0.0504	-
	Cumulative risk Bystander – Child (HI)[2]	**0.0504**	**-**
Adult[1] Root and tuber vegetables	Fluopyram	-	-
	Trifloxystrobin	0.0221	-
	Cumulative risk Bystander – Adult (HI)[2]	**0.0221**	**-**
Child[1] Root and tuber vegetables	Fluopyram	-	-
	Trifloxystrobin	0.0535	-
	Cumulative risk Bystander – Child (HI)[2]	**0.0535**	**-**
Adult[1] Ornamentals	Fluopyram	-	-
	Trifloxystrobin	0.0218	0.0194
	Cumulative risk Bystander – Adult (HI)[2]	**0.0218**	**0.0194**
Child[1] Ornamentals	Fluopyram	-	-
	Trifloxystrobin	0.0604	0.0561
	Cumulative risk Bystander – Child (HI)[2]	**0.0604**	**0.0561**
Adult[1] Ornamentals	Fluopyram	-	-
	Trifloxystrobin	0.0253	0.0157
	Cumulative risk Bystander – Adult (HI)[2]	**0.0253**	**0.0157**

Child[1] *Ornamentals*	Fluopyram	-	-
	Trifloxystrobin	0.0583	0.0409
	Cumulative risk Bystander – Child (HI)[2]	**0.0583**	**0.0409**
~~*Adult[1]*~~ ~~*Golf course, turf or other sports lawns*~~	~~Fluopyram~~	~~-~~	~~-~~
	~~Trifloxystrobin~~	~~0.0121~~	~~-~~
	~~**Cumulative risk Bystander – Adult (HI)[2]**~~	~~**0.0121**~~	~~-~~
~~*Child[1]*~~ ~~*Golf course, turf or other sports lawns*~~	~~Fluopyram~~	~~-~~	~~-~~
	~~Trifloxystrobin~~	~~0.0435~~	~~-~~
	~~**Cumulative risk Bystander – Child (HI)[2]**~~	~~**0.0435**~~	~~-~~

[1] The higher exposure value either from the 95[th] percentile of each of the four pathways (spray drift, vapour, surface deposits, entry into treated crops) or the sum of the mean exposure values is taken into consideration
[2] HI = Hazard Index
[3] HQ = Hazard Quotient

Table 6.6-67: Risk assessment from combined exposure for Residents

Application scenario	Active Substance	Estimated exposure / AOEL (RVNAS) (HQ)[3]	Measured DFR
Adult[1] *Grapes*	Fluopyram	0.0514	0.0379
	Trifloxystrobin	0.0385	0.0274
	Cumulative risk Resident – Adult (HI)[2]	**0.0899**	**0.0653**
Child[1] *Grapes*	Fluopyram	0.107	0.0822
	Trifloxystrobin	0.0812	0.0611
	Cumulative risk Resident – Child (HI)[2]	**0.188**	**0.143**
Adult[1] *Low berries and other small fruits*	Fluopyram	0.118	0.146
	Trifloxystrobin	0.08	0.0557
	Cumulative risk Resident – Adult (HI)[2]	**0.198**	**0.202**
Child[1] *Low berries and other small fruits*	Fluopyram	0.255	0.303
	Trifloxystrobin	0.191	0.131
	Cumulative risk Resident – Child (HI)[2]	**0.446**	**0.434**
Adult[1] *Hops*	Fluopyram	0.0945	-
	Trifloxystrobin	0.0704	-
	Cumulative risk Resident – Adult (HI)[2]	**0.165**	**-**
Child[1] *Hops*	Fluopyram	0.19	-
	Trifloxystrobin	0.143	-
	Cumulative risk Resident – Child (HI)[2]	**0.333**	**-**
Adult[1] *Root and tuber vegetables*	Fluopyram	0.0901	-
	Trifloxystrobin	0.0671	-
	Cumulative risk Resident – Adult (HI)[2]	**0.157**	**-**
Child[1]	Fluopyram	0.197	-

Application scenario	Active Substance	Estimated exposure / AOEL (RVNAS) (HQ)[3]	Measured DFR
Root and tuber vegetables	Trifloxystrobin	0.148	-
	Cumulative risk Resident – Child (HI)[2]	**0.345**	-
Adult[1] Ornamentals	Fluopyram	0.073	0.071
	Trifloxystrobin	0.0545	0.045
	Cumulative risk Resident – Adult (HI)[2]	**0.128**	**0.116**
Child[1] Ornamentals	Fluopyram	0.182	0.178
	Trifloxystrobin	0.137	0.12
	Cumulative risk Resident – Child (HI)[2]	**0.319**	**0.298**
Adult[1] Ornamentals	Fluopyram	0.108	0.0644
	Trifloxystrobin	0.0804	0.0401
	Cumulative risk Resident – Adult (HI)[2]	**0.202**	**0.105**
Child[1] Ornamentals	Fluopyram	0.227	0.146
	Trifloxystrobin	0.171	0.096
	Cumulative risk Resident – Child (HI)[2]	**0.398**	**0.242**
~~*Adult[1] Golf course, turf or other sports lawns*~~	~~Fluopyram~~	~~0.0271~~	~~-~~
	~~Trifloxystrobin~~	~~0.0205~~	~~-~~
	~~**Cumulative risk Resident – Adult (HI)[2]**~~	~~**0.0476**~~	~~-~~
~~*Child[1] Golf course, turf or other sports lawns*~~	~~Fluopyram~~	~~0.0909~~	~~-~~
	~~Trifloxystrobin~~	~~0.0695~~	~~-~~
	~~**Cumulative risk Resident – Child (HI)[2]**~~	~~**0.16**~~	~~-~~

[1] The higher exposure value either from the 75th percentile of each of the four pathways (spray drift, vapour, surface deposits, entry into treated crops) or the sum of the mean exposure values is taken into consideration

[2] HI = Hazard Index

[3] HQ = Hazard Quotient

Appendix 1 Lists of data considered in support of the evaluation

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
KCP 7.1.1 / 01	xxx	2007	AE C656948 & trifloxystrobin SC 250 & 250 - Acute toxicity in the rat after oral administration Report No.: AT03692, Edition Number: M-287410-01-1 xxx GLP/GEP: Yes unpublished	Yes	Bayer
KCP 7.1.2 / 01	xxx	2007	AE C656948 & trifloxystrobin SC 250 & 250 - Acute toxicity in the rat after dermal application Report No.: AT03690, Edition Number: M-287408-01-1 xxx GLP/GEP: Yes unpublished	Yes	Bayer
KCP 7.1.3 / 01	xxx.	2007	AE C656948 & trifloxystrobin SC 250 & 250 - Activity ID TXGMP033- Acute inhalation toxicity in rats Report No.: AT03716, Edition Number: M-287413-01-1 xxx GLP/GEP: Yes unpublished	Yes	Bayer
KCP 7.1.4 / 01	xxx	2007	AE C656948 & trifloxystrobin SC 250 & 250 - Acute skin irritation/corrosion on rabbits Report No.: AT03623, Edition Number: M-283572-01-1 xxx GLP/GEP: Yes unpublished	Yes	Bayer
KCP 7.1.5 / 01	xxx	2007	AE C656948 & trifloxystrobin SC 250 & 250 (AE C656948 + TFS SC 250+250 G) - Acute eye irritation on rabbits Report No.: AT03624, Edition Number: M-283570-01-1 xxx GLP/GEP: Yes unpublished	Yes	Bayer
KCP 7.1.6 / 01	xxx	2006	AE C656948 and trifloxystrobin SC 250 & 250 - Evaluation of potential dermal sensitization in the local lymph node assay in the mouse Report No.: SA 06266, Edition Number: M-281763-01-1	Yes	Bayer

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**
			xxx GLP/GEP: Yes unpublished		
KCP 7.3 / 01	Bernal, J.	2014	In vitro human skin penetration of 14C-fluopyram in the fluopyram and trifloxystrobin SC 500 formulation Report No.: S13-04169, Edition Number: M-475331-01-1 Eurofins Agroscience Services, Chem SAS, Vergèze, France GLP/GEP: Yes unpublished	No	Bayer
KCP 7.3 / 02	Odin, M.	2014	[14C]-trifloxystrobin (FLU + TFS SC 500) - In vitro dermal absorption study using human skin Report No.: SA 13189, Edition Number: M-486321-01-1 Bayer S.A.S., Bayer CropScience, Sophia Antipolis, France GLP/GEP: Yes unpublished	No	Bayer
KCA 6.10 / 01	Stuke, S.; Daniela, M.; van Berkum, S.	2016	Determination of the dislodgeable foliar residues (DFR) of trifloxystrobin and AE C656948 in/on grape after spraying of AE C656948 & CGA279202 SC 500 in the field in the North of France Report No.: 15-2924, Edition Number: M-569303-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.10 / 02	Daniels, M. ; van Berkum, S.	2020	Determination of the dislodgeable foliar residues (DFR) of trifloxystrobin and AE C656948 in/on raspberry after spray application of AE C656948 & CGA279202 SC 500 in the field in Italy Report No.: 18-2905, Edition Number: M-677729-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.10 / 03	Stuke, S.; van Berkum, S.	2016	Determination of the dislodgeable foliar residues (DFR) of trifloxystrobin and AE C656948 in/on lily after spraying of AE C656948 & CGA279202 SC 500 in the field in the Netherlands Report No.: 15-2925, Edition Number: M-558518-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer

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

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
KCA 5.1.1 /01	xxx	1996	Absorption, distribution and excretion of (glyoxyl-phenyl-U-14C) and (trifluormethyl-phenyl-U-14C) CGA 279202 in the rat xxx xxx Report No.: 13/96, Edition Number: M-136746-01-1 EPA MRID No.: 44496821 Date: 1996-08-29 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.1.1 /02	xxx	1998	Absorption, distribution amd excretion of [trifluormethyl-phenyl-(U)-14C] and [glyoxyl-phenyl-(U)-14C] CGA 279202 in the rat (extension) xxx, Report No.: 20/97, Edition Number: M-136744-01-1 Date: 1998-01-08 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.1.1 /03 KCA 6.2 /01	xxx	1997	The metabolism of [glyoxyl-phenyl-(U)-14C] and [trifluormethyl-phenyl-(U)-14C] CGA 279202 in the rat xxx, Report No.: 12/97, Edition Number: M-136745-01-1 EPA MRID No.: 44496722, 44636001 Date: 1997-11-14 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.1.1 /04 KCA 6.2.3 /01	xxx	1997	The metabolism of [trifluormethyl-phenyl(U)-14C] CGA 279202 after multiple oral administration to lactating goats xxx, Report No.: 09/97, Edition Number: M-034501-01-1 EPA MRID No.: 44496818 Date: 1997-08-27 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
KCA 5.1.1 /05 KCA 6.2.3 /02	xxx	1997	The metabolism of [glyoxyl-phenyl-(U)-14C] CGA 279202 after multiple oral administration to lactating goats xxx, Report No.: 14/97, Edition Number: M-034517-01-1 EPA MRID No.: 44496823 Date: 1997-12-09 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.1.1 /06 KCA 6.2.2 /01	xxx	1997	The metabolism of [trifluormethyl-phenyl-(U)-14C] CGA 279202 after multiple oral administration to laying hens xxx Report No.: 10/97, Edition Number: M-034526-01-1 EPA MRID No.: 44496820 Date: 1997-12-08 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.1.1 /07 KCA 6.2.2 /02	xxx	1998	The metabolism of [glyoxyl-phenyl-(U)-14C] CGA 279202 after multiple oral administration to laying hens xxx, Report No.: 22/97, Edition Number: M-034534-01-1 EPA MRID No.: 44496825 Date: 1998-01-19 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.1.2 /01	xxx	1997	In vitro percutaneous absorption of [glyoxyl-phenyl-U-14C] CGA 279202 formulated as A-9604 A through rat and human epidermis xxx, Report No.: V97.977, Edition Number: M-056952-01-1 Date: 1997-12-09 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.1.2 /02	xxx.	1997	Dermal absorption study with [Glyoxyl-phenyl-U-14C] CGA 279202 formulated as A-9604 A in rats. xxx, Report No.: 470955, Edition Number: M-049913-01-1 Date: 1997-12-10 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
KCA 5.2.1 /01 KCA 8.7 /01	xxx	1994	Acute oral toxicity study of CGA-279202 technical in rats xxx, Report No.: HWI 40702444, Edition Number: M-039034-01-1 EPA MRID No.: 44496622 Date: 1994-10-05 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.1 /02	xxx	1996	CGA 279202 tech. - Acute oral toxicity in the mouse (limit test) xxx xxx Report No.: 963002, Edition Number: M-039046-02-1 Date: 1996-03-18 **...Amended: 1997-12-10** GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.1 /03 KCA 5.2.2 /03 KCA 5.2.3 /02 KCA 5.2.4 /02 KCA 5.2.6 /03	xxx	2000	CGA 279202 50 WG (A 9360 B) - Acute toxicity xxx, Report No.: MO-02-006590, Edition Number: M-060912-01-1 GLP/GEP: n.a., unpublished	Y	Bayer
KCA 5.2.1 /04	xxx	1998	CA 2248 A (intermediate of CGA 279202), CGA 107170 (metabolite of CGA 279202) - Acute oral toxicity in the rat (limit test) xxx, Report No.: 983091, Edition Number: M-065073-01-1 Date: 1998-08-20 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.1 /05	xxx	1996	CGA 279202 EC 125 (A-9604 A) - Acute oral toxicity in the rat (limit test) xxx, Report No.: 963036, Edition Number: M-040606-01-1 Date: 1996-05-20 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
KCA 5.2.1 /06	xxx	1997	CGA 279202 WG 50 (A-9360 B) - Acute oral toxicity in the rat (limit test) xxx, Report No.: 963148, Edition Number: M-041006-01-1 EPA MRID No.: 44496624 Date: 1997-01-08 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.2 /01	xxx	1995	CGA 279202 tech. - Acute dermal toxicity in the rat xxx, Report No.: 943161, Edition Number: M-040043-02-1 Date: 1995-02-21 **...Amended: 1997-12-10** GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.2 /02	xxx	1994	Acute dermal toxicity study of CGA 279202 technical in rabbits xxx, Report No.: HWI 40702445, Edition Number: M-039075-01-1 EPA MRID No.: 44496626 Date: 1994-10-07 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.2 /03 KCA 5.2.1 /03 KCA 5.2.3 /02 KCA 5.2.4 /02 KCA 5.2.6 /03	xxx	2000	CGA 279202 50 WG (A 9360 B) - Acute toxicity xxx, Report No.: MO-02-006590, Edition Number: M-060912-01-1 GLP/GEP: n.a., unpublished	Y	Bayer
KCA 5.2.2 /04	xxx	1996	CGA 279202 EC 125 (A-9604 A) - Acute dermal toxicity in the rat (limit test) xxx, Report No.: 963037, Edition Number: M-040631-01-1 Date: 1996-05-23 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.2 /05	xxx	1997	CGA 279202 WG 50 (A-9360 B) - Acute dermal toxicity in the rat (limit test) xxx, Report No.: 963149, Edition Number: M-041407-01-1 Date: 1997-02-03 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
KCA 5.2.2 /06	xxx	1996	CGA 279202 WG 50 (A-9360 B) - Acute dermal irritation/corrosion study in the rabbit xxx, Report No.: 963041, Edition Number: M-041411-01-1 EPA MRID No.: 44496636 Date: 1996-04-18 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.3 /01	xxx	1995	CGA-279202 technical - Acute inhalation toxicity study in rats xxx Report No.: 1815-95, Edition Number: M-040049-01-1 EPA MRID No.: 44496630 Date: 1995-04-05 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.3 /02 KCA 5.2.1 /03 KCA 5.2.2 /03 KCA 5.2.4 /02 KCA 5.2.6 /03	xxx	2000	CGA 279202 50 WG (A 9360 B) - Acute toxicity xxx Report No.: MO-02-006590, Edition Number: M-060912-01-1 GLP/GEP: n.a., unpublished	Y	Bayer
KCA 5.2.4 /01	xxx	1994	Primary dermal irritation study of CGA 279202 technical in rabbits xxxx, Report No.: HWI40702446, Edition Number: M-040053-01-1 EPA MRID No.: 44496635 Date: 1994-10-05 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.4 /02 KCA 5.2.1 /03 KCA 5.2.2 /03 KCA 5.2.3 /02 KCA 5.2.6 /03	xxx	2000	CGA 279202 50 WG (A 9360 B) - Acute toxicity xxx, Report No.: MO-02-006590, Edition Number: M-060912-01-1 GLP/GEP: n.a., unpublished	Y	Bayer
KCA 5.2.4 /03	xxx	1996	CGA 279202 EC 125 (A-9604 A) - Acute dermal irritation/corrosion study in the rabbit xxx, Report No.: 963038, Edition Number: M-039508-01-1 Date: 1996-04-23 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCA 5.2.5 /01	xxx	1994	Primary eye irritation study of CGA 279202 technical in rabbits xxx Report No.: HWI40702447, Edition Number: M-040060-01-1 EPA MRID No.: 44496632 Date: 1994-10-07 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.5 /02	xxx	1996	CGA 279202 EC 125 (A-9604 A) - Acute eye irritation/corrosion study in the rabbit xxx Report No.: 963039, Edition Number: M-040686-01-1 Date: 1996-06-03 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.5 /03	xxx	1996	CGA 279202 WG 50 (A-9360 B) - Acute eye irritation/corrosion study in the rabbit xxx, Report No.: 963042, Edition Number: M-041414-01-1 Date: 1996-05-08 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.6 /01	xxx	1994	CGA 279202 tech. - Skin sensitisation test in the guinea pig - maximisation test xxx Report No.: 943047, Edition Number: M-040063-01-1 EPA MRID No.: 44496637 Date: 1994-09-28 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.6 /02	xxx	1994	Dermal sensitization study of CGA-279202 technical in guinea pigs - closed patch technique xxx, Report No.: HWI40702448, Edition Number: M-040068-01-1 EPA MRID No.: 44496639 Date: 1994-11-18 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.6 /03 KCA 5.2.1 /03 KCA 5.2.2 /03 KCA 5.2.3 /02 KCA 5.2.4 /02	xxx	2000	CGA 279202 50 WG (A 9360 B) - Acute toxicity xxx, Report No.: MO-02-006590, Edition Number: M-060912-01-1 GLP/GEP: n.a., unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCA 5.2.6 /04	xxx	1996	CGA 279202 EC 125 (A-9604 A) - Skin sensitisation test in the guinea pig - Buehler test xxx, Report No.: 963040, Edition Number: M-040748-01-1 Date: 1996-06-10 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.6 /05	xxx	1996	CGA 279202 EC 125 (A-9604 A) - Skin sensitisation test in the guinea pig - Buehler test xxx Report No.: 963084, Edition Number: M-040761-01-1 Date: 1996-10-24 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.6 /06	xxx	1996	CGA 279202 WG 50 (A-9360 B) - Skin sensitization test in the guinea pig - Buehler test xxx, Report No.: 963043, Edition Number: M-041417-01-1 Date: 1996-06-10 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.6 /07	xxx	1997	CGA 279202 WG 50 (A-9360 B) - Skin sensitization in the guinea pig - maximization test xxx, Report No.: 973026, Edition Number: M-041422-01-1 Date: 1997-08-28 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.6 /08	xxx	2003	CGA 279202 - Local lymph node assay in mice (LLNA/IMDS) xxx, Report No.: AT00432, Edition Number: M-104762-01-1 Date: 2003-05-23 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.2.7 /01	Heppenheimer, A.	2013	Trifloxystrobin TC: Cytotoxicity assay in vitro with BALB/c 3T3 cells - Neutral red (NR) test during simultaneous irradiation with artificial sunlight Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1561100, Edition Number: M-463801-01-1 Date: 2013-09-12 GLP/GEP: yes, unpublished	N	Bayer

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
KCA 5.3.1 /01	xxx	1994	CGA 279202 tech. - 28-days range finding study in rats (administration in food) xxx, Report No.: 933099, Edition Number: M-040074-01-1 EPA MRID No.: 44496643 Date: 1994-02-04 GLP/GEP: no, unpublished	Y	Bayer
KCA 5.3.1 /02	xxx	1994	CGA 279202 tech. - 28-day range finding toxicity study in Beagle dogs xxx, Report No.: 933163, Edition Number: M-040122-01-1 EPA MRID No.: 44496642 Date: 1994-09-28 GLP/GEP: no, unpublished	Y	Bayer
KCA 5.3.1 /03 KCA 5.8.1 /17	xxx	2000	NOA 413161 tech. (metabolite of CGA 279202 tech.) - 28-day subacute oral toxicity study in rats xxx, Report No.: 993090, Edition Number: M-137124-01-1 Date: 2000-03-30 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.3.2 /01 KCA 8.7 /02	xxx	1995	CGA 279202 tech. - 3-month oral toxicity study in rats (administration in food) xxx Report No.: 933164, Edition Number: M-040135-01-1 EPA MRID No.: 44496701 Date: 1995-01-19 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.3.2 /02	xxx	1994	CGA 272902 tech. - 3-month range finding toxicity study in mice (administration in food) xxx, Report No.: 933165, Edition Number: M-040129-01-2 EPA MRID No.: 44496641 Date: 1994-11-14 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
KCA 5.3.2 /03	xxx	1996	CGA 279202 tech. - 3-month subchronic oral toxicity study in Beagle dogs xxx, Report No.: 943040, Edition Number: M-040184-01-1 EPA MRID No.: 44496702 Date: 1996-06-26 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.3.2 /04 KCA 5.4.2 /02	xxx	1995	CGA 279202: Assessment of replicative DNA synthesis in the course of a 3-month oral toxicity study in rats xxx, Report No.: CB 94/61, Edition Number: M-039187-01-1 Date: 1995-09-25 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.3.2 /05 KCA 5.4.2 /03	xxx	1995	CGA 279202: Assessment of replicative DNA synthesis in the course of a 3-month range finding toxicity in mice xxx, Report No.: CB 94/60, Edition Number: M-039206-01-1 Date: 1995-09-25 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.3.3 /01	xxx	1996	CGA 279202 tech. - 28-day repeated dose dermal toxicity study in the rat xxx, Report No.: 943046, Edition Number: M-040287-01-1 EPA MRID No.: 44496703 Date: 1996-03-05 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.4 /01	Hartmann, K.	2013	Trifloxystrobin - Overview on photosafety and waiver for conduct of a photomutagenicity study Bayer CropScience, Report No.: M-467988-01-1, Edition Number: M-467988-01-1 GLP/GEP: n.a., unpublished	N	Bayer

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
KCA 5.4.1 /01	Hertner, T.	1994	CGA 279202 tech. - Salmonella and escherichia/mammalian-microsome mutagenicity test Ciba-Geigy Limited, Basel, Switzerland Bayer CropScience, Report No.: 943074, Edition Number: M-040308-01-1 EPA MRID No.: 44496712 Date: 1994-09-26 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.4.1 /02	Hertner, T.	1994	CGA 279202 tech. - Cytogenetic test on chinese hamster cells in vitro (EC-conform) Ciba-Geigy Limited, Basel, Switzerland Bayer CropScience, Report No.: 943076, Edition Number: M-040332-01-1 EPA MRID No.: 44496718 Date: 1994-12-06 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.4.1 /03	xxx	1995	CGA 279202 tech. - Autoradiographic DNA repair test on rat hepatocytes (OECD conform) in vitro xxx, Report No.: 943077, Edition Number: M-040338-01-1 EPA MRID No.: 44496719 Date: 1995-06-09 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.4.1 /04	Hertner, T.	1995	CGA 279202 tech. - Gene mutation test with chinese hamster cells V79 Ciba-Geigy Limited, Basel, Switzerland Bayer CropScience, Report No.: 943075, Edition Number: M-040439-01-1 EPA MRID No.: 44496713 Date: 1995-07-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.4.2 /01	xxx	1995	CGA 279202 tech. - Micronucleus test, mouse (OECD conform) xxx Report No.: 943078, Edition Number: M-040451-02-1 Date: 1995-02-01 **...Amended: 2000-03-31** GLP/GEP: yes, unpublished	Y	Bayer

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KCA 5.4.2 /02 KCA 5.3.2 /04	xxx	1995	CGA 279202: Assessment of replicative DNA synthesis in the course of a 3-month oral toxicity study in rats xxx, Report No.: CB 94/61, Edition Number: M-039187-01-1 Date: 1995-09-25 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.4.2 /03 KCA 5.3.2 /05	xxx	1995	CGA 279202: Assessment of replicative DNA synthesis in the course of a 3-month range finding toxicity in mice xxx, Report No.: CB 94/60, Edition Number: M-039206-01-1 Date: 1995-09-25 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.5 /01	xxx	1997	CGA 279202 tech. - 24-month carcinogenicity and chronic toxicity study in rats xxx, Report No.: 943038, Edition Number: M-040512-02-1 Date: 1997-10-22 **...Amended: 1998-05-12** GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.5 /02	xxx	2001	Historical incidence of systemic neoplasias in untreated male rats /Tif:RAI f (SPF), hybrids of RII/1xRII/2) at Health Assessment 2 Stein, RT 6.51 xxx) xxx, Report No.: MO-01-004216, Edition Number: M-043299-01-1 Date: 2001-02-19 GLP/GEP: no, unpublished	Y	Bayer
KCA 5.5 /03	xxx	2000	Response to special queries concerning: 24-month carcinogenicity and chronic toxicity study in rats xxx, Report No.: MO-01-000929, Edition Number: M-032173-01-1 Date: 2000-01-26 GLP/GEP: no, unpublished	Y	Bayer

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KCA 5.5 /04	xxx	2001	CGA 279202 techn., 24 months carcinogenicity and chronic toxicity study in rats, test no. 943038, final report, xxx; author xxx; author of the pathology report xxx; T5064230 xxx, Report No.: MO-01-010535, Edition Number: M-033658-01-1 Date: 2001-05-23 GLP/GEP: no, unpublished	Y	Bayer
KCA 5.5 /05	xxx	2001	CGA 279202 techn., 24 months carcinogenicity and chronic toxicity study in rats, test no. 943030, final report, xxx, author xxx; author of the pathology report xxx xxx Report No.: MO-01-002450, Edition Number: M-037045-01-1 Date: 2001-02-23 GLP/GEP: no, unpublished	Y	Bayer
KCA 5.5 /06	xxx	1997	CGA 279202 tech. - 18-Months carcinogenicity study in mice xxx Report No.: 943039, Edition Number: M-039533-03-1 Date: 1997-10-22 **...Amended: 1999-04-28** GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.5 /07	xxx	1999	CGA 279202 tech. - 18-month oncogenicity study in mice (study no. 943039) - historical data of malignant lymphoma xxx, Report No.: MO-01-000927, Edition Number: M-032168-01-1 Date: 1999-12-22 GLP/GEP: no, unpublished	Y	Bayer
KCA 5.5 /08	xxx	1997	CGA 279202 tech. - 12-month chronic oral toxicity study in Beagle dogs xxx, Report No.: 943041, Edition Number: M-040217-01-1 EPA MRID No.: 44496704 Date: 1997-12-02 GLP/GEP: yes, unpublished	Y	Bayer

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KCA 5.6.1 /01 KCA 8.7 /03	xxx	1997	CGA 279202 Technical - Rat dietary two-generation reproduction study xxx, Report No.: 943045, Edition Number: M-039264-02-1 Date: 1997-10-20 **...Amended: 2001-01-29** GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.6.2 /01	xxx	1995	CGA 279202 technical - Rat oral teratogenicity xxx, Report No.: 943042, Edition Number: M-039420-01-1 EPA MRID No.: 44496708 Date: 1995-03-07 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.6.2 /02	xxx	1994	CGA 279202 technical - Rabbit oral teratogenicity xxx Report No.: 943043, Edition Number: M-039377-03-1 Date: 1994-12-21 **...Amended: 1999-12-20** GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.7.1 /01	xxx	1997	CGA 279202 tech. - Acute oral neurotoxicity study in rats xxx, Report No.: 973005, Edition Number: M-039223-03-1 Date: 1997-12-02 **...Amended: 1999-05-31** GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8 /01	Heimann, K. G.	2001	Refined threshold approach for metabolites of Trifloxystrobin Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MO-01-022159, Edition Number: M-088872-01-1 Date: 2001-12-14 GLP/GEP: no, unpublished	N	Bayer

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KCA 5.8.1 /01	xxx	1997	CGA 357261 tech. (Z,E-isomer of CGA 279202) - Acute oral toxicity in the rat (limit test) xxx, Report No.: 973006, Edition Number: M-039079-02-1 EPA MRID No.: 44496620 Date: 1997-05-22 **...Amended: 1997-12-10** GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.1 /02	Deparade, E.	1997	CGA 357261 tech. (Z,E-isomer of CGA 279202) - Salmonella and escherichia/mammalian-microsome mutagenicity test Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 973007, Edition Number: M-039138-01-1 EPA MRID No.: 44496715 Date: 1997-09-18 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /03	xxx	1997	CGA 373466 tech. (metabolite of CGA 279202) - Acute oral toxicity in the rat (limit test) xxx, Report No.: 973024, Edition Number: M-039100-02-1 EPA MRID No.: 44496619 Date: 1997-07-18 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.1 /04	Deparade, E.	1997	CGA 373466 tech. - Salmonella and escherichia/mammalian-microsome mutagenicity test Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 973025, Edition Number: M-039119-01-1 EPA MRID No.: 44496716 Date: 1997-09-16 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /05	Herbold, B.	2002	CGA 279202-CGA 373466 - In vitro chromosome aberration test with chinese hamster V79 cells Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 31961, Edition Number: M-054928-01-1 Date: 2002-04-17 GLP/GEP: yes, unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCA 5.8.1 /06	Herbold, B.	2002	CGA 279202-CGA 373466 - V79/HPRT-test in vitro for the detection of induced forward mutations Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 31962, Edition Number: M-054116-01-1 Date: 2002-04-17 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /07	xxx	1997	NOA 414412 tech. (metabolite of CGA 279202) - Acute oral toxicity in the rat (limit test) xxx, Report No.: 973064, Edition Number: M-039147-01-1 EPA MRID No.: 44496621 Date: 1997-10-20 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.1 /08	Deparade, E.	1997	NOA 414412 tech. (metabolite of CGA 279202) - Salmonella and escherichia/mammalian-microsome mutagenicity test Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 973065, Edition Number: M-039158-01-1 EPA MRID No.: 44496717 Date: 1997-10-29 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /09	xxx	1998	NOA 413163 tech. (metabolite of CGA 279202) - Acute oral toxicity in the rat (limit test) xxx, Report No.: 983103, Edition Number: M-052684-01-1 Date: 1998-08-18 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.1 /10	Deparade, E.	1998	NOA 413163 tech. (metabolite of CGA 279202) - Salmonella and escherichia/mammalian-microsome mutagenicity test Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 983104, Edition Number: M-052705-01-1 Date: 1998-09-29 GLP/GEP: yes, unpublished	N	Bayer

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
KCA 5.8.1 /11	Herbold, B.	2002	CGA 279202-NOA 413161/413163 - In vitro chromosome aberration test with Chinese hamster V79 cells Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 32151, Edition Number: M-069747-01-1 Date: 2002-07-02 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /12	Herbold, B.	2002	CGA 279202-NOA 413161/413163 - V79/HPRT-test in vitro for the detection of induced forward mutations Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 32150, Edition Number: M-069760-01-1 Date: 2002-07-02 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /13	xxx	1998	NOA 413161 tech. (metabolite of CGA 279202) - Acute oral toxicity in the rat (limit test) xxx Report No.: 983068, Edition Number: M-052694-01-1 Date: 1998-08-18 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.1 /14	Deparade, E.	1998	NOA 413161 tech. (metabolite of CGA 279202) - Salmonella and escherischia/mammalian-microsome mutagenicity test Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 983069, Edition Number: M-054210-01-1 Date: 1998-09-16 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /15	Ogorek, B.	1999	NOA 413161 (metabolite of CGA 279202) - Cytogenetic test on chinese hamster cells in vitro Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 993094, Edition Number: M-054214-01-1 Date: 1999-12-13 GLP/GEP: yes, unpublished	N	Bayer

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KCA 5.8.1 /16	Ogorek, B.	2000	NOA 413161 (metabolite of CGA 279202) - Gene mutation test with chinese hamster cells V79 Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 993095, Edition Number: M-054225-01-1 Date: 2000-04-25 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /17 KCA 5.3.1 /03	xxx	2000	NOA 413161 tech. (metabolite of CGA 279202 tech.) - 28-day subacute oral toxicity study in rats xxx, Report No.: 993090, Edition Number: M-137124-01-1 Date: 2000-03-30 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.1 /18	Heimann, K. G.	2001	CGA 321113 - Statement on the relevance of the Trifloxystrobin metabolite Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: MO-01-000794, Edition Number: M-031965-01-1 Date: 2001-01-18 GLP/GEP: no, unpublished	N	Bayer
KCA 5.8.1 /19	Bouis, P.	1997	CGA 279202 and CGA 321113 - Cytotoxicity in primary cultured rat hepatocytes and effects on mito-chondrial function of rat liver Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: CB97/59, Edition Number: M-039240-01-1 EPA MRID No.: 44496720 Date: 1997-12-17 GLP/GEP: no, unpublished	N	Bayer
KCA 5.8.1 /20	Freyberger, A.	2002	Effects of trifloxystrobin (CGA 279202) and its metabolites CGA 321113, CGA 373466, NOA 413161 and NOA 413163 on succinate-supported rat liver mitochondrial respiration Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 31746, Edition Number: M-034840-02-1 Date: 2002-02-06 **...Amended: 2003-03-03** GLP/GEP: no, unpublished	N	Bayer

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KCA 5.8.1 /21	Wasinska-Kempka, G.	2002	Investigation of the hepatotoxic potential of trifloxystrobin and its metabolites on primary rat hepatocytes in an in vitro model Bayer AG, Wuppertal, Germany Bayer CropScience, Report No.: 31822, Edition Number: M-090653-02-1 Date: 2002-01-09 **...Amended: 2002-03-01** GLP/GEP: no, unpublished	N	Bayer
KCA 5.8.1 /22	Schoefer, S.; Ecker, U.; Heimann, K.G. Weber, E.; Ohs, P.	2001	Trifloxystrobin - Assessment on the relevance of metabolites found in lysimeter leachate (Biological, environmental, toxicological and ecotoxicological properties) Bayer AG, Bayer CropScience, Monheim, Germany Bayer CropScience, Report No.: REG01-0030, Edition Number: M-055085-06-1 GLP/GEP: n.a., unpublished	N	Bayer
KCA 5.8.1 /23	Freyberger, A.	2013	Trifloxystrobin (CGA 279202), isomers and metabolites - Studies on potential interactions with the mitochondrial respiration of freshly isolated rat liver mitochondria Bayer Pharma AG, Wuppertal, Germany Bayer CropScience, Report No.: AT06643, Edition Number: M-463641-01-1 Date: 2013-10-16 GLP/GEP: no, unpublished	N	Bayer
KCA 5.8.1 /24	Ellinger-Ziegelbauer, H	2013	Trifloxystrobin, isomers and metabolites - Cytotoxicity in rat hepatocytes Bayer Pharma AG, Wuppertal, Germany Bayer CropScience, Report No.: AT06630, Edition Number: M-463388-01-2 Date: 2013-09-02 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /25	Bohnenberger, S.	2013	CGA 279202-CGA 357261 - Micronucleus test in human lymphocytes in vitro Bayer CropScience, Report No.: 1553700, Edition Number: M-463623-01-1 Date: 2013-10-17 GLP/GEP: yes, unpublished	N	Bayer

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KCA 5.8.1 /26	Sokolowski, A.	2011	Salmonella typhimurium reverse mutattion assay with CGA279202-CGA331409 Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1429201, Edition Number: M-414991-01-1 Date: 2011-09-30 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /27	Bohnenberger, S.	2013	CGA 279202-CGA 331409 - Micronucleus test in human lymphocytes in vitro Harlan Cytotest Cell Research (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1553600, Edition Number: M-463619-01-1 Date: 2013-10-17 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /28	Sokolowski, A.	2011	Salmonella typhimurium reverse mutattion assay with CGA279202-CGA357262 Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1429202, Edition Number: M-414989-01-1 Date: 2011-09-29 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /29	Bohnenberger, S.	2013	CGA 279202-CGA 357262 - Micronucleus test in human lymphocytes in vitro Harlan Cytotest Cell Research (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1553800, Edition Number: M-463639-01-1 Date: 2013-10-17 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /30	Sokolowski, A.	2011	Salmonella typhimurium reverse mutation assay with CGA 279202-CGA 321113 Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1390501, Edition Number: M-406346-01-1 Date: 2011-04-27 GLP/GEP: yes, unpublished	N	Bayer

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KCA 5.8.1 /31	Wollny, H. E.	2011	CGA 279202-CGA 321113 - Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1390503, Edition Number: M-411413-01-1 Date: 2011-07-27 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /32	Hall, C.	2011	CGA 279202-CGA 321113 - In vitro chromosome aberration test in Chinese hamster V79 cells Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1390502, Edition Number: M-413745-01-1 Date: 2011-09-08 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.1 /33	xxx	2013	CGA 279202-CGA 321113: Micronucleus test in bone marrow cells of the mouse xxx, Report No.: 1578200, Edition Number: M-463614-01-1 Date: 2013-01-01 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.1 /34	xxx	2013	In vivo unscheduled DNA synthesis in rat hepatocytes with trifloxystrobin-CGA 321113 xxx, Report No.: 1504401, Edition Number: M-458428-01-1 Date: 2013-06-17 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.1 /35	xxx	2003	CGA 279202-CGA 373466 - Study for subacute oral toxicity in rats (feeding study for 4 weeks and 4 weeks recovery period) xxx, Report No.: AT00343, Edition Number: M-088404-01-1 Date: 2003-03-31 GLP/GEP: yes, unpublished	Y	Bayer

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KCA 5.8.1 /36	xxx	2003	CGA 279202-NOA 413161/413163 - Study for subacute oral toxicity in rats (4-week application by gavage and 4 weeks recovery period) xxx, Report No.: AT00342, Edition Number: M-084123-01-1 Date: 2003-03-31 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.1 /37	Lee, K. H.; Lee, B. M	2007	Study of mutagenicities of phthalic acid and terephthalic acid using in vitro and in vivo genotoxicity tests Publisher: Taylor & Francis Group, LLC, Journal: Journal of Toxicology and Environmental Health, Part A, Volume:70, Pages:1329-1335, Year:2007, Report No.: M-462063-01-1, Edition Number: M-462063-01-1 Date: 2007-12-31 GLP/GEP: n.a., published	N	Bayer
KCA 5.8.1 /38	Buerkle, L.; Hartmann, K.; Sonder, K.; Weile, M.	2013	Trifloxystrobin - Toxicological profile and exposure assessment of the plant metabolites Bayer CropScience, Report No.: M-469186-01-1, Edition Number: M-469186-01-1 GLP/GEP: n.a., unpublished	N	Bayer
KCA 5.8.2 /01	xxx	1998	CA 2446 A (intermediate of CGA 279202) - Acute oral toxicity in the rat (limit test) xxx, Report No.: 983073, Edition Number: M-072479-01-1 Date: 1998-07-09 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /02	xxx	1998	CA 2446 A (intermediate of CGA 279202) - Acute dermal toxicity in the rat (limit test) xxx Report No.: 983074, Edition Number: M-072484-01-1 Date: 1998-08-20 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCA 5.8.2 /03	xxx	1998	CA 2446 A (intermediate of CGA 279202) - 4 hour acute inhalation toxicity study in rats xxx, Report No.: 983078, Edition Number: M-072489-01-1 Date: 1998-09-10 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /04	xxx	1998	CA 2446 A (intermediate of CGA 279202) - Acute dermal irritation/corrosion in the rabbit xxx, Report No.: 983075, Edition Number: M-072502-01-1 Date: 1998-07-01 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /05	xxx	1998	CA 2446 A (intermediate of CGA 279202) - Acute eye irritation/corrosion in the rabbit xxx, Report No.: 983076, Edition Number: M-072511-01-1 Date: 1998-07-03 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /06	xxx	1998	CA 2446 A (intermediate of CGA 279202) - Skin sensitization in the guinea pig (maximization test) xxx, Report No.: 983077, Edition Number: M-072530-01-1 Date: 1998-08-18 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /07	xxx	1999	CA 2446 A (intermediate of CGA 279202) - 28 days subacute, oral toxicity study in rats (gavage) xxx, Report No.: 983081, Edition Number: M-072591-01-1 Date: 1999-06-30 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /08	Deparade, E.	1998	CA 2446A (intermediate of CGA 279202) - Salmonella and escherichia/mammalian-microsome muta-genicity test Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 983079, Edition Number: M-072538-01-1 Date: 1998-09-16 GLP/GEP: yes, unpublished	N	Bayer

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KCA 5.8.2 /09	Ogorek, B.	1998	CA 2446 A (intermediate of CGA 279202) - Cytogenetic test on chinese hamster cells in vitro Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 983080, Edition Number: M-072553-01-1 Date: 1998-12-02 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.2 /10	xxx	2000	CGA 289998 tech. (by product of CGA 279202) - Acute oral toxicity study in the rat (limit test) xxx, Report No.: 20003018, Edition Number: M-137220-01-1 Date: 2000-03-30 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /11	Deparade, E.	2000	CGA 289998 tech. (by-product of CGA 279202) - Salmonella and escherichia/mammalian-microsome mutagenicity test Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 20003019, Edition Number: M-073574-01-1 Date: 2000-04-13 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.2 /12	Deparade, E.	1998	CA 2249 A (intermediate of CGA 279202) - Salmonella and Escherichia/mammalian-microsome muta-genicity test Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 983025, Edition Number: M-073323-01-1 Date: 1998-04-22 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.8.2 /13	Ogorek, B.	1998	CA 2249 A (intermediate of CGA 279202) - Cytogenic test on the chinese hamster cells in vitro xxx Report No.: 983026, Edition Number: M-137214-01-1 Date: 1998-04-28 GLP/GEP: yes, unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCA 5.8.2 /14	xxx	1998	CA 2249 A (intermediate of CGA 279202) - Micronucleus test, mouse (OECD conform) xxx, Report No.: 983067, Edition Number: M-073331-01-1 Date: 1998-11-24 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /15	xxx	1998	CA 2249 A (intermediate of CGA 279202) - Acute oral toxicity in the rat (limit test) xxx, Report No.: 983019, Edition Number: M-073084-01-1 Date: 1998-04-28 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /16	xxx	1998	CA 2249 A (intermediate of CGA 279202) - Acute dermal toxicity in the rat (limit test) xxx, Report No.: 983020, Edition Number: M-073088-01-1 Date: 1998-04-15 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /17	xxx	1998	Technical trials preceding a proposed 4 hour acute inhalation study with CA 2249 A (intermediate of CGA 279202) in rats xxx, Report No.: 685113, Edition Number: M-073091-01-1 Date: 1998-07-21 GLP/GEP: no, unpublished	Y	Bayer
KCA 5.8.2 /18	xxx	1998	CA 2249 A (intermediate of CGA 279202) - Acute dermal irritation/corrosion in the rabbit xxx Report No.: 983022, Edition Number: M-073294-01-1 Date: 1998-04-14 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /19	xxx	1998	CA 2249 A (intermediate of CGA 279202) - Acute eye irritation/corrosion in the rabbit xxx, Report No.: 983023, Edition Number: M-073304-01-1 Date: 1998-04-14 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
KCA 5.8.2 /20	xxx	1998	CA 2249 A (intermediate of CGA 279202) - Skin sensitization in the guinea pig (maximization test) xxx, Report No.: 983024, Edition Number: M-073314-01-1 Date: 1998-04-14 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /21	xxx	1999	CA 2249 A (intermediate of CGA 279202) - 28 days subacute, oral toxicity study in rats (gavage) xxx, Report No.: 983033, Edition Number: M-137216-01-1 Date: 1999-04-23 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /22	xxx	2012	Trifloxystrobin - 28-day immunotoxicity study in the male Sprague-Dawley rat by dietary administration xxx, Report No.: SA 10359, Edition Number: M-429141-01-1 EPA MRID No.: 48856301 Date: 2012-04-11 GLP/GEP: yes, unpublished	Y	Bayer
KCA 5.8.2 /23	Vincent, M.; Amir Tahmasseb, L.	2011	Trifloxystrobin - Determination by high performance liquid chromatography analysis in ground rodent diet Bayer S.A.S., Bayer CropScience, Sophia Antipolis, France Bayer CropScience, Report No.: SA 11197, Edition Number: M-411302-01-1 Date: 2011-07-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 5.9.1 /01 KCA 5.9.2 /01 KCA 5.9.3 /01 KCA 5.9.4 /01 KCA 5.9.5 /01 KCA 5.9.6 /01 KCA 5.9.7 /01	Ohs, P.	2001	CGA 279'202 - Medical data Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MO-01-008629, Edition Number: M-053751-01-1 Date: 2001-03-05 GLP/GEP: no, unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCA 5.9.1 /02	Steffens, W.	2013	Occupational medical experiences with trifloxystrobin Bayer CropScience, Report No.: M-465980-01-1, Edition Number: M-465980-01-1 Date: 2013-10-01 GLP/GEP: no, unpublished	N	Bayer

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
-	-	-	-	-	-

List of data relied on 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
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

All the toxicological studies on acute oral, dermal and inhalation toxicity as well as skin irritation, eye irritation and skin sensitisation, were performed in 2006 with the formulated product fluopyram + trifloxystrobin SC 500 (250+250 g/L), batch 2006-004983.

Although the specification of the product has been changed, the available toxicological studies are still considered to be valid for this application. Full details of the formulation specification and related bridging statement can be found in the confidential Part C of the draft Registration Report.

Comments of zRMS:	Detailed bridging assessment provided in the Part C (Vinck, K.; Immink, H.; 2020) is considered as sufficient to conclude applicability of submitted toxicity studies for the current registration process.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	Product has been previously evaluated in Poland (2014) according to Uniform Principles: Poland Luna Sensation MRiRW nr R-82/2014. Study was considered as acceptable (2014), thus no new assessment has been done. However to reflect technical progress, Reviewer (2021) briefly confront agreed end points with current requirements and TG. The study is suitable for the current registration.

Reference:	**KCP 7.1.1/01**
Title:	AE C656948 & trifloxystrobin SC 250 & 250 - Acute toxicity in the rat after oral administration
Report:	xxx
Authority registration No:	MRiRW nr R-82/2014
Guideline(s):	OECD 423 (2001); EEC Directive 67/548 Annex V - Method B.1.tris; EPA 712-C-98-190, OPPTS 870.1100
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	Yes; see our comment Point A 2.1 and also bridging assessment provided in the Part C
Duplication (if vertebrate study):	No

Materials and methods

Test material (Lot/Batch No.)	AE C656948 & trifloxystrobin SC 250&250 (2006-004983)
Species	Rat, Wistar HsdCpb:Wu
No. of animals (group size)	3 female rats per group
Dose(s)	300 and 2000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	Tap water
Post exposure observation period	14 days
Remarks	The substance is tested using a stepwise procedure, each step using three animals of a single sex (normally females).

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of FLU+TFS SC 500

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD50 (mg/kg bw) (14 days)
Female rats (1st)				
300	0/0/3	-	-	-
2000	0/3/3	20´ - 6h	-	> 2000
Female rats (2nd)				
300	0/0/3	-	-	-
2000	2/3/3	35´ - 4h	2h – 4h	< 2000

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 2: Summary of findings of acute oral toxicity study in rats of FLU+TFS SC 500

Mortality:	Yes (2000 mg/kg: 2/6).
Clinical signs:	Yes (decreased motility, uncoordinated gait, abdominal position, labored breathing)
Body weight:	Body weight gain was considered to be normal.
Macroscopic examination:	The necropsies performed in animals that died revealed dark-red spottet liver. The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the oral LD50 cut-off of FLU+TFS SC 500 is 2000 mg/kg bw in rats. Thus, classification is required according to Regulation (EC) No. 1272/2008.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	Product has been previously evaluated in Poland (2014) according to Uniform Principles: Poland Luna Sensation MRiRW nr R-82/2014. Study was considered as acceptable (2014), thus no new assessment has been done. However to reflect technical progress, Reviewer (2021) briefly confront agreed end points with current requirements and TG. The study is suitable for the current registration.

Reference:	**KCP 7.1.2/01**
Title:	AE C656948 & trifloxystrobin SC 250 & 250 - Acute toxicity in the rat after dermal application
Report:	xxx
Authority registration No:	MRiRW nr R-82/2014
Guideline(s):	OECD 402 (1987); EEC Directive 67/548 Annex V - Method B.3.; EPA 712-C-98-192, OPPTS 870.1200
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	Yes; see our comment Point A 2.1 and also bridging assessment provided in the Part C
Duplication (if vertebrate study):	No

Materials and methods

Test material (Lot/Batch No.)	AE C656948 & trifloxystrobin SC 250&250 (2006-004983)
Species	Rat, Wistar HsdCpb:Wu
No. of animals (group size)	5 rats/sex
Dose(s)	2000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)

Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 3: Results of acute dermal toxicity study in rats of FLU+TFS SC 500

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD50 (mg/kg bw) (14 days)
Male rats				
2000	0/0/5	-	-	> 2000
Female rats				
2000	0/0/5	-	-	> 2000

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 4: Summary of findings of acute dermal toxicity study in rats of FLU+TFS SC 500

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed.
Body weight:	Body weight gain was considered to be normal.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the dermal LD_{50} of FLU+TFS SC 500 is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	Product has been previously evaluated in Poland (2014) according to Uniform Principles: Poland Luna Sensation MRiRW nr R-82/2014. Study was considered as acceptable (2014), thus no new assessment has been done. However to reflect technical progress, Reviewer (2021) briefly confront agreed end points with current requirements and TG. The study is suitable for the current registration.

Reference:	**KCP 7.1.3/01**
Title:	AE C656948 & trifloxystrobin SC 250 & 250 - Activity ID TXGMP033- Acute inhalation toxicity in rats
Report:	xxx
Authority registration No:	MRiRW nr R-82/2014
Guideline(s):	OECD 403 (1981); Directive 92/69/EEC, Annex V - Method B.2. (1992); US EPA OPPTS 870.1300 (1998); Japan MAFF, Notification No. 12 Nousan-8147 (2000)
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	Yes; see our comment Point A 2.1 and also bridging assessment provided in the Part C
Duplication (if vertebrate study):	No

Materials and methods

Test material (Lot/Batch No.)	AE C656948 & trifloxystrobin SC 250&250 (2006-004983)
Species	Rat, Wistar HsdCpb:Wu
No. of animals (group size)	5 rats/sex
Concentration(s)	0, 1.742 mg/L air (maximum attainable concentration)
Exposure	4 hours (nose only)
Vehicle/Dilution	Water
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 5: Concentration(s) and exposure conditions

Target conc. (mg/L air)	or	**Nominal conc. (mg/L air)**	**Actual conc. (mg/L air)**	**MMAD * (µm)**	**GSD ** (µm)**
5.000		14.6553	1.742	2.81	1.84

* MMAD = Mass Median Aerodynamic Diameter
** GSD = Geometric Standard Deviation

Table A 6: Results of acute inhalation toxicity study in rats of FLU+TFS SC 500

Concentration (mg/L air)	Toxicological results *	Duration of signs	Time of death	LC_{50} (mg/L air) (14 days)
Male rats				
0	0/0/5	-	-	-
5.000	0/5/5	0d	-	> 1.742
Female rats				
0	0/0/5	-	-	-
5.000	0/5/5	0d	-	> 1.742

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 7: Summary of findings of acute inhalation toxicity study in rats of FLU+TFS SC 500

Mortality:	No mortality occurred.
Clinical signs:	Yes clinical signs of toxicity were observed (bradypnea, laboured breathing patterns, motility reduced and piloerection). Reflex measurements: none of the rats exhibited changes in reflexes. Rectal temperature: comparisons between the control and exposure groups revealed a significant decrease of body temperature.
Body weight:	After exposure body weight of both groups revealed a slight decrease. Comparison of body weight development during the observation period between the control and the test group indicate no significant differences.
Macroscopic examination:	Apparent abnormalities in 2 males and 2 females (lung: light colored areas)

Conclusion

Under the experimental conditions, the inhalation LC_{50} of FLU+TFS SC 500 is higher than 1.742 mg/L air (maximum attainable concentration) in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Product has been previously evaluated in Poland (2014) according to Uniform Principles: Poland Luna Sensation MRiRW nr R-82/2014. Study was considered as acceptable (2014), thus no new assessment has been done. However to reflect technical progress, Reviewer (2021) briefly confront agreed end points with current requirements and TG. The study is suitable for the current registration.

Reference:	**KCP 7.1.4/01**
Title:	AE C656948 & trifloxystrobin SC 250 & 250 - Acute skin irritation/corrosion on rabbits
Report:	xxx
Authority registration No:	MRiRW nr R-82/2014
Guideline(s):	OECD 404 (2002); EEC Directive 67/548 Annex V - Method B.4 (1967); EPA OPPTS 870.2500; MAFF 12 Nousan No 8628 (December 06, 2000)
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	Yes; see our comment Point A 2.1 and also bridging assessment provided in the Part C
Duplication (if vertebrate study):	No

Materials and methods

Test material (Lot/Batch No.)	AE C656948 & trifloxystrobin SC 250&250 (2006-004983)
Species	Rabbit, New Zealand White (Crl:KBL(NZW)BR)
No. of animals (group size)	3 females
Initial test using one animal	Yes
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	3 days
Remarks	None

Results and discussions

Table A 8: Skin irritation of FLU+TFS SC 500

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Erythema Oedema	1 0	0 0	0 0	0 0	0 0	1# na
2	Erythema Oedema	0 0	0 0	0 0	0 0	0 0	na na
3	Erythema Oedema	0 0	0 0	0 0	0 0	0 0	na na

* scores in the range of 0 to 4
\# in respect of the result 1h post application

Clinical signs:	No clinical signs of toxicity were observed.

Conclusion

Under the experimental conditions, FLU+TFS SC 500 is not a skin irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	Product has been previously evaluated in Poland (2014) according to Uniform Principles: Poland Luna Sensation MRiRW nr R-82/2014. Study was considered as acceptable (2014), thus no new assessment has been done. However to reflect technical progress, Reviewer (2021) briefly confront agreed end points with current requirements and TG. The study is suitable for the current registration.

Reference:	**KCP 7.1.5/01**
Title:	AE C656948 & trifloxystrobin SC 250 & 250 (AE C656948 + TFS SC 250+250 G) - Acute eye irritation on rabbits
Report:	xxx
Authority registration No:	MRiRW nr R-82/2014
Guideline(s):	OECD 405 (2002) EEC Directive 67/548 Annex V - Method B.5. (1967) EPA OPPTS 870.2400 MAFF 12 Nousan No 8628 (December 06, 2000)
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	Yes; see our comment Point A 2.1 and also bridging assessment provided in the Part C
Duplication (if vertebrate study):	No

Materials and methods

Test material (Lot/Batch No.)	AE C656948 & trifloxystrobin SC 250&250 (2006-004983)
Species	Rabbit, New Zealand White (Crl:KBL(NZW)BR)
No. of animals (group size)	3 females
Initial test using one animal	Yes
Exposure	0.1 mL (single instillation in conjunctival sac)
Irrigation (time point)	No
Vehicle/Dilution	None
Post exposure observation period	3 days
Remarks	None

Results and discussions

Table A 9: Eye irritation of FLU+TFS SC 500

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Corneal opacity	0	0	0	0	0	-
	Iritis	0	0	0	0	0	-
	Redness conjunctivae	0	0	0	0	0	-
	Chemosis conjunctivae	0	0	0	0	0	-
2	Corneal opacity	0	0	0	0	0	-
	Iritis	0	0	0	0	0	-
	Redness conjunctivae	1	0	0	0	0	1#
	Chemosis conjunctivae	0	0	0	0	0	-
3	Corneal opacity	0	0	0	0	0	-
	Iritis	0	0	0	0	0	-
	Redness conjunctivae	2	0	0	0	0	1#
	Chemosis conjunctivae	0	0	0	0	0	-

* scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 4 for redness of conjunctivae and 0 to 2 for iritis
\# in respect of the result 1h post application

Clinical signs:	There were no relevant systemic intelorance reactions.

Conclusion

Under the experimental conditions, FLU+TFS SC 500 is not an eye irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	Product has been previously evaluated in Poland (2014) according to Uniform Principles: Poland Luna Sensation MRiRW nr R-82/2014. Study was considered as acceptable (2014), thus no new assessment has been done. However to reflect technical progress, Reviewer (2021) briefly confront agreed end points with current requirements and TG. The study is suitable for the current registration.

Reference:	**KCP 7.1.6/01**
Title:	AE C656948 and trifloxystrobin SC 250 & 250 - Evaluation of potential dermal sensitization in the local lymph node assay in the mouse
Report:	xxx
Authority registration No:	MRiRW nr R-82/2014
Guideline(s):	OECD guideline 429 (2002)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Yes; see our comment Point A 2.1 and also bridging assessment provided in the Part C
Duplication (if vertebrate study):	No

Materials and methods

Test material (Lot/Batch No.)	AE C656948 & trifloxystrobin SC 250&250 (2006-004983)
Species	Mouse, CBA/J strain
No. of animals (group size)	Test substance group: 5 female mice Vehicle control goup: 5 female mice
Range finding:	Yes
Exposure (concentration(s), no. of applications)	Test substance group: 25 µL (25, 50, 100 % for 3 consecutive days) Vehicle control goup: 25 µL (vehicle for 3 consecutive days)
Vehicle	1% aqueous Pluronic Acid

Reliability check	Yes/ Classical positive control substances are tested routinely in this laboratory to show consistency of a satisfactory response over a six-month period.
Remarks	None

Results and discussions

Table A 10: Results of skin sensitisation study of FLU+TFS SC 500

	No. of animals	**Concentration (%)**	**DPM / group**	**Stimulation index (SI)**
FLU+TFS SC 500	5	25	3915	1.2
	5	50	3276	0.99
	5	100	3362	1.0
Test Vehicle Control Group	5	0	3304	
Positive control*				

* Classical positive control substances are tested routinely in this laboratory to show consistency of a satisfactory response over a six-month period.

Negative lymphoproliferative responses (SI<3) was noted for FLU+TFS SC 500 at all concentrations tested.

Clinical signs:	100%: all animals had depilation around the ears. No cutaneous reactions and no irritation were observed in the vehicle or treated groups.

Conclusion

Under the experimental conditions, FLU+TFS SC 500 is not a skin sensitiser. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplemental studies submitted.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co- formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

Comments of zRMS:	Detailed bridging assessment provided in the Part C (Vinck, K.; Immink, H.; 2020) is considered as sufficient to conclude applicability of submitted dermal absorption studies for the current registration process and the dermal absorption values for trifloxystrobin can be used when moving from the formulation specification 10200002886-04 to specification 10200002886-05. This assessment aims to demonstrate that dermal absorption studies prepared for the formulation coded 102000012886-04 are also usable without further

	testing for the formulation coded 102000012886-05. In accordance with the EFSA guidance on dermal absorption 2017 (EFSA (European Food Safety Authority), 2017. Guidance on dermal absorption. EFSA Journal 2017; 15(6): 4873). The study is performed according to OECD guideline 428 and is considered acceptable. The dermal absorption values as proposed by the applicant are acceptable. However, a pro-rata consideration has been performed reflecting applications rate (spray dilution) proposed in the GAP: 1) The concentrate tested (fluopyram 250 g/L) is equal to the concentrate concentration of Luna Sensation, a pro rata correction is therefore not considered necessary. 2) Taking into account the most critical uses according to the GAP, the concentration of the spray dilution ranges between 0,05g/L and 1.3g/L. Since a lower concentration generally results in a higher dermal absorption, the dermal absorption derived for the 0.033 g/L spray dilution as tested in the *in vitro* study is considered acceptable for spray dilutions with a concentration of 0,05g/L as a worst-case approach thus a pro rata correction is therefore not considered necessary.

A 2.10.1 Fluopyram

Comparative dermal absorption, *in vitro* using rat and human skin

Reference:	**KCP 7.3/01**
Title:	In vitro human skin penetration of 14C-fluopyram in the fluopyram and trifloxystrobin SC 500 formulation
Report:	Bernal, J.; 2014; S13-04169; M-475331-01-1
Authority registration No:	N/A
Guideline(s):	OECD Guideline for the testing of Chemicals Skin Absorption In Vitro Method Guideline 428 (April 2004). OECD Environmental Health and Safety Publication Series on testing and Assessment N° 28, Guidance Document for the Conduct of Skin Absorption Studies (March 2004). EFSA Panel on Plant Protection Products and their Residues (PPR): Guidance on Dermal Absorption, EFSA Journal 2012: 10(4): 2665.
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	Yes; see our comment Point A 2.1 and also bridging assessment provided in the Part C
Duplication (if vertebrate study):	

Material and methods

Human skin:
Source: Banque de Tissu de Lyon and Biopredic, France.
Number and sex: 3 donors, female.
Anatomical region: Abdomen.
Thickness: 312 to 400 µm.

Test Material:

Non-radiolabelled:
Batch: NLL7687-2.
Purity = 99.4%.

Radiolabelled:
[phenyl-UL-^{14}C]-fluopyram
Batch: KML 9643.
Specific activity: 139.06 µCi/mg.
Radiopurity of the formulation: >99%.

Formulation:
The formulation used in this experiment was the Fluopyram + Trifloxystrobin SC 500 formulation containing fluopyram at a concentration of 250 g/L and

trifloxystrobin at a concentration of 250 g/L. It was used at three nominal concentrations of fluopyram: neat; 250 g/L, 0.2 g/L and 0.033 g/L.

Test system: A flow-through diffusion cell system was used to study the absorption of the test substance (exposure area of 1 cm^2 skin). A diffusion cell consisted of a donor chamber and a receptor chamber between which the skin was positioned. The receptor fluid used in this study was PBS 0.01M pH 7.4 + 6% polyoxyethylene 20 oleyl ether. The skin surface temperature was maintained at 32°C ± 1°C, with a fixed water bath integrated in the dynamic system (close to the normal skin temperature). The receptor fluid was pumped through the receptor chamber at a rate of 1 mL/h.

Skin integrity: Before dose application, the integrity of the skin samples was assessed by measuring the trans-epidermal water loss (TEWL) from the stratum corneum. The skin integrity was evaluated before use by measuring the TEWL. The absence of water on the skin was controlled using a Tewameter which allows measurement of water evaporation from skin surfaces based on the diffusion principle and expresses the results digitally in $g/m^2/h$. The measurement was carried out away from any heating source and air stream after at least 1 hour stabilisation. The human skin was included in the study if the TEWL was ≤ 4 $g/m^2/h$.

Treatment: The dose preparation was applied to the split-thickness skin sample with a positive displacement pipette at the rate of approximately 10 $\mu L/cm^2$ exposed skin. The specific activity of 6 aliquots of fluopyram and the homogeneity of the test items were checked on the day of preparation, before and during application. The homogeneity of the test items before the application was acceptable if the obtained CV was < 5%. The specific activity of the test items obtained during the application was used to calculate the recovery. The coefficient of variation between this series of samples was stated as a measure of variability of the application system.

Sampling: The receptor fluid passing through the receptor chamber was collected in glass vials held in a fraction collector. The receptor fluid was collected in one vial per time point and per cell at 1h, 2h, 3h, 4h, 5h, 6h, 7h, 8h, 10h, 12h, 15h, 18h, 21h and 24h post the start of application. At 8 hours post-application, the skin was swabbed with 10% v/v Tween 80 in water using cotton buds and then with 9 x 1 mL of UHQ water. The washing solution was added to the skin surface then removed using a pipette and was collected for analysis. Then, skin surface was carefully dried with three cotton-buds in order to remove and retain the non-absorbed dose. At the end of the study (24 hours after application), the treated skin and the skin adjacent to the treatment site (surrounding swabs) were swabbed. Each skin sample was tape-stripped to remove the stratum corneum. The strips were performed using adhesive scotch tape Magic 3M®. In order to standardise stripping, a weight of 150 g/cm^2 was placed top of the Scotch tape for 10 s before taking off. A maximum of 15 strips were performed until the slightly shiny layer below the *stratum corneum* was visible, corresponding to the viable epidermis (presumed to be the region around the *stratum spinosum*). All strips were analysed separately. The first two strips are considered in the calculation as material likely to be lost to the external environment due to desquamation of the superficial external layers of the skin surface.

Radioassay: Samples were analysed for radiolabel content by scintillation counter (LS6500, Beckman). The related software is WinConnection P/W 513860 V2.11. Calculations were performed using Excel 2010 directly from the raw data obtained with the scintillation counter. The software runs calculations using 7 decimal points, but in general less numbers are printed on the raw data sheets. Conversion of the counts per minute (cpm) to disintegrations per minute (dpm) was performed directly by the microprocessor in the instrument using a quench curve of the appropriate scintillation cocktail stored in the instrument database.

Findings:

Fluopyram was demonstrated to be sufficiently soluble in the receptor fluid to avoid any risk of back diffusion.

Measurements of the homogeneity of the three concentrations of formulation applied indicated that it was acceptable.

The study results are presented in the following tables.

Table A 11: **Distribution of radioactivity at 24 hours after dose application of [14C]- fluopyram in the FLU+TFS SC 500 formulation at the rate of 250 g/L to human skin samples (All cells).**

Results expressed in terms of percentage of applied radioactivity.

	Distribution of radioactivity (% dose applied)						Group Human HD N= 6 K N° = 1	
Sex	Female	Female	Female	Female	Female	Female		
Donor N°	250	250	234	234	TRA0010 00AJ340	TRA0010 00AJ340		
Cell N°	A	B	C	D	E	F	MEAN	SD
Skin Excess	99.12	96.94	99.98	99.04	97.27	97.49	98.31	1.23
SC1	0.05	0.01	0.04	0.04	0.08	n.d.	0.04	0.03
SC2	0.03	0.01	0.01	0.02	0.03	n.d.	0.02	0.01
Total SC1 + SC2	**0.08**	**0.02**	**0.05**	**0.06**	**0.11**	**n.d.**	**0.05**	**0.04**
TOTAL NON-ABSORBED	**99.20**	**96.96**	**100.03**	**99.10**	**97.38**	**97.49**	**98.36**	**1.24**
Skin	n.d.	n.d.	n.d.	0.01	0.09	n.d.	0.02	0.04
Stratum Corneum (SC3+)	0.40	0.21	0.22	0.07	0.08	n.d.	0.16	0.14
TOTAL DOSE SITE	**0.40**	**0.21**	**0.22**	**0.08**	**0.17**	**n.d.**	**0.18**	**0.14**
Receptor fluid (0 - 12h)	n.d.	n.d.	n.d.	n.d.	0.05	0.02	0.01	0.02
Receptor fluid (0 - 24h)	n.d.	n.d.	n.d.	n.d.	0.05	0.02	0.01	0.02
%Ratio receptor 12h/24h	100	100	100	100	100	100	**100**	**0**
Receptor chamber	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.00
TOTAL DIRECT	**0.00**	**0.00**	**0.00**	**0.00**	**0.05**	**0.02**	**0.01**	**0.02**
POTENTIAL (dose site+ receptor)	0.40	0.21	0.22	0.08	0.22	0.02	0.19	0.13
POTENTIAL (skin+ receptor)	**0.00**	**0.00**	**0.00**	**0.01**	**0.14**	**0.02**	**0.03**	**0.06**
TOTAL RECOVERY	**99.6**	**97.2**	**100.3**	**99.2**	**97.6**	**97.5**	**98.6**	**1.3**
Evaluation according to EFSA Guidance (2017)								
Absorption >75% within half of study duration?					Yes. (exclude SC values)			
Mean Recovery <95%?					No correction needed			
Total % Potentially Absorbable adjusted according to EFSA (2017)					Mean (%skin +%receptor) + (SD*1) = **0.083%**			

SD: standard deviation; N: number of skin cells used for calculation
n.d.: not detected (below the limit of detection); n.a. : not applicable
In the above table, the presented means do not always calculate exactly from the presented individual data. This is due to rounding-up differences resulting from the use of the spreadsheet program.

Table A 12: **Distribution of radioactivity at 24 hours after dose application of [^{14}C]- fluopyram in the FLU+TFS SC 500 formulation at the rate of 0.20 g/L to human skin samples (All cells).**

Results expressed in terms of percentage of applied radioactivity.

	Distribution of radioactivity (% dose applied)						Group Human HD N= 6 K N° = 1	
Sex	Female	Female	Female	Female	Female	Female		
Donor N°	250	250	234	234	TRA0010 00AJ340	TRA0010 00AJ340		
Cell N°	G	H	I	J	K	L	MEAN	SD
Skin Excess	127.60	134.62	110.67	98.30	97.82	101.73	111.79	15.82
SC1	4.32	4.02	2.38	4.14	3.12	2.90	3.48	0.79
SC2	2.52	0.63	0.78	1.60	1.53	1.35	1.40	0.68
Total SC1 + SC2	**6.84**	**4.65**	**3.16**	**5.74**	**4.65**	**4.25**	**4.88**	**1.27**
TOTAL NON-ABSORBED	**134.44**	**139.27**	**113.83**	**104.04**	**102.47**	**105.98**	**116.67**	**16.19**
Skin	2.59	0.41	0.37	0.77	0.27	0.09	0.75	0.93
Stratum Corneum (SC3+)	8.83	3.20	2.61	3.62	2.80	1.48	3.76	2.59
TOTAL DOSE SITE	**11.42**	**3.61**	**2.98**	**4.39**	**3.07**	**1.57**	**4.51**	**3.51**
Receptor fluid (0 - 12h)	3.91	2.04	1.32	1.09	3.25	2.97	2.43	1.13
Receptor fluid (0 - 24h)	5.05	2.51	1.70	1.58	3.47	3.18	2.92	1.29
%Ratio receptor 12h/24h	77	81	78	69	94	93	82	10
Receptor chamber	0.19	0.05	0.08	0.10	0.19	0.12	0.12	0.06
TOTAL DIRECT	**5.24**	**2.56**	**1.78**	**1.68**	**3.66**	**3.30**	**3.04**	**1.34**
POTENTIAL (dose site+ receptor)	16.66	6.17	4.76	6.07	6.73	4.87	7.54	4.53
POTENTIAL (skin+ receptor)	**7.83**	**2.97**	**2.15**	**2.45**	**3.93**	**3.39**	**3.79**	**2.08**
TOTAL RECOVERY	151.1	145.4	118.6	110.1	109.2	110.9	124.2	19.0
Evaluation according to EFSA Guidance (2017)								
Absorption >75% within half of study duration?					Yes. (exclude SC values)			
Mean Recovery <95%?					No correction needed			
Total % Potentially Absorbable adjusted according to EFSA (2017)					Mean (%dose site +%receptor) + (SD*1) = **5.9%**			

SD: standard deviation; N: number of skin cells used for calculation
n.d.: not detected (below the limit of detection); n.a. : not applicable
In the above table, the presented means do not always calculate exactly from the presented individual data. This is due to rounding-up differences resulting from the use of the spreadsheet program.

Table A 13: **Distribution of radioactivity at 24 hours after dose application of [14C]- fluopyram in the FLU+TFS SC 500 formulation at the rate of 0.033 g/L to human skin samples (All cells).**

Results expressed in terms of percentage of applied radioactivity.

	Distribution of radioactivity (% dose applied)						Group Human HD N= 6 K N° = 1	
Sex	Female	Female	Female	Female	Female	Female		
Donor N°	250	250	234	234	TRA0010 00AJ340	TRA0010 00AJ340		
Cell N°	M	N	O	P	Q	R	MEAN	SD
Skin Excess	92.50	105.18	81.88	81.20	61.81	85.84	84.74	14.32
SC1	2.01	5.14	6.62	5.68	3.64	2.12	4.20	1.92
SC2	0.72	3.40	3.08	2.34	2.08	1.02	2.11	1.08
Total SC1 + SC2	**2.73**	**8.54**	**9.70**	**8.02**	**5.72**	**3.14**	**6.31**	**2.92**
TOTAL NON-ABSORBED	**95.23**	**113.72**	**91.58**	**89.22**	**67.53**	**88.98**	**91.04**	**14.78**
Skin	0.19	0.80	0.54	1.82	0.36	0.10	0.64	0.63
Stratum Corneum (SC3+)	2.15	6.45	2.83	3.02	5.12	2.60	3.70	1.70
TOTAL DOSE SITE	**2.34**	**7.25**	**3.37**	**4.84**	**5.48**	**2.70**	**4.33**	**1.88**
Receptor fluid (0 - 12h)	7.58	11.99	9.84	7.18	23.37	11.68	11.94	5.95
Receptor fluid (0 - 24h)	8.39	13.73	11.86	8.47	26.14	12.26	13.48	6.56
%Ratio receptor 12h/24h	90	87	83	85	89	95	88	4
Receptor chamber	0.00	5.62	0.49	0.26	0.86	0.37	1.27	2.15
TOTAL DIRECT	**8.39**	**19.35**	**12.35**	**8.73**	**27.00**	**12.63**	**14.74**	**7.19**
POTENTIAL (dose site+ receptor)	10.73	26.60	15.72	13.57	32.48	15.33	19.07	8.50
POTENTIAL (skin+ receptor)	**8.58**	**20.15**	**12.89**	**10.55**	**27.36**	**12.73**	**15.38**	**7.06**
TOTAL RECOVERY	**106.0**	**140.3**	**107.3**	**102.8**	**100.0**	**104.3**	**110.1**	**15.0**
Evaluation according to EFSA Guidance (2017)								
Absorption >75% within half of study duration?					Yes (exclude SC values)			
Mean Recovery <95%?					No correction needed			
Total % Potentially Absorbable adjusted according to EFSA (2017)					Mean (%skin +%receptor) + (SD*1) = **22%**			

SD: standard deviation; N: number of skin cells used for calculation
n.d.: not detected (below the limit of detection); n.a. : not applicable
In the above table, the presented means do not always calculate exactly from the presented individual data. This is due to rounding-up differences resulting from the use of the spreadsheet program.

The data from Cell Q differ from the data for Cell R which used the same donor. The swabbing procedure appears to have been less efficient and the levels found in the receptor fluid are approximately double those of cell R suggesting that the skin sample may have been damaged. The following chart visually demonstrates the difference in profile obtained for cell Q compared to the duplicate cell R and the other skin samples that were tested.

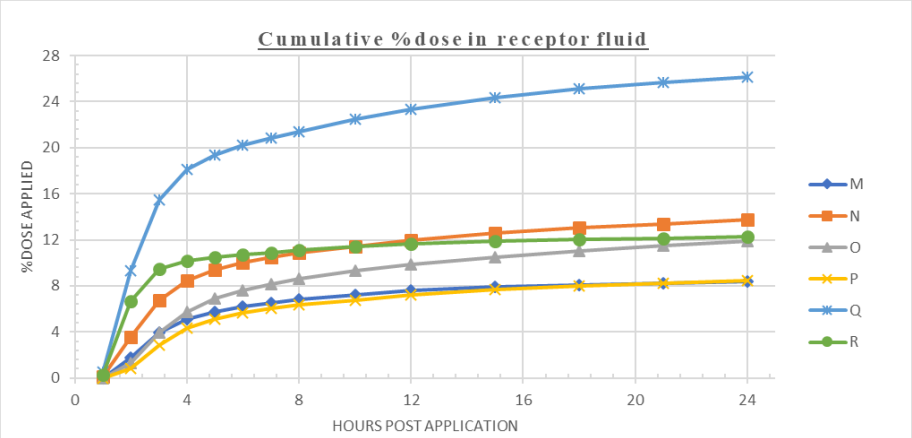

Table A 14: **Distribution of radioactivity at 24 hours after dose application of [14C]- fluopyram in the FLU+TFS SC 500 formulation at the rate of 0.033 g/L to human skin samples (Reported cells).**

Results expressed in terms of percentage of applied radioactivity.

	Distribution of radioactivity (% dose applied)					Group Human HD N= 5 K N° = 1.2	
Sex	Female	Female	Female	Female	Female		
Donor N°	250	250	234	234	TRA001000A J340		
Cell N°	M	N	O	P	R	MEAN	SD
Skin Excess	92.50	105.18	81.88	81.20	85.84	89.32	9.94
SC1	2.01	5.14	6.62	5.68	2.12	4.31	2.12
SC2	0.72	3.40	3.08	2.34	1.02	2.11	1.20
Total SC1 + SC2	**2.73**	**8.54**	**9.70**	**8.02**	**3.14**	**6.43**	**3.25**
TOTAL NON-ABSORBED	**95.23**	**113.72**	**91.58**	**89.22**	**88.98**	**95.75**	**10.36**
Skin	0.19	0.80	0.54	1.82	0.10	0.69	0.69
Stratum Corneum (SC3+)	2.15	6.45	2.83	3.02	2.60	3.41	1.73
TOTAL DOSE SITE	**2.34**	**7.25**	**3.37**	**4.84**	**2.70**	**4.10**	**2.00**
Receptor fluid (0 - 12h)	7.58	11.99	9.84	7.18	11.68	9.65	2.24
Receptor fluid (0 - 24h)	8.39	13.73	11.86	8.47	12.26	10.94	2.40
%Ratio receptor 12h/24h	90	87	83	85	95	**88**	**5**
Receptor chamber	0.00	5.62	0.49	0.26	0.37	1.35	2.39
TOTAL DIRECT	**8.39**	**19.35**	**12.35**	**8.73**	**12.63**	**12.29**	**4.41**
POTENTIAL (dose site+ receptor)	10.73	26.60	15.72	13.57	15.33	16.39	6.04
POTENTIAL (skin+ receptor)	**8.58**	**20.15**	**12.89**	**10.55**	**12.73**	**12.98**	**4.38**
TOTAL RECOVERY	**106.0**	**140.3**	**107.3**	**102.8**	**104.3**	**112.14**	**15.83**
Evaluation according to EFSA Guidance (2017)							
Absorption >75% within half of study duration?					Yes (exclude SC values)		
Mean Recovery <95%?					No correction needed		
Total % Potentially Absorbable adjusted according to EFSA (2017)					Mean (%skin +%receptor) + (SD*1.2) = **18%**		

SD: standard deviation; N: number of skin cells used for calculation
n.d.: not detected (below the limit of detection); n.a.: not applicable
In the above table, the presented means do not always calculate exactly from the presented individual data. This is due to rounding-up differences resulting from the use of the spreadsheet program.

Conclusion:

The dermal penetration through human dermatomed skin of [^{14}C]-fluopyram in the fluopyram + trifloxystrobin SC 500 formulation was investigated at three nominal concentrations corresponding to the neat product (250 g /L) and to two representative spray dilutions of 0.20 and 0.033 g/L.

Concentrate

The mean percentage of fluopyram in the FLU+TFS SC 500 formulation that was considered to be potentially absorbable for the neat formulation applying the EFSA guidance (2017) to the study data was 0.083%.

Intermediate Dose level

The mean percentage of fluopyram in the FLU+TFS SC 500 formulation that was considered to be potentially absorbable for the neat formulation applying the EFSA guidance (2017) to the study data was 5.9%.

Low Dose level (Spray dilution)

The mean percentage of fluopyram in the FLU+TFS SC 500 formulation that was considered to be potentially absorbable for the neat formulation applying the EFSA guidance (2017) to the study data was 18%.

Therefore, the following dermal absorption values can be proposed for use in the non-dietary risk assessments for fluopyram in the FLU+TFS SC 500 formulation:

- 0.083% for the neat formulation (250 g/L)
- 5.9% for the intermediate dose (0.20 g/L)
- 18% for the low dose (0.033 g/L)

A 2.10.2 Trifloxystrobin

Comparative dermal absorption, *in vitro* using rat and human skin

Comments of zRMS:	Detailed bridging assessment provided in the Part C (Vinck, K.; Immink, H.; 2020) is considered as sufficient to conclude applicability of submitted dermal absorption studies for the current registration process and the dermal absorption values for trifloxystrobin can be used when moving from the formulation specification 10200002886-04 to specification 10200002886-05. This assessment aims to demonstrate that dermal absorption studies prepared for the formulation coded 102000012886-04 are also usable without further testing for the formulation coded 102000012886-05. In accordance with the EFSA guidance on dermal absorption 2017 (EFSA (European Food Safety Authority), 2017. Guidance on dermal absorption. EFSA Journal 2017; 15(6): 4873). The study is performed according to OECD guideline 428 and is considered acceptable. The dermal absorption values as proposed by the applicant are acceptable. However, a pro-rata consideration has been performed reflecting applications rate (spray dilution) proposed in the GAP: 1) The concentrate tested (trifloxystrobin 250 g/L) is equal to the concentrate concentration of Luna Sensation, a pro rata correction is therefore not considered necessary. 2) Taking into account the most critical uses according to the GAP, the concentration of the spray dilution ranges between 0,05g/L and 1.3g/L. Since a lower concentration generally results in a higher dermal absorption, the dermal absorption derived for the 0.033 g/L spray dilution as tested in the *in vitro* study is considered acceptable for spray dilutions with a concentration of 0,05g/L as a worst-case approach thus a pro rata correction is therefore not considered necessary.

Reference:	**KCP 7.3/02**
Title:	[14C]-trifloxystrobin (FLU + TFS SC 500) - In vitro dermal absorption study using human skin
Report:	Odin, M.; 2014; SA 13189; M-486321-01-1
Authority registration No:	N/A
Guideline(s):	OECD Guideline for the testing of Chemicals Skin Absorption In Vitro Method Guideline 428 (April 2004). OECD Environmental Health and Safety Publication Series on testing and Assessment N° 28, Guidance Document for the Conduct of Skin Absorption Studies (March 2004). EFSA Panel on Plant Protection Products and their Residues (PPR): Guidance on Dermal Absorption, EFSA Journal 2012: 10(4): 2665.
Deviations:	none
GLP/GEP:	yes
Acceptability:	Yes; see our comment Point A 2.1 and also bridging assessment provided in the Part C
Duplication (if vertebrate study):	

Material and methods

Human skin:
Source: Xenometrix, Hégenheim, France.
Number and sex: 6 donors, female.
Anatomical region: Abdomen.
Thickness: 389.4 to 483 µm.

Test Material:

Non-radiolabelled:
Batch: NLL5391-14.
Purity = 99.6%.

Radiolabelled:
[trifluoromethylphenyl-^{14}C]-trifloxystrobin
Batch: KML 9678.
Specific activity: 3.72 MBq/mg.
Radiopurity of the formulation: >98%.

Formulation: The formulation used in this experiment was the FLU+TFS SC 500 formulation (specification N° 102000012886) containing trifloxystrobin (250 g/L) and fluopyram (250 g/L). It was used at three nominal concentrations of trifloxystrobin: neat, 250 g/L, 0.2 g/L and 0.033 g/L.

Test system: A flow-through diffusion cell system (Franz's cell modified, Gallas, France) was used to study the absorption of the test substance (exposure area of 1 cm^2 skin). A diffusion cell consisted of a donor chamber and a receptor chamber between which the skin was positioned. The receptor fluid was Eagle's medium supplemented with 5% bovine serum albumin and gentamycin (50 mg/L) at a pH of 7.4. The receptor chamber was warmed by a constant circulation of warm water which maintained the receptor fluid at 32 ± 2°C (close to the normal skin temperature). The receptor fluid was pumped through the receptor chamber at a rate of 1.5 mL/h and stirred continuously whilst in the receptor chamber by means of a magnetic bar.

Skin integrity: Before dose application, the integrity of the skin samples was assessed by measuring the trans-epidermal water loss (TEWL) from the stratum corneum. An evaporimeter probe (Tewameter TM300®, System, Courage & Khazaka) was placed securely on the top of the donor chamber and the amount of water diffusing through the skin was measured. Human and rat skin with a TEWL of greater than 15 g/hm² were considered potentially damaged and were not used. These samples were replaced by new skin fragments which were also tested for integrity before use in the study.

Treatment: The dose preparation was applied to the split-thickness skin sample with a pipette at the rate of approximately 10 µL/cm^2 exposed skin. The dose preparations were assayed for radioactivity content (by LSC) by using dose checks (surrogate dose) taken before, during and after the dosing process.

Sampling: The receptor fluid passing through the receptor chamber was collected in glass vials held in a fraction collector. The fraction collector was started after dose application. Samples were then collected hourly for the duration of the experiment (24 hours). At 8 hours post-application, the skin was swabbed with freshly prepared 1% v/v Tween 80 in PBS (phosphate buffer saline) using natural sponge swabs, in order to remove and retain the non-absorbed dose, until no radioactivity was detected with a Geiger-Müller monitor. At the end of the study (24 hours after application), the treated skin and the skin adjacent to the treatment site (surrounding swabs) were swabbed. Each skin sample was tape-stripped to remove the stratum corneum. This involved the application of Monaderm adhesive tape (Monaderm, Monaco) for 5 seconds before the tape was carefully removed against the direction of hair growth. This procedure was continued until a 'shiny' appearance of the epidermis was evident, which indicated that the stratum corneum had been removed. The tape-strips were collected into scintillation vials for analysis. The skin surrounding the application site (surrounding skin) was separated from the treated skin. Both surrounding skin and tape-stripped treated skin were retained for analysis.

Radioassay: The amounts of radioactivity in the various samples were determined by liquid scintillation counting (LSC). Samples were counted for 10 minutes or for 2

sigma % in an appropriate scintillation cocktail using a Packard 1900 TR counter with on-line computing facilities. Quenching effects were determined using an external standard and spectral quench parameter (tSIE) method. Efficiency correlation curves were prepared for each scintillation cocktail and were regularly checked by the use of [^{14}C-n-hexadecane standards. The scintillation counter was recalibrated when a deviation of greater than 2% was observed when counting quality control standards. The limit of detection was taken to be twice the background values for blank samples in appropriate scintillation cocktails.

Findings:

Trifloxystrobin was demonstrated to be sufficiently soluble in the receptor fluid to avoid any risk of back diffusion.

Measurements of the homogeneity of the three concentrations of formulation applied indicated that it was acceptable.

The study results are presented in the following tables.

Table A 15: **Distribution of radioactivity at 24 hours after dose application of [^{14}C]- trifloxystrobin in the FLU+TFS SC 500 formulation at the rate of 250 g/L to human skin samples (All cells).**

Results expressed in terms of percentage of applied radioactivity.

	Distribution of radioactivity (% dose applied)						Group Human HD N= 6 K N° = 1	
Sex	Female	Female	Female	Female	Female	Female		
Donor N°	522-01-0812 II	528-01-0913 II	524-01-0813 V	527-01-0913 III	520-01-0813 II	524-01-0813 VI		
Cell N°	H01	H02	H03	H04	H05	H06	MEAN	SD
Skin wash 8h	101.15	97.86	95.37	101.07	101.83	95.43	98.79	2.96
Skin wash 24h	n.d.	0.01	0.09	0.01	0.01	n.d.	0.02	0.03
Surrounding swabs 24 h	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Total swabs	**101.15**	**97.87**	**95.46**	**101.08**	**101.84**	**95.43**	**98.81**	**2.94**
SC1	0.006	0.024	0.106	0.042	0.010	0.001	0.03	0.04
SC2	0.002	0.007	0.037	0.010	0.007	0.001	0.01	0.01
Total SC1 + SC2	**0.01**	**0.03**	**0.15**	**0.05**	**0.02**	**0.003**	**0.04**	**0.05**
Donor chamber	0.09	0.03	0.26	0.04	n.d.	n.d.	0.07	0.10
TOTAL NON-ABSORBED	**101.25**	**97.94**	**95.87**	**101.17**	**101.86**	**95.44**	**98.92**	**2.88**
Skin	0.0020	0.0048	0.0414	0.0247	0.0023	0.0035	0.01	0.02
Surrounding skin	n.d.	0.0014	0.0009	0.0011	0.0021	0.0013	n.d.	0.00
Total skin	**0.002**	**0.006**	**0.042**	**0.026**	**0.004**	**0.005**	**0.01**	**0.02**
SC3	0.0022	0.0028	0.0186	0.0135	0.0023	0.0015	0.007	0.007
SC4	0.0014	0.0033	0.0146	0.0037	0.0023	0.0013	0.004	0.005
SC5	0.0017	0.0022	0.0322	0.0031	0.0023	0.0011	0.007	0.012
SC6	0.0015	0.0016	0.0076	n.s.	0.0017	0.0010	0.003	0.003
SC7	0.0012	0.0018	0.0132	n.s.	0.0014	0.0011	0.004	0.005
SC8	0.0016	0.0012	n.s.	n.s.	0.0018	0.0010	0.001	0.000
SC9	0.0013	0.0013	n.s.	n.s.	ND	n.s.	0.001	0.000
SC10	0.0012	0.0012	n.s.	n.s.	0.0013	n.s.	0.001	0.000
SC11	0.0013	n.s.	n.s.	n.s.	n.s.	n.s.	0.001	0.000
SC12	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.a.	n.a.
SC13	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.a.	n.a.
SC14	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.a.	n.a.
SC15	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.a.	n.a.
Total SC3+	**0.01**	**0.02**	**0.09**	**0.02**	**0.01**	**0.01**	**0.03**	**0.03**
TOTAL DOSE SITE	**0.02**	**0.02**	**0.13**	**0.05**	**0.02**	**0.01**	**0.04**	**0.04**
Receptor fluid (0 - 12h)	0.032	0.033	0.031	0.040	0.030	0.028	**0.032**	**0.004**
Receptor fluid (0 - 24h)	0.051	0.052	0.050	0.062	0.049	0.046	**0.052**	**0.005**
%Ratio receptor 12h/24h	62	63	62	65	62	61	**63**	**1**
Residual Rec Fluid	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.a.
Receptor chamber	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.a.
TOTAL DIRECT	**0.05**	**0.05**	**0.05**	**0.06**	**0.05**	**0.05**	**0.05**	**0.01**
POTENTIAL (dose site+ receptor)	**0.07**	**0.07**	**0.18**	**0.11**	**0.07**	**0.06**	**0.09**	**0.05**
POTENTIAL (skin+ receptor)	0.05	0.06	0.09	0.09	0.05	0.05	0.07	0.02
TOTAL RECOVERY	**101.3**	**98.0**	**96.1**	**101.3**	**101.9**	**95.5**	**99.01**	**2.87**
Evaluation according to EFSA Guidance (2017)								
Absorption >75% within half of study duration?					No. (include SC values except SC1 & SC2))			
Mean Recovery <95%?					No correction needed			
Total % Potentially Absorbable adjusted according to EFSA (2017)					Mean (%dose site +%receptor) + (SD*1) = **0.14%**			

SD: standard deviation; N: number of skin cells used for calculation
n.d.: not detected (below the limit of detection); n.a. : not applicable
In the above table, the presented means do not always calculate exactly from the presented individual data. This is due to rounding-up differences resulting from the use of the spreadsheet program.

Table A 16: **Distribution of radioactivity at 24 hours after dose application of [^{14}C]- trifloxystrobin in the FLU+TFS SC 500 formulation at the rate of 0.20 g/L to human skin samples (All cells).**

Results expressed in terms of percentage of applied radioactivity.

	Distribution of radioactivity (% dose applied)						Group Human HD N= 6 K N° = 1	
Sex	Female	Female	Female	Female	Female	Female		
Donor N°	522-01-0813 I	520-01-0813 II	524-01-0813 IV	527-01-0913 III	524-01-0813 VI	476-01-0912 III-1		
Cell N°	H07	H08	H09	H010	H11	H12	MEAN	SD
Skin wash 8h	86.61	78.69	101.43	97.02	94.31	100.61	93.11	8.86
Skin wash 24h	3.29	6.09	1.35	0.45	1.20	0.77	2.19	2.15
Surrounding swabs 24 h	0.005	n.d.	0.029	n.d.	n.d.	0.039	0.01	0.02
Total swabs	**89.91**	**84.78**	**102.81**	**97.47**	**95.52**	**101.43**	**95.32**	**6.90**
SC1	0.20	2.61	0.15	0.04	1.71	0.30	0.83	1.07
SC2	0.09	1.07	0.08	0.02	0.00	0.14	0.23	0.42
Total SC1 + SC2	**0.28**	**3.68**	**0.23**	**0.06**	**1.71**	**0.43**	**1.07**	**1.41**
Donor chamber	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.a.
TOTAL NON-ABSORBED	**90.19**	**88.46**	**103.04**	**97.53**	**97.22**	**101.86**	**96.38**	**5.95**
Skin	0.03	1.40	0.02	0.09	0.04	0.12	0.28	0.55
Surrounding skin	n.d.	n.d.	0.02	n.d.	0.01	0.03	0.01	0.01
Total skin	**0.03**	**1.40**	**0.04**	**0.09**	**0.05**	**0.15**	**0.29**	**0.55**
SC3	0.055	0.619	0.207	0.018	0.000	0.088	0.165	0.235
SC4	0.036	0.324	0.257	0.028	0.000	0.071	0.119	0.136
SC5	0.029	0.700	n.s.	0.017	n.s.	0.068	0.204	0.332
SC6	0.024	0.399	n.s.	0.014	n.s.	0.046	0.121	0.186
SC7	0.016	n.s.	n.s.	0.008	n.s.	0.036	0.020	0.015
SC8	0.012	n.s.	n.s.	0.010	n.s.	0.031	0.018	0.012
SC9	0.006	n.s.	n.s.	0.006	n.s.	0.024	0.012	0.010
SC10	0.013	n.s.	n.s.	n.s.	n.s.	0.021	0.017	0.006
SC11	0.000	n.s.	n.s.	n.s.	n.s.	0.019	0.010	0.014
SC12	0.000	n.s.	n.s.	n.s.	n.s.	0.014	0.007	0.010
SC13	n.s.	n.s.	n.s.	n.s.	n.s.	0.017	0.017	0.000
SC14	n.s.	n.s.	n.s.	n.s.	n.s.	0.051	0.051	0.000
SC15	n.s.	n.s.	n.s.	n.s.	n.s.	0.008	0.008	0.000
Total SC3+	**0.19**	**2.04**	**0.46**	**0.10**	n.d.	**0.49**	**0.55**	**0.76**
TOTAL DOSE SITE	**0.22**	**3.44**	**0.50**	**0.19**	**0.05**	**0.64**	**0.84**	**1.29**
Receptor fluid (0 - 12h)	0.062	0.044	0.154	0.171	0.217	0.143	0.13	0.07
Receptor fluid (0 - 24h)	0.072	0.061	0.245	0.238	0.391	0.332	0.22	0.13
%Ratio receptor 12h/24h	86	72	63	72	55	43	65	15
Residual Rec Fluid	n.d.	n.d.	0.03	n.d.	0.04	0.05	0.02	0.02
Receptor chamber	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.a.
TOTAL DIRECT	**0.07**	**0.06**	**0.27**	**0.24**	**0.43**	**0.38**	**0.24**	**0.15**
POTENTIAL (dose site+ receptor)	0.29	3.50	0.77	0.42	0.48	1.02	1.08	1.22
POTENTIAL (skin+ receptor)	0.10	1.46	0.31	0.32	0.48	0.52	0.53	0.48
TOTAL RECOVERY	**90.5**	**92.0**	**103.8**	**98.0**	**97.7**	**102.9**	**97.5**	**5.5**
Evaluation according to EFSA Guidance (2017)								
Absorption >75% within half of study duration?					No. (include SC values except SC1 & SC2)			
Mean Recovery <95%?					No correction needed			
Total % Potentially Absorbable adjusted according to EFSA (2017)					Mean (%dose site +%receptor) + (SD*1) = **2.3%**			

SD: standard deviation; N: number of skin cells used for calculation
n.d.: not detected (below the limit of detection); n.a. : not applicable
In the above table, the presented means do not always calculate exactly from the presented individual data. This is due to rounding-up differences resulting from the use of the spreadsheet program.

In the study report both Cells H07 and H08 were excluded from the reported cells due to “technical problems with the swabbing”. However, using the modified Z-score as a statistical test for outliers it would appear that only cell H08 should be considered to be an outlier due principally to the higher levels of radioactivity found in the stratum corneum and skin compared to the other cells. This is most probably linked to the relatively low swabbing efficiency observed by the study director in the report for this cell.

In general, finding the "Outliers" in a data set can be done by calculating the deviation for each number, expressed as either a "Z-score" or "modified Z-score" and testing it against certain predefined threshold. Z-score typically refers to number of standard deviation relative to the statistical average. The Modified Z-score applies the median computation technique to measure the deviation. Mathematically the Modified Z-score can be written as:

$$Mi=0.6745 * (Xi - Median(Xi)) / MAD,$$

where MAD stands for Median Absolute Deviation. Any number in a data set with the absolute value of a modified Z-score exceeding 3.5 is considered an "Outlier".

Table A 17: **Modified Z-score result for the stratum corneum (SC3+), skin and potential absorption results for TFS following application of [14C]- trifloxystrobin in the FLU+TFS SC 500 formulation at the rate of 0.20 g/L to human skin samples (All cells).**

Cell N°	**SC3+**		mean-value	mod Z score
H07	0.19	NORMAL	0.14	-0.4
H08	2.04	OUTLIER	-1.71	**5.2**
H09	0.47	NORMAL	-0.14	0.4
H10	0.06	NORMAL	0.27	-0.8
H11	0	NORMAL	0.33	-1.0
H12	0.5	NORMAL	-0.17	0.5
	SKIN		mean-value	mod Z score
H07	0.03	NORMAL	0.035	-0.6
H08	1.4	OUTLIER	-1.335	**22.5**
H09	0.02	NORMAL	0.045	-0.8
H10	0.09	NORMAL	-0.025	0.4
H11	0.04	NORMAL	0.025	-0.4
H12	0.12	NORMAL	-0.055	0.9
	POTENTIAL (%dose site+ direct)		mean-value	mod Z score
H07	0.32	NORMAL	0.315	-0.8
H08	3.53	OUTLIER	-2.895	**7.5**
H09	0.78	NORMAL	-0.145	0.4
H10	0.43	NORMAL	0.205	-0.5
H11	0.49	NORMAL	0.145	-0.4
H12	1.05	NORMAL	-0.415	1.1

Table A 18: **Distribution of radioactivity at 24 hours after dose application of [14C]-trifloxystrobin in the FLU+TFS SC 500 formulation at the rate of 0.20 g/L to human skin samples (Reported cells).**

Results expressed in terms of percentage of applied radioactivity.

	Distribution of radioactivity (% dose applied)					Group Human HD N= 5 K N° = 1.2	
Sex	Female	Female	Female	Female	Female		
Donor N°	522-01-0813 I	524-01-0813 IV	527-01-0913 III	524-01-0813 VI	476-01-0912 III-1		
Cell N°	H07	H09	H010	H11	H12	MEAN	SD
Skin wash 8h	86.61	101.43	97.02	94.31	100.61	96.00	5.97
Skin wash 24h	3.29	1.35	0.45	1.20	0.77	1.42	1.11
Surrounding swabs 24 h	0.005	0.029	n.d.	n.d.	0.039	0.01	0.02
Total swabs	**89.91**	**102.81**	**97.47**	**95.52**	**101.43**	97.43	5.13
SC1	0.20	0.15	0.04	1.71	0.30	0.48	0.69
SC2	0.09	0.08	0.02	n.d.	0.14	0.06	0.05
Total SC1 + SC2	**0.28**	**0.23**	**0.06**	**1.71**	**0.43**	0.54	0.66
Donor chamber	n.d.	n.d.	n.d.	n.d.	n.d.	0.00	0.00
TOTAL NON-ABSORBED	**90.19**	**103.04**	**97.53**	**97.22**	**101.86**	97.97	5.05
Skin	0.03	0.02	0.09	0.04	0.12	0.06	0.04
Surrounding skin	n.d.	0.02	n.d.	0.01	0.03	0.01	0.01
Total skin	**0.03**	**0.04**	**0.09**	**0.05**	**0.15**	0.07	0.05
SC3	0.055	0.207	0.018	0.000	0.088	0.07	0.08
SC4	0.036	0.257	0.028	0.000	0.071	0.08	0.10
SC5	0.029	n.s.	0.017	n.s.	0.068	0.04	0.03
SC6	0.024	n.s.	0.014	n.s.	0.046	0.03	0.02
SC7	0.016	n.s.	0.008	n.s.	0.036	0.02	0.01
SC8	0.012	n.s.	0.010	n.s.	0.031	0.02	0.01
SC9	0.006	n.s.	0.006	n.s.	0.024	0.01	0.01
SC10	0.013	n.s.	n.s.	n.s.	0.021	0.02	0.01
SC11	0.000	n.s.	n.s.	n.s.	0.019	0.01	0.01
SC12	0.000	n.s.	n.s.	n.s.	0.014	0.01	0.01
SC13	n.s.	n.s.	n.s.	n.s.	0.017	0.02	0.00
SC14	n.s.	n.s.	n.s.	n.s.	0.051	0.05	0.00
SC15	n.s.	n.s.	n.s.	n.s.	0.008	0.01	0.00
Total SC3+	**0.19**	**0.46**	**0.10**	n.d.	**0.49**	**0.25**	**0.22**
TOTAL DOSE SITE	**0.22**	**0.50**	**0.19**	**0.05**	**0.64**	**0.32**	**0.24**
Receptor fluid (0 - 12h)	0.062	0.154	0.171	0.217	0.143	0.15	0.06
Receptor fluid (0 - 24h)	0.072	0.245	0.238	0.391	0.332	0.26	0.12
%Ratio receptor 12h/24h	86	63	72	55	43	58	12
Residual Rec Fluid	n.d.	0.03	n.d.	0.04	0.05	0.02	0.02
Receptor chamber	n.d.	n.d.	n.d.	n.d.	n.d.	0.00	0.00
TOTAL DIRECT	**0.07**	**0.27**	**0.24**	**0.43**	**0.38**	**0.28**	**0.14**
POTENTIAL (dose site+ receptor)	**0.29**	**0.77**	**0.42**	**0.48**	**1.02**	**0.60**	**0.29**
POTENTIAL (skin+ receptor)	**0.10**	**0.31**	**0.32**	**0.48**	**0.52**	**0.35**	**0.17**
TOTAL RECOVERY	**90.5**	**103.8**	**98.0**	**97.7**	**102.9**	**98.57**	**5.30**

Evaluation according to EFSA Guidance (2017)	
Absorption >75% within half of study duration?	No. (include SC values except SC1 & SC2)
Mean Recovery <95%?	No correction needed
Total % Potentially Absorbable adjusted according to EFSA (2017)	Mean (%dose site +%receptor) + (SD*1.2) = **0.95%**

SD: standard deviation; N: number of skin cells used for calculation
n.d.: not detected (below the limit of detection); n.a.: not applicable
In the above table, the presented means do not always calculate exactly from the presented individual data. This is due to rounding-up differences resulting from the use of the spreadsheet program.

Table A 19: **Distribution of radioactivity at 24 hours after dose application of [14C]-trifloxystrobin in the FLU+TFS SC 500 formulation at the rate of 0.033 g/L to human skin samples (All cells).**

Results expressed in terms of percentage of applied radioactivity.

	Distribution of radioactivity (% dose applied)						Group Human HD N= 6 K N° = 1	
Sex	Female	Female	Female	Female	Female	Female		
Donor N°	520-01-0813 IV	522-01-0813 II	476-01-0912 III-1	528-01-0913 III	527-01-0913 III	524-01-0813 V		
Cell N°	H013	H014	H15	H16	H17	H18	MEAN	SD
Skin wash 8h	74.64	83.87	91.48	78.52	80.26	56.90	77.61	11.64
Skin wash 24h	4.44	9.76	6.13	11.85	1.77	2.67	6.10	3.99
Surrounding swabs 24 h	0.00	0.00	0.00	0.55	0.10	0.05	0.12	0.22
Total swabs	**79.08**	**93.63**	**97.60**	**90.92**	**82.13**	**59.62**	**83.83**	**13.77**
SC1	9.67	2.00	2.82	4.26	4.99	11.16	5.82	3.74
SC2	2.98	0.96	1.01	1.47	2.06	3.10	1.93	0.95
Total SC1 + SC2	**12.65**	**2.96**	**3.83**	**5.73**	**7.06**	**14.27**	**7.75**	**4.68**
Donor chamber	0.00	0.00	0.00	0.72	1.04	0.00	0.29	0.46
TOTAL NON-ABSORBED	**91.73**	**96.59**	**101.43**	**97.37**	**90.22**	**73.89**	**91.87**	**9.70**
Skin	5.35	1.25	0.60	2.76	3.47	12.43	4.31	4.32
Surrounding skin	0.07	0.05	0.07	0.13	0.10	0.07	0.08	0.03
Total skin	**5.42**	**1.30**	**0.67**	**2.89**	**3.57**	**12.50**	**4.39**	**4.32**
SC3	2.33	1.18	0.66	1.45	1.48	2.91	1.67	0.81
SC4	2.85	0.52	0.62	0.85	1.79	1.48	1.35	0.89
SC5	1.43	0.49	0.55	0.84	1.35	n.s.	0.78	0.55
SC6	n.s.	0.21	0.25	n.s.	1.48	n.s.	0.32	0.58
SC7	n.s.	0.67	0.33	n.s.	1.80	n.s.	0.47	0.71
SC8	n.s.	0.16	0.28	n.s.	1.15	n.s.	0.27	0.45
SC9	n.s.	0.10	0.20	n.s.	0.60	n.s.	0.15	0.23
SC10	n.s.	0.18	0.22	n.s.	2.74	n.s.	0.52	1.09
SC11	n.s.	n.s.	0.13	n.s.	0.00	n.s.	0.02	0.05
SC12	n.s.	n.s.	0.14	n.s.	0.00	n.s.	0.02	0.06
SC13	n.s.	n.s.	0.11	n.s.	0.00	n.s.	0.02	0.04
Total SC3+	**6.62**	**3.52**	**3.49**	**3.14**	**12.38**	**4.40**	**5.59**	**3.56**
TOTAL DOSE SITE	**12.04**	**4.82**	**4.16**	**6.03**	**15.95**	**16.90**	**9.98**	**5.73**
Receptor fluid (0 - 12h)	0.035	0.302	0.456	0.309	0.093	0.711	0.32	0.25
Receptor fluid (0 - 24h)	0.085	0.443	0.909	1.182	0.093	1.326	0.67	0.54
%Ratio receptor 12h/24h	41	68	50	26	100	54	57	25
Residual Rec Fluid	0.00	0.00	0.00	0.26	0.29	0.00	0.09	0.14
Receptor chamber	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
TOTAL DIRECT	**0.08**	**0.44**	**0.91**	**1.45**	**0.38**	**1.33**	**0.77**	**0.55**
POTENTIAL (dose site+ receptor)	**12.12**	**5.26**	**5.07**	**7.48**	**16.33**	**18.23**	**10.75**	**5.69**
POTENTIAL (skin+ receptor)	5.50	1.74	1.58	4.34	3.95	13.83	5.16	4.51
TOTAL RECOVERY	**103.9**	**101.9**	**106.5**	**104.8**	**106.6**	**92.1**	**102.62**	**5.44**
Evaluation according to EFSA Guidance (2017)								
Absorption >75% within half of study duration?					No. (include SC values except SC1 & SC2)			
Recovery <95%?					No correction needed			
Total % Potentially Absorbable adjusted according to EFSA (2017)					Mean (%dose site +%receptor) + (SD*1) = **16%**			

SD: standard deviation; N: number of skin cells used for calculation
n.d.: not detected (below the limit of detection); n.a.: not applicable
In the above table, the presented means do not always calculate exactly from the presented individual data. This is due to rounding-up differences resulting from the use of the spreadsheet program.

Whilst the study director eliminated cell H18 due to the relatively low swabbing efficiency there was no statistically significant difference in the final potentially absorbed values, so all of the cells have been retained in this summary.

Conclusion:

The dermal penetration through human dermatomed skin of [^{14}C]-trifloxystrobin in the trifloxystrobin SC 500 formulation was investigated at three nominal concentrations corresponding to the neat product (250 g /L) and to two representative spray dilutions of 0.20 and 0.033 g/L.

Concentrate

The mean percentage of trifloxystrobin in the FLU+TFS SC 500 formulation that was considered to be potentially absorbable for the neat formulation applying the EFSA guidance (2017) to the study data was 0.14%.

Intermediate Dose level

The mean percentage of trifloxystrobin in the FLU+TFS SC 500 formulation that was considered to be potentially absorbable for the neat formulation applying the EFSA guidance (2017) to the study data was 0.95%.

Low Dose level (Spray dilution)

The mean percentage of trifloxystrobin in the FLU+TFS SC 500 formulation that was considered to be potentially absorbable for the neat formulation applying the EFSA guidance (2017) to the study data was 16%.

Therefore, the following dermal absorption values can be proposed for use in the non-dietary risk assessments for trifloxystrobin in the FLU+TFS SC 500 formulation:

- 0.14% for the neat formulation (250 g/L)
- 0.95% for the intermediate dose (0.20 g/L)
- 16% for the low dose (0.033 g/L)

A 2.11 Other/Special Studies

No other studies included.

Appendix 3 Exposure calculations

The following tables provide an overview of exposure calculations for all active substances, relevant crops and PPE scenarios as an outcome of the most updated version of the EFSA calculator.

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

Table A 20: Operator exposure, Fluopyram, Grapes, no PPE / with PPE

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.05 kg a.s. /ha	**Spray dilution** = 0.125 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Grapes, Outdoor, Upward spraying, Vehicle-mounted			**Buffer =** 5 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.0199	% of RVNAS[1]	39.8%
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.00681**	% of RVNAS[1]	**13.6%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.00273**	% of RVNAS[1]	**5.46%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 21: Operator exposure, Fluopyram, Low berries and other small fruits, no PPE / with PPE

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution** = 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.00788	% of RVNAS[1]	15.8%
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.00522**	% of RVNAS[1]	**10.4%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.000819**	% of RVNAS[1]	**1.64%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 22: Operator exposure, Fluopyram, Low berries and other small fruits, no PPE / with PPE

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution** = 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Manual-Hand held			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.272	% of RVNAS[1]	544%
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.0319**	% of RVNAS[1]	**63.9%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.0273**	% of RVNAS[1]	**54.5%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 23: Operator exposure, Fluopyram, Low berries and other small fruits, no PPE / with PPE

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution** = 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Manual-Knapsack			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.272	% of RVNAS[1]	545%
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.0324**	% of RVNAS[1]	**64.7%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.0276**	% of RVNAS[1]	**55.2%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 24: Operator exposure, Fluopyram, Hops, no PPE / with PPE

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.15 kg a.s. /ha	**Spray dilution** = 0.075 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Hops, Outdoor, Upward spraying, Vehicle-mounted			**Buffer =** 5 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.0573	% of RVNAS[1]	115%
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.0181**	% of RVNAS[1]	**36.1%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.0073**	% of RVNAS[1]	**14.6%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 25: Operator exposure, Fluopyram, Root and tuber vegetables, no PPE / with PPE

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.075 kg a.s. /ha	**Spray dilution** = 0.5 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Root and tuber vegetables, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 5 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.00308	% of RVNAS[1]	6.17%
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.00205**	% of RVNAS[1]	**4.11%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.00046**	% of RVNAS[1]	**0.92%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 26: Operator exposure, Fluopyram, Ornamentals, no PPE / with PPE

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution** = 0.4 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Ornamentals, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.0235	% of RVNAS[1]	47.1%
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.0103**	% of RVNAS[1]	**20.6%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.000546**	% of RVNAS[1]	**1.09%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 27: Operator exposure, Fluopyram, Golf course, turf or other sports lawns, no PPE / with PPE

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.125 kg a.s. /ha	**Spray dilution =** 0.625 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Golf course, turf or other sports lawns, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	-
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.00502	% of RVNAS[1]	10%
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.00333**	% of RVNAS[1]	**6.66%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.000617**	% of RVNAS[1]	**1.23%**
	Acute systemic exposure mg/kg bw/day		-	% of RVAAS[2]	-%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 28: Operator exposure, Trifloxystrobin, Grapes, no PPE / with PPE

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.05 kg a.s. /ha	**Spray dilution** = 0.125 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Grapes, Outdoor, Upward spraying, Vehicle-mounted			**Buffer =** 5 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.0178	% of RVNAS[1]	29.7%
	Acute systemic exposure mg/kg bw/day		0.0891	% of RVAAS[2]	29.7%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.00617**	% of RVNAS[1]	**10.3%**
	Acute systemic exposure mg/kg bw/day		0.0195	% of RVAAS[2]	6.5%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.00251**	% of RVNAS[1]	**4.19%**
	Acute systemic exposure mg/kg bw/day		0.0122	% of RVAAS[2]	4.06%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 29: Operator exposure, Trifloxystrobin, Low berries and other small fruits, no PPE / with PPE

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution** = 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.00755	% of RVNAS[1]	12.6%
	Acute systemic exposure mg/kg bw/day		0.0512	% of RVAAS[2]	17.1%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.00498**	% of RVNAS[1]	**8.3%**
	Acute systemic exposure mg/kg bw/day		0.0367	% of RVAAS[2]	12.2%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.000757**	% of RVNAS[1]	**1.26%**
	Acute systemic exposure mg/kg bw/day		0.0129	% of RVAAS[2]	4.31%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 30: Operator exposure, Trifloxystrobin, Low berries and other small fruits, no PPE / with PPE

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution** = 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Manual-Hand held			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.242	% of RVNAS[1]	403%
	Acute systemic exposure mg/kg bw/day		0.38	% of RVAAS[2]	127%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.0285**	% of RVNAS[1]	**47.5%**
	Acute systemic exposure mg/kg bw/day		0.18	% of RVAAS[2]	59.9%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.0243**	% of RVNAS[1]	**40.5%**
	Acute systemic exposure mg/kg bw/day		0.168	% of RVAAS[2]	56.1%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 31: Operator exposure, Trifloxystrobin, Low berries and other small fruits, no PPE / with PPE

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution** = 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Manual-Knapsack			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.242	% of RVNAS[1]	404%
	Acute systemic exposure mg/kg bw/day		0.378	% of RVAAS[2]	126%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.029**	% of RVNAS[1]	**48.3%**
	Acute systemic exposure mg/kg bw/day		0.18	% of RVAAS[2]	60%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.0246**	% of RVNAS[1]	**41.1%**
	Acute systemic exposure mg/kg bw/day		0.168	% of RVAAS[2]	56.1%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 32: Operator exposure, Trifloxystrobin, Hops, no PPE / with PPE

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.15 kg a.s. /ha	**Spray dilution** = 0.075 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Hops, Outdoor, Upward spraying, Vehicle-mounted			**Buffer =** 5 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.0512	% of RVNAS[1]	85.3%
	Acute systemic exposure mg/kg bw/day		0.264	% of RVAAS[2]	88%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.0163**	% of RVNAS[1]	**27.2%**
	Acute systemic exposure mg/kg bw/day		0.0574	% of RVAAS[2]	19.1%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.00664**	% of RVNAS[1]	**11.1%**
	Acute systemic exposure mg/kg bw/day		0.0356	% of RVAAS[2]	11.9%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 33: Operator exposure, Trifloxystrobin, Root and tuber vegetables, no PPE / with PPE

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.075 kg a.s. /ha	**Spray dilution** = 0.5 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Root and tuber vegetables, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 5 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.00301	% of RVNAS[1]	5.01%
	Acute systemic exposure mg/kg bw/day		0.0247	% of RVAAS[2]	8.25%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.00199**	% of RVNAS[1]	**3.32%**
	Acute systemic exposure mg/kg bw/day		0.0181	% of RVAAS[2]	6.02%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.000427**	% of RVNAS[1]	**0.711%**
	Acute systemic exposure mg/kg bw/day		0.0112	% of RVAAS[2]	3.73%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 34: Operator exposure, Trifloxystrobin, Ornamentals, no PPE / with PPE

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution** = 0.4 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Ornamentals, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM		
Potential exposure	Longer term systemic exposure mg/kg bw/day	0.0211	% of RVNAS[1]	35.2%
	Acute systemic exposure mg/kg bw/day	0.0367	% of RVAAS[2]	12.2%
Mixing and Loading	**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application	**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day	**0.00926**	% of RVNAS[1]	**15.4%**
	Acute systemic exposure mg/kg bw/day	0.0198	% of RVAAS[2]	6.61%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day	**0.00051**	% of RVNAS[1]	**0.849%**
	Acute systemic exposure mg/kg bw/day	0.00259	% of RVAAS[2]	0.863%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 35: Operator exposure, Trifloxystrobin, Golf course, turf or other sports lawns, no PPE / with PPE

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.125 kg a.s. /ha	**Spray dilution =** 0.625 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Golf course, turf or other sports lawns, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	-
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.00484	% of RVNAS[1]	8.07%
	Acute systemic exposure mg/kg bw/day		0.036	% of RVAAS[2]	12%
Mixing and Loading		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Soluble bags = No
Application		**Gloves = Yes**	Clothing = Work wear - arms, body and legs covered	PPE = None	Closed cabin = No
Exposure (Workwear)	Longer term systemic exposure mg/kg bw/day		**0.0032**	% of RVNAS[1]	**5.33%**
	Acute systemic exposure mg/kg bw/day		0.0261	% of RVAAS[2]	8.7%
Exposure (Including PPE options above)	Longer term systemic exposure mg/kg bw/day		**0.000572**	% of RVNAS[1]	**0.953%**
	Acute systemic exposure mg/kg bw/day		0.012	% of RVAAS[2]	4.01%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

Table A 36: Worker exposure, Fluopyram, Grapes

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.05 kg a.s. /ha	**Spray dilution =** 0.125 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Grapes, Outdoor, Upward spraying, Vehicle-mounted			**Buffer =** 5 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Hand harvesting	Potential exposure mg/kg bw/day		0.186	% of RVNAS[1]	372%
	Working clothing mg/kg bw/day		0.0627	% of RVNAS[1]	125%
	Working clothing and gloves mg/kg bw/day		-	% of RVNAS[1]	-%
Measured DFR	2.24 µg a.s./cm² per kg a.s./ha				
Worker – Hand harvesting (Measured)	Potential exposure mg/kg bw/day		0.0806	% of RVNAS[1]	161%
	Working clothing mg/kg bw/day		0.0271	% of RVNAS[1]	54.3%
	Working clothing and gloves mg/kg bw/day		-	% of RVNAS[1]	-%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 37: Worker exposure, Fluopyram, Low berries and other small fruits

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Reaching, picking	Potential exposure mg/kg bw/day		0.155	% of RVNAS[1]	309%
	Working clothing mg/kg bw/day		0.0799	% of RVNAS[1]	160%
	Working clothing and gloves mg/kg bw/day		0.02	% of RVNAS[1]	40%
Measured DFR	7.3 µg a.s./cm² per kg a.s./ha				
Worker – Reaching, picking (Measured)	Potential exposure mg/kg bw/day		0.203	% of RVNAS[1]	406%
	Working clothing mg/kg bw/day		0.105	% of RVNAS[1]	210%
	Working clothing and gloves mg/kg bw/day		0.0263	% of RVNAS[1]	52.6%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 38: Worker exposure, Fluopyram, Hops

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.15 kg a.s. /ha	**Spray dilution =** 0.075 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Hops, Outdoor, Upward spraying, Vehicle-mounted			**Buffer =** 5 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Inspection, irrigation	Potential exposure mg/kg bw/day		0.0582	% of RVNAS[1]	116%
	Working clothing mg/kg bw/day		0.00652	% of RVNAS[1]	13%
	Working clothing and gloves mg/kg bw/day		-	% of RVNAS[1]	-%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 39: Worker exposure, Fluopyram, Root and tuber vegetables

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.075 kg a.s. /ha	**Spray dilution =** 0.5 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Root and tuber vegetables, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 5 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Inspection, irrigation	Potential exposure mg/kg bw/day		0.0627	% of RVNAS[1]	125%
	Working clothing mg/kg bw/day		0.00702	% of RVNAS[1]	14%
	Working clothing and gloves mg/kg bw/day		-	% of RVNAS[1]	-%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 40: Worker exposure, Fluopyram, Ornamentals

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 1 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Ornamentals, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 1 **Application interval =** 365 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Cutting, sorting, bundling, carrying	Potential exposure mg/kg bw/day		0.202	% of RVNAS[1]	403%
	Working clothing mg/kg bw/day		0.072	% of RVNAS[1]	144%
	Working clothing and gloves mg/kg bw/day		0.0202	% of RVNAS[1]	40.3%
Measured DFR	2.885 µg a.s./cm² per kg a.s./ha				
Worker – Cutting, sorting, bundling, carrying (Measured)	Potential exposure mg/kg bw/day		0.194	% of RVNAS[1]	388%
	Working clothing mg/kg bw/day		0.0692	% of RVNAS[1]	138%
	Working clothing and gloves mg/kg bw/day		0.0194	% of RVNAS[1]	38.8%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 41: Worker exposure, Fluopyram, Ornamentals

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.4 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Ornamentals, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Cutting, sorting, bundling, carrying	Potential exposure mg/kg bw/day		0.347	% of RVNAS[1]	695%
	Working clothing mg/kg bw/day		0.124	% of RVNAS[1]	248%
	Working clothing and gloves mg/kg bw/day		0.0347	% of RVNAS[1]	69.5%
Measured DFR	2.885 µg a.s./cm² per kg a.s./ha				
Worker – Cutting, sorting, bundling, carrying (Measured)	Potential exposure mg/kg bw/day		0.194	% of RVNAS[1]	388%
	Working clothing mg/kg bw/day		0.0692	% of RVNAS[1]	138%
	Working clothing and gloves mg/kg bw/day		0.0194	% of RVNAS[1]	38.8%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

~~**Table A 42: Worker exposure, Fluopyram, Golf course, turf or other sports lawns**~~

~~**Substance**~~	~~Fluopyram~~	~~**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.~~	~~**Application rate =** 0.125 kg a.s. /ha~~	~~**Spray dilution =** 0.625 g a.s./l~~	~~**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa~~
~~**Scenario**~~	~~Golf course, turf or other sports lawns, Outdoor, Downward spraying, Vehicle-mounted~~			~~**Buffer =** 2-3 m~~	~~**Number of applications =** 2 **Application interval =** 14 days~~
~~**Percentage Absorption**~~	~~Dermal for product = 0.083%~~	~~**Dermal for in use dilution** = 18%~~	~~**Oral =** 100%~~	~~**Inhalation =** 100%~~	-
~~RVNAS[1] (AOEL)~~	~~0.05 mg/kg bw/day~~		~~RVAAS[2]~~	~~- mg/kg bw/day~~	
~~DFR~~	~~3 µg a.s./cm² per kg a.s./ha~~	-	~~DT50~~	~~30 days~~	-
~~Worker – Maintenance~~	~~Potential exposure mg/kg bw/day~~		~~0.09~~	~~% of RVNAS[1]~~	~~180%~~
	~~Working clothing mg/kg bw/day~~		~~0.0388~~	~~% of RVNAS[1]~~	~~77.6%~~
	~~Working clothing and gloves mg/kg bw/day~~		~~0.009~~	~~% of RVNAS[1]~~	~~18%~~

~~[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL~~
~~[2] RVAAS = Reference Value Acutely toxic active Substance~~

Table A 43: Worker exposure, Trifloxystrobin, Grapes

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.05 kg a.s. /ha	**Spray dilution =** 0.125 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Grapes, Outdoor, Upward spraying, Vehicle-mounted			**Buffer =** 5 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Hand harvesting	Potential exposure mg/kg bw/day	0.165	% of RVNAS[1]	276%	
	Working clothing mg/kg bw/day	0.0557	% of RVNAS[1]	92.8%	
	Working clothing and gloves mg/kg bw/day	-	% of RVNAS[1]	-%	
Measured DFR	1.93 µg a.s./cm² per kg a.s./ha				
Worker – Hand harvesting (Measured)	Potential exposure mg/kg bw/day	0.0618	% of RVNAS[1]	103%	
	Working clothing mg/kg bw/day	0.0208	% of RVNAS[1]	34.7%	
	Working clothing and gloves mg/kg bw/day	-	% of RVNAS[1]	-%	

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 44: Worker exposure, Trifloxystrobin, Low berries and other small fruits

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Reaching, picking	Potential exposure mg/kg bw/day	0.137	% of RVNAS[1]	229%	
	Working clothing mg/kg bw/day	0.0711	% of RVNAS[1]	118%	
	Working clothing and gloves mg/kg bw/day	0.0178	% of RVNAS[1]	29.6%	
Measured DFR	3.29 µg a.s./cm² per kg a.s./ha				
Worker – Reaching, picking (Measured)	Potential exposure mg/kg bw/day	0.0814	% of RVNAS[1]	136%	
	Working clothing mg/kg bw/day	0.0421	% of RVNAS[1]	70.2%	
	Working clothing and gloves mg/kg bw/day	0.0105	% of RVNAS[1]	17.5%	

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 45: Worker exposure, Trifloxystrobin, Low berries and other small fruits

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Manual-Hand held			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Reaching, picking	Potential exposure mg/kg bw/day	0.137	% of RVNAS[1]	229%	
	Working clothing mg/kg bw/day	0.0711	% of RVNAS[1]	118%	
	Working clothing and gloves mg/kg bw/day	0.0178	% of RVNAS[1]	29.6%	
Measured DFR	3.29 µg a.s./cm² per kg a.s./ha				
Worker – Reaching, picking (Measured)	Potential exposure mg/kg bw/day	0.0814	% of RVNAS[1]	136%	
	Working clothing mg/kg bw/day	0.0421	% of RVNAS[1]	70.2%	
	Working clothing and gloves mg/kg bw/day	0.0105	% of RVNAS[1]	17.5%	

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 46: Worker exposure, Trifloxystrobin, Low berries and other small fruits

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Manual-Knapsack			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Reaching, picking	Potential exposure mg/kg bw/day	0.137	% of RVNAS[1]	229%	
	Working clothing mg/kg bw/day	0.0711	% of RVNAS[1]	118%	
	Working clothing and gloves mg/kg bw/day	0.0178	% of RVNAS[1]	29.6%	
Measured DFR	3.29 µg a.s./cm² per kg a.s./ha				
Worker – Reaching, picking (Measured)	Potential exposure mg/kg bw/day	0.0814	% of RVNAS[1]	136%	
	Working clothing mg/kg bw/day	0.0421	% of RVNAS[1]	70.2%	
	Working clothing and gloves mg/kg bw/day	0.0105	% of RVNAS[1]	17.5%	

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 47: Worker exposure, Trifloxystrobin, Hops

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.15 kg a.s. /ha	**Spray dilution =** 0.075 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Hops, Outdoor, Upward spraying, Vehicle-mounted			**Buffer =** 5 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Inspection, irrigation	Potential exposure mg/kg bw/day	0.0517	% of RVNAS[1]	86.2%	
	Working clothing mg/kg bw/day	0.00579	% of RVNAS[1]	9.65%	
	Working clothing and gloves mg/kg bw/day	-	% of RVNAS[1]	-%	

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 48: Worker exposure, Trifloxystrobin, Root and tuber vegetables

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.075 kg a.s. /ha	**Spray dilution =** 0.5 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Root and tuber vegetables, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 5 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Inspection, irrigation	Potential exposure mg/kg bw/day	0.0557	% of RVNAS[1]	92.8%	
	Working clothing mg/kg bw/day	0.00624	% of RVNAS[1]	10.4%	
	Working clothing and gloves mg/kg bw/day	-	% of RVNAS[1]	-%	

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 49: Worker exposure, Trifloxystrobin, Ornamentals

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 1 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Ornamentals, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 1 **Application interval =** 365 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Cutting, sorting, bundling, carrying	Potential exposure mg/kg bw/day	0.179	% of RVNAS[1]	299%	
	Working clothing mg/kg bw/day	0.064	% of RVNAS[1]	107%	
	Working clothing and gloves mg/kg bw/day	0.0179	% of RVNAS[1]	29.9%	
Measured DFR	2.285 µg a.s./cm² per kg a.s./ha				
Worker – Cutting, sorting, bundling, carrying (Measured)	Potential exposure mg/kg bw/day	0.136	% of RVNAS[1]	227%	
	Working clothing mg/kg bw/day	0.0487	% of RVNAS[1]	81.2%	
	Working clothing and gloves mg/kg bw/day	0.0136	% of RVNAS[1]	22.7%	

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 50: Worker exposure, Trifloxystrobin, Ornamentals

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.4 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Ornamentals, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	
Worker – Cutting, sorting, bundling, carrying	Potential exposure mg/kg bw/day		0.309	% of RVNAS[1]	515%
	Working clothing mg/kg bw/day		0.11	% of RVNAS[1]	184%
	Working clothing and gloves mg/kg bw/day		0.0309	% of RVNAS[1]	51.5%
Measured DFR	2.285 µg a.s./cm² per kg a.s./ha				
Worker – Cutting, sorting, bundling, carrying (Measured)	Potential exposure mg/kg bw/day		0.136	% of RVNAS[1]	227%
	Working clothing mg/kg bw/day		0.0487	% of RVNAS[1]	81.2%
	Working clothing and gloves mg/kg bw/day		0.0136	% of RVNAS[1]	22.7%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

~~**Table A 51: Worker exposure, Trifloxystrobin, Golf course, turf or other sports lawns**~~

~~**Substance**~~	~~Trifloxystrobin~~	~~**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.~~	~~**Application rate =** 0.125 kg a.s. /ha~~	~~**Spray dilution =** 0.625 g a.s./l~~	~~**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa~~
~~**Scenario**~~	~~Golf course, turf or other sports lawns, Outdoor, Downward spraying, Vehicle-mounted~~			~~**Buffer =** 2-3 m~~	~~**Number of applications =** 2 **Application interval =** 14 days~~
~~**Percentage Absorption**~~	~~Dermal for product = 0.14%~~	~~**Dermal for in use dilution** = 16%~~	~~**Oral =** 100%~~	~~**Inhalation =** 100%~~	-
~~RVNAS[1] (AOEL)~~	~~0.06 mg/kg bw/day~~		~~RVAAS[2]~~	~~0.3 mg/kg bw/day~~	
~~DFR~~	~~3 µg a.s./cm² per kg a.s./ha~~	-	~~DT50~~	~~30 days~~	-
~~Worker – Maintenance~~	~~Potential exposure mg/kg bw/day~~		~~0.08~~	~~% of RVNAS[1]~~	~~133%~~
	~~Working clothing mg/kg bw/day~~		~~0.0345~~	~~% of RVNAS[1]~~	~~57.5%~~
	~~Working clothing and gloves mg/kg bw/day~~		~~0.008~~	~~% of RVNAS[1]~~	~~13.3%~~

~~[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL~~
~~[2] RVAAS = Reference Value Acutely toxic active Substance~~

A 3.2.1 Calculations for the active substance(s)

Please refer to A 3.

A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

Table A 52: Bystander and resident exposure, Fluopyram, Grapes

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.05 kg a.s. /ha	**Spray dilution =** 0.125 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Grapes, Outdoor, Upward spraying, Vehicle-mounted			**Buffer =** 5 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00314	% of RVNAS[1]	6.27%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	2.14%
	Surface deposits (75th percentile) mg/kg bw/day	0.000162	% of RVNAS[1]	0.324%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00262	% of RVNAS[1]	5.24%
	All pathways (mean) mg/kg bw/day	0.00534	% of RVNAS[1]	10.7%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.00174	% of RVNAS[1]	3.47%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.46%
	Surface deposits (75th percentile) mg/kg bw/day	5.79E-05	% of RVNAS[1]	0.116%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00145	% of RVNAS[1]	2.91%
	All pathways (mean) mg/kg bw/day	0.00257	% of RVNAS[1]	5.14%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 53: Bystander and resident exposure, Fluopyram, Low berries and other small fruits

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00323	% of RVNAS[1]	6.46%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	2.14%
	Surface deposits (75th percentile) mg/kg bw/day	0.00127	% of RVNAS[1]	2.54%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0112	% of RVNAS[1]	22.5%
	All pathways (mean) mg/kg bw/day	0.0127	% of RVNAS[1]	25.5%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.000772	% of RVNAS[1]	1.54%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.46%
	Surface deposits (75th percentile) mg/kg bw/day	0.000454	% of RVNAS[1]	0.908%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00625	% of RVNAS[1]	12.5%
	All pathways (mean) mg/kg bw/day	0.00591	% of RVNAS[1]	11.8%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 54: Bystander and resident exposure, Fluopyram, Low berries and other small fruits

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Manual-Hand held			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00323	% of RVNAS[1]	6.46%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	2.14%
	Surface deposits (75th percentile) mg/kg bw/day	0.00127	% of RVNAS[1]	2.54%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0112	% of RVNAS[1]	22.5%
	All pathways (mean) mg/kg bw/day	0.0127	% of RVNAS[1]	25.5%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.000772	% of RVNAS[1]	1.54%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.46%
	Surface deposits (75th percentile) mg/kg bw/day	0.000454	% of RVNAS[1]	0.908%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00625	% of RVNAS[1]	12.5%
	All pathways (mean) mg/kg bw/day	0.00591	% of RVNAS[1]	11.8%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 55: Bystander and resident exposure, Fluopyram, Low berries and other small fruits

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Manual-Knapsack			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00323	% of RVNAS[1]	6.46%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	2.14%
	Surface deposits (75th percentile) mg/kg bw/day	0.00127	% of RVNAS[1]	2.54%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0112	% of RVNAS[1]	22.5%
	All pathways (mean) mg/kg bw/day	0.0127	% of RVNAS[1]	25.5%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.000772	% of RVNAS[1]	1.54%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.46%
	Surface deposits (75th percentile) mg/kg bw/day	0.000454	% of RVNAS[1]	0.908%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00625	% of RVNAS[1]	12.5%
	All pathways (mean) mg/kg bw/day	0.00591	% of RVNAS[1]	11.8%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 56: Bystander and resident exposure, Fluopyram, Hops

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.15 kg a.s. /ha	**Spray dilution =** 0.075 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Hops, Outdoor, Upward spraying, Vehicle-mounted			**Buffer =** 5 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00188	% of RVNAS[1]	3.76%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	2.14%
	Surface deposits (75th percentile) mg/kg bw/day	0.00136	% of RVNAS[1]	2.72%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00785	% of RVNAS[1]	15.7%
	All pathways (mean) mg/kg bw/day	0.00951	% of RVNAS[1]	19%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.00104	% of RVNAS[1]	2.08%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.46%
	Surface deposits (75th percentile) mg/kg bw/day	0.000485	% of RVNAS[1]	0.97%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00436	% of RVNAS[1]	8.73%
	All pathways (mean) mg/kg bw/day	0.00472	% of RVNAS[1]	9.45%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 57: Bystander and resident exposure, Fluopyram, Root and tuber vegetables

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.075 kg a.s. /ha	**Spray dilution =** 0.5 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Root and tuber vegetables, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 5 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00242	% of RVNAS[1]	4.85%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	2.14%
	Surface deposits (75th percentile) mg/kg bw/day	0.000956	% of RVNAS[1]	1.91%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00846	% of RVNAS[1]	16.9%
	All pathways (mean) mg/kg bw/day	0.00985	% of RVNAS[1]	19.7%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.000579	% of RVNAS[1]	1.16%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.46%
	Surface deposits (75th percentile) mg/kg bw/day	0.000342	% of RVNAS[1]	0.683%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0047	% of RVNAS[1]	9.4%
	All pathways (mean) mg/kg bw/day	0.0045	% of RVNAS[1]	9.01%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 58: Bystander and resident exposure, Fluopyram, Ornamentals

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 1 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Ornamentals, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 1 **Application interval =** 365 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00485	% of RVNAS[1]	9.7%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	2.14%
	Surface deposits (75th percentile) mg/kg bw/day	0.000687	% of RVNAS[1]	1.37%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00608	% of RVNAS[1]	12.2%
	All pathways (mean) mg/kg bw/day	0.00909	% of RVNAS[1]	18.2%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.00116	% of RVNAS[1]	2.32%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.46%
	Surface deposits (75th percentile) mg/kg bw/day	0.000245	% of RVNAS[1]	0.491%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00338	% of RVNAS[1]	6.75%
	All pathways (mean) mg/kg bw/day	0.00365	% of RVNAS[1]	7.3%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 59: Bystander and resident exposure, Fluopyram, Ornamentals

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.4 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Ornamentals, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00194	% of RVNAS[1]	3.88%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	2.14%
	Surface deposits (75th percentile) mg/kg bw/day	0.00118	% of RVNAS[1]	2.37%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0105	% of RVNAS[1]	20.9%
	All pathways (mean) mg/kg bw/day	0.0114	% of RVNAS[1]	22.7%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.000463	% of RVNAS[1]	0.926%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.46%
	Surface deposits (75th percentile) mg/kg bw/day	0.000423	% of RVNAS[1]	0.846%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00582	% of RVNAS[1]	11.6%
	All pathways (mean) mg/kg bw/day	0.0054	% of RVNAS[1]	10.8%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 60: Bystander and resident exposure, Fluopyram, Golf course, turf or other sports lawns

Substance	Fluopyram	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.125 kg a.s. /ha	**Spray dilution =** 0.625 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Golf course, turf or other sports lawns, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.083%	**Dermal for in use dilution** = 18%	**Oral =** 100%	**Inhalation =** 100%	-
RVNAS[1] (AOEL)	0.05 mg/kg bw/day		RVAAS[2]	- mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha	-	DT50	30 days	-

Bystander – child	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
Bystander – adult	Spray drift (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Vapour (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Surface deposits (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%
	Entry into treated crops (95th percentile) mg/kg bw/day	-	% of RVNAS[1]	-%

Resident – child	Spray drift (75th percentile) mg/kg bw/day	0.00303	% of RVNAS[1]	6.06%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	2.14%
	Surface deposits (75th percentile) mg/kg bw/day	0.00074	% of RVNAS[1]	1.48%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00259	% of RVNAS[1]	5.19%
	All pathways (mean) mg/kg bw/day	0.00454	% of RVNAS[1]	9.09%
Resident – adult	Spray drift (75th percentile) mg/kg bw/day	0.000724	% of RVNAS[1]	1.45%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.46%
	Surface deposits (75th percentile) mg/kg bw/day	0.000264	% of RVNAS[1]	0.528%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00059	% of RVNAS[1]	1.18%
	All pathways (mean) mg/kg bw/day	0.00136	% of RVNAS[1]	2.71%

[1] RVNAS = Reference Value Non-Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 61: Bystander and resident exposure, Trifloxystrobin, Grapes

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.05 kg a.s. /ha	**Spray dilution =** 0.125 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Grapes, Outdoor, Upward spraying, Vehicle-mounted			**Buffer =** 5 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	0.00639	% of RVNAS[1]	2.13%
	Vapour (95th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	0.357%
	Surface deposits (95th percentile) mg/kg bw/day	0.000338	% of RVNAS[1]	0.113%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00233	% of RVNAS[1]	0.776%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	0.00354	% of RVNAS[1]	1.18%
	Vapour (95th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.0767%
	Surface deposits (95th percentile) mg/kg bw/day	0.000121	% of RVNAS[1]	0.0402%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00129	% of RVNAS[1]	0.431%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00279	% of RVNAS[1]	4.65%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	1.78%
	Surface deposits (75th percentile) mg/kg bw/day	0.000148	% of RVNAS[1]	0.247%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00233	% of RVNAS[1]	3.88%
	All pathways (mean) mg/kg bw/day	0.00487	% of RVNAS[1]	8.12%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.00154	% of RVNAS[1]	2.57%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.383%
	Surface deposits (75th percentile) mg/kg bw/day	5.15E-05	% of RVNAS[1]	0.0858%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00129	% of RVNAS[1]	2.15%
	All pathways (mean) mg/kg bw/day	0.00231	% of RVNAS[1]	3.85%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 62: Bystander and resident exposure, Trifloxystrobin, Low berries and other small fruits

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	0.00655	% of RVNAS[1]	2.18%
	Vapour (95th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	0.357%
	Surface deposits (95th percentile) mg/kg bw/day	0.0034	% of RVNAS[1]	1.13%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00999	% of RVNAS[1]	3.33%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	0.00177	% of RVNAS[1]	0.59%
	Vapour (95th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.0767%
	Surface deposits (95th percentile) mg/kg bw/day	0.00122	% of RVNAS[1]	0.406%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00555	% of RVNAS[1]	1.85%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00287	% of RVNAS[1]	4.79%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	1.78%
	Surface deposits (75th percentile) mg/kg bw/day	0.00116	% of RVNAS[1]	1.94%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00999	% of RVNAS[1]	16.7%
	All pathways (mean) mg/kg bw/day	0.0115	% of RVNAS[1]	19.1%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.000686	% of RVNAS[1]	1.14%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.383%
	Surface deposits (75th percentile) mg/kg bw/day	0.000403	% of RVNAS[1]	0.672%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00555	% of RVNAS[1]	9.25%
	All pathways (mean) mg/kg bw/day	0.00528	% of RVNAS[1]	8.8%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 63: Bystander and resident exposure, Trifloxystrobin, Low berries and other small fruits

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Manual-Hand held			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	0.00655	% of RVNAS[1]	2.18%
	Vapour (95th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	0.357%
	Surface deposits (95th percentile) mg/kg bw/day	0.0034	% of RVNAS[1]	1.13%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00999	% of RVNAS[1]	3.33%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	0.00177	% of RVNAS[1]	0.59%
	Vapour (95th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.0767%
	Surface deposits (95th percentile) mg/kg bw/day	0.00122	% of RVNAS[1]	0.406%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00555	% of RVNAS[1]	1.85%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00287	% of RVNAS[1]	4.79%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	1.78%
	Surface deposits (75th percentile) mg/kg bw/day	0.00116	% of RVNAS[1]	1.94%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00999	% of RVNAS[1]	16.7%
	All pathways (mean) mg/kg bw/day	0.0115	% of RVNAS[1]	19.1%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.000686	% of RVNAS[1]	1.14%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.383%
	Surface deposits (75th percentile) mg/kg bw/day	0.000403	% of RVNAS[1]	0.672%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00555	% of RVNAS[1]	9.25%
	All pathways (mean) mg/kg bw/day	0.00528	% of RVNAS[1]	8.8%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 64: Bystander and resident exposure, Trifloxystrobin, Low berries and other small fruits

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.667 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Low berries and other small fruits, Outdoor, Downward spraying, Manual-Knapsack			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	0.00655	% of RVNAS[1]	2.18%
	Vapour (95th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	0.357%
	Surface deposits (95th percentile) mg/kg bw/day	0.0034	% of RVNAS[1]	1.13%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00999	% of RVNAS[1]	3.33%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	0.00177	% of RVNAS[1]	0.59%
	Vapour (95th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.0767%
	Surface deposits (95th percentile) mg/kg bw/day	0.00122	% of RVNAS[1]	0.406%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00555	% of RVNAS[1]	1.85%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00287	% of RVNAS[1]	4.79%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	1.78%
	Surface deposits (75th percentile) mg/kg bw/day	0.00116	% of RVNAS[1]	1.94%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00999	% of RVNAS[1]	16.7%
	All pathways (mean) mg/kg bw/day	0.0115	% of RVNAS[1]	19.1%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.000686	% of RVNAS[1]	1.14%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.383%
	Surface deposits (75th percentile) mg/kg bw/day	0.000403	% of RVNAS[1]	0.672%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00555	% of RVNAS[1]	9.25%
	All pathways (mean) mg/kg bw/day	0.00528	% of RVNAS[1]	8.8%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 65: Bystander and resident exposure, Trifloxystrobin, Hops

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.15 kg a.s. /ha	**Spray dilution =** 0.075 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Hops, Outdoor, Upward spraying, Vehicle-mounted			**Buffer =** 5 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	0.00383	% of RVNAS[1]	1.28%
	Vapour (95th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	0.357%
	Surface deposits (95th percentile) mg/kg bw/day	0.00324	% of RVNAS[1]	1.08%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00698	% of RVNAS[1]	2.33%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	0.00212	% of RVNAS[1]	0.707%
	Vapour (95th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.0767%
	Surface deposits (95th percentile) mg/kg bw/day	0.00116	% of RVNAS[1]	0.386%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00388	% of RVNAS[1]	1.29%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00167	% of RVNAS[1]	2.79%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	1.78%
	Surface deposits (75th percentile) mg/kg bw/day	0.00124	% of RVNAS[1]	2.07%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00698	% of RVNAS[1]	11.6%
	All pathways (mean) mg/kg bw/day	0.0086	% of RVNAS[1]	14.3%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.000926	% of RVNAS[1]	1.54%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.383%
	Surface deposits (75th percentile) mg/kg bw/day	0.000431	% of RVNAS[1]	0.719%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00388	% of RVNAS[1]	6.46%
	All pathways (mean) mg/kg bw/day	0.00423	% of RVNAS[1]	7.04%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 66: Bystander and resident exposure, Trifloxystrobin, Root and tuber vegetables

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.075 kg a.s. /ha	**Spray dilution =** 0.5 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Root and tuber vegetables, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 5 **Application interval =** 7 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	0.00491	% of RVNAS[1]	1.64%
	Vapour (95th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	0.357%
	Surface deposits (95th percentile) mg/kg bw/day	0.00256	% of RVNAS[1]	0.854%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00752	% of RVNAS[1]	2.51%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	0.00133	% of RVNAS[1]	0.442%
	Vapour (95th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.0767%
	Surface deposits (95th percentile) mg/kg bw/day	0.000915	% of RVNAS[1]	0.305%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00418	% of RVNAS[1]	1.39%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00216	% of RVNAS[1]	3.59%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	1.78%
	Surface deposits (75th percentile) mg/kg bw/day	0.000875	% of RVNAS[1]	1.46%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00752	% of RVNAS[1]	12.5%
	All pathways (mean) mg/kg bw/day	0.0089	% of RVNAS[1]	14.8%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.000515	% of RVNAS[1]	0.858%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.383%
	Surface deposits (75th percentile) mg/kg bw/day	0.000304	% of RVNAS[1]	0.506%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00418	% of RVNAS[1]	6.96%
	All pathways (mean) mg/kg bw/day	0.00403	% of RVNAS[1]	6.71%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 67: Bystander and resident exposure, Trifloxystrobin, Ornamentals

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 1 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Ornamentals, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 1 **Application interval =** 365 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	0.00982	% of RVNAS[1]	3.27%
	Vapour (95th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	0.357%
	Surface deposits (95th percentile) mg/kg bw/day	0.00184	% of RVNAS[1]	0.613%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.0054	% of RVNAS[1]	1.8%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	0.00265	% of RVNAS[1]	0.885%
	Vapour (95th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.0767%
	Surface deposits (95th percentile) mg/kg bw/day	0.000657	% of RVNAS[1]	0.219%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.003	% of RVNAS[1]	1%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00431	% of RVNAS[1]	7.19%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	1.78%
	Surface deposits (75th percentile) mg/kg bw/day	0.000628	% of RVNAS[1]	1.05%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0054	% of RVNAS[1]	9%
	All pathways (mean) mg/kg bw/day	0.00821	% of RVNAS[1]	13.7%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.00103	% of RVNAS[1]	1.72%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.383%
	Surface deposits (75th percentile) mg/kg bw/day	0.000218	% of RVNAS[1]	0.363%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.003	% of RVNAS[1]	5%
	All pathways (mean) mg/kg bw/day	0.00327	% of RVNAS[1]	5.45%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 68: Bystander and resident exposure, Trifloxystrobin, Ornamentals

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.2 kg a.s. /ha	**Spray dilution =** 0.4 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Ornamentals, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha		DT50	30 days	

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	0.00393	% of RVNAS[1]	1.31%
	Vapour (95th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	0.357%
	Surface deposits (95th percentile) mg/kg bw/day	0.00317	% of RVNAS[1]	1.06%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00931	% of RVNAS[1]	3.1%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	0.00106	% of RVNAS[1]	0.354%
	Vapour (95th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.0767%
	Surface deposits (95th percentile) mg/kg bw/day	0.00113	% of RVNAS[1]	0.378%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00517	% of RVNAS[1]	1.72%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.00172	% of RVNAS[1]	2.87%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	1.78%
	Surface deposits (75th percentile) mg/kg bw/day	0.00108	% of RVNAS[1]	1.8%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00931	% of RVNAS[1]	15.5%
	All pathways (mean) mg/kg bw/day	0.0102	% of RVNAS[1]	17.1%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.000412	% of RVNAS[1]	0.686%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.383%
	Surface deposits (75th percentile) mg/kg bw/day	0.000376	% of RVNAS[1]	0.626%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00517	% of RVNAS[1]	8.62%
	All pathways (mean) mg/kg bw/day	0.00482	% of RVNAS[1]	8.04%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

Table A 69: Bystander and resident exposure, Trifloxystrobin, Golf course, turf or other sports lawns

Substance	Trifloxystrobin	**Formulation =** Soluble concentrates, emulsifiable concentrate, etc.	**Application rate =** 0.125 kg a.s. /ha	**Spray dilution =** 0.625 g a.s./l	**Vapour pressure =** low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Golf course, turf or other sports lawns, Outdoor, Downward spraying, Vehicle-mounted			**Buffer =** 2-3 m	**Number of applications =** 2 **Application interval =** 14 days
Percentage Absorption	Dermal for product = 0.14%	**Dermal for in use dilution** = 16%	**Oral =** 100%	**Inhalation =** 100%	-
RVNAS[1] (AOEL)	0.06 mg/kg bw/day		RVAAS[2]	0.3 mg/kg bw/day	
DFR	3 µg a.s./cm² per kg a.s./ha	-	DT50	30 days	-

Bystander – child	Spray drift (95th percentile) mg/kg bw/day	0.00614	% of RVNAS[1]	2.05%
	Vapour (95th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	0.357%
	Surface deposits (95th percentile) mg/kg bw/day	0.00198	% of RVNAS[1]	0.661%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00386	% of RVNAS[1]	1.29%
Bystander – adult	Spray drift (95th percentile) mg/kg bw/day	0.00166	% of RVNAS[1]	0.553%
	Vapour (95th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.0767%
	Surface deposits (95th percentile) mg/kg bw/day	0.000708	% of RVNAS[1]	0.236%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.00104	% of RVNAS[1]	0.347%

Resident – child	Spray drift (75th percentile) mg/kg bw/day	0.0027	% of RVNAS[1]	4.49%
	Vapour (75th percentile) mg/kg bw/day	0.00107	% of RVNAS[1]	1.78%
	Surface deposits (75th percentile) mg/kg bw/day	0.000677	% of RVNAS[1]	1.13%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.00245	% of RVNAS[1]	4.09%
	All pathways (mean) mg/kg bw/day	0.00417	% of RVNAS[1]	6.95%
Resident – adult	Spray drift (75th percentile) mg/kg bw/day	0.000643	% of RVNAS[1]	1.07%
	Vapour (75th percentile) mg/kg bw/day	0.00023	% of RVNAS[1]	0.383%
	Surface deposits (75th percentile) mg/kg bw/day	0.000235	% of RVNAS[1]	0.391%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.000524	% of RVNAS[1]	0.874%
	All pathways (mean) mg/kg bw/day	0.00123	% of RVNAS[1]	2.05%

[1] RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
[2] RVAAS = Reference Value Acutely toxic active Substance

A 3.3.1 Calculations for the active substance(s)

Please refer to Appendix 3

A 3.4 Combined exposure calculations for active substances

Please refer to 6.6.7.

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Comments of zRMS:	All studies (study 01 Stuke, S 2016; study 02 Daniels, M 2020 and study 03 Stuke, S 2016 were conducted according to the accepted US EPA Guideline. Thus it is scientifically valid and acceptable.

A 4.1 DFR studies – Fluopyram and Trifloxystrobin (KCA 6.10)

A 4.1.1 DFR study for fluopyram & trifloxystrobin on grapes, conducted in the Netherlands, with an application rate of 0.2 L/ha (50 g FLU/ha & 50 g TFS/ha)

Reference:	**KCA 6.10/01**
Title:	Determination of the dislodgeable foliar residues (DFR) of trifloxystrobin and AE C656948 in/on grape after spraying of AE C656948 & CGA279202 SC 500 in the field in the North of France
Report:	Stuke, S.; Daniela, M.; van Berkum, S.; 2016; 15-2924; M-569303-01-1
Authority registration No:	
Guideline(s):	US EPA OPPTS 875.2100 Foliar Dislodgeable Residue Dissipation
Deviations:	none
GLP/GEP:	yes
Acceptability:	Yes
Duplication (if vertebrate study):	

The magnitude of the dislodgeable foliar residues (DFR) of the substances AE C656948 (fluopyram, FLU) and CGA279202 (trifloxystrobin, TFS) in washings from grape leaf punches was determined after two spray applications of the formulation AE C656948 & CGA279202 SC 500 (containing 250 g/L AE C656948 and 250 g/L trifloxystrobin).

The study included one supervised residue trial conducted in Northern Europe (France) during the 2015 season.

The actual application data are presented in the following table. These data reflect the intended application scheme, or, if minor deviations occurred, these were within the acceptable range.

Table A 70: Application summary

Trial Number / Country	Crop	Appl. Number	Interval (days)	Growth Stage (BBCH)	Dose rate (L/ha)	Water rate (L/ha)	Appl. rate (kg a.s./ha)	
							FLU	TFS
15-2924-01 France	Grape	1	-	73	0.2	262	0.05	0.05
		2	14	77	0.2	292	0.05	0.05

Appl. = Application; a.s. = active substance.

Representative leaf punch samples were obtained, prepared, identified, transported and stored following the corresponding study plan and EPA OPPTS Guideline 875.2100 (1996).

Preparation of Control and Field Recovery Samples

Field fortification samples were used to demonstrate the stability of the samples during storage period of the study and the ability of the analytical laboratory to recover an analyte fortified into a sample at the field test site. The solutions from dislodged control samples were fortified with AE C656948 and trifloxystrobin at the LOQ and at a level of 10 to 100 times of the LOQ. Field spikes were performed by the field technician (PI field) prior to the 1st application. The field recovery samples were treated in the same manner as the field residue samples until analysis. LOQ was set to 0.01 µg/cm² (corresponding to 20 µg/L). Spiking levels were:

0.01 µg/cm² (corresponds to 20 µg/L), 0.1 µg/cm² (corresponds to 200 µg/L) and 1 µg/cm² (corresponds to 2000 µg/L). For each level (unspiked control, 20 µg/L, 200 µg/L and 2000 µg/L) three replicates were performed.

Forty leaf disks representing a total area of 400 cm² (double-sided surface) were collected out of the potential worker contact zone including upper, middle, lower, interior and exterior portions of grape foliage after the spray application was dry, according to study schedule. The application equipment used in the study was representative for the crop, the region and the task.

Control samples were collected prior to the first application. Field fortification samples were also generated at the field test site.

Leaf discs were dislodged with a 0.01 % Aerosol OT surfactant solution yielding a total amount of 200 mL of dislodging solution. The dislodging of the leaf samples was performed as soon as possible, but not later than 4 hours after sample collection.

Sampling information is given in Chapter 4.3 and Appendix 3 of the report.

Absolut (µg/cm²) DFR of fluopyram and trifloxystrobin are summarised in the following table. No residues above the LOQ were found in the control samples. Results were neither corrected for laboratory nor for field spike recoveries.

Table A 71: Dislodgeable Foliar Residue summary in/on grape

Trial No. Country	DALT	Residues [µg/cm²]*	
		a.s. fluopyram	a.s. trifloxystrobin
15-2924-01 France	-1	< 0.01	< 0.01
	0	0.112	0.0965
	3	0.0442	0.0417
	7	0.00962	0.0128
	14/-0	< 0.01	< 0.01
	0	0.0925	0.0775
	3	0.0432	0.0325
	7	0.0111	< 0.01
	14	< 0.01	< 0.01
	21	< 0.01	< 0.01
	28	< 0.01	< 0.01
	35	< 0.01	< 0.01

DALT = Days After Last Treatment; a.s. = active substance; "-" = before the application; * = average values of sub-plots T1, T2 and T3

The maximum initial DFR value of 0.112 µg FLU/cm² (2.24 µg/kg a.s. applied/ha/cm²) and 0.0965 µg TFS/cm² (1.93 µg/kg a.s. applied/ha/cm²) was determined after the first application.

A 4.1.2 DFR study for fluopyram & trifloxystrobin in/on raspberry, conducted in Italy, with an application rate of 0.8 L/ha (200 g FLU/ha & 200 g TFS/ha)

Reference:	**KCA 6.10/02**
Title:	Determination of the dislodgeable foliar residues (DFR) of trifloxystrobin and AE C656948 in/on raspberry after spray application of AE C656948 & CGA279202 SC 500 in the field in Italy
Report:	Daniels, M. ; van Berkum, S.; 2020; 18-2905; M-677729-01-1
Authority registration No:	
Guideline(s):	US EPA OPPTS 875.2100 Foliar Dislodgeable Residue Dissipation
Deviations:	Yes (see report)
GLP/GEP:	yes
Acceptability:	Yes
Duplication (if vertebrate study):	

The magnitude of the dislodgeable foliar residues (DFR) of the substances AE C656948 (FLU) and trifloxystrobin (TFS) in washings from raspberry leaf punches was determined after two spray applications with the suspension concentrate formulation AE C656948 & CGA279202 SC 500 (containing 250 g/L AE C656948 and 250 g/L trifloxystrobin).

The study included one supervised residue trial conducted in the field in Southern Europe (Italy) during the 2018 season.

The actual application data are presented in the following table. These data reflect the intended application scheme, or, if minor deviations occurred, these were within the acceptable range.

Table A 72: Application summary

Trial Number Country	Crop	Appl. Number	Interval (days)	Growth Stage (BBCH)	Dose rate (L/ha)	Water rate (L/ha)	Appl. rate (kg a.s./ha) trifloxystrobin	Appl. rate (kg a.s./ha) AE C656948
18-2905-01 Italy	Raspberry	1	-	19	0.8	600	0.200	0.200
		2	7	19	0.8	600	0.200	0.200

Appl. = Application; a.s. = active substance.

Representative leaf punch samples were obtained, prepared, identified, transported and stored following the corresponding study plan and the US EPA OPPTS Guideline 875.2100 (1996).

Preparation of Control and Field Recovery Samples

Field fortification samples were used to demonstrate the stability of the samples during storage period of the study and the ability of the analytical laboratory to recover an analyte fortified into a sample at the field test site. The solutions from dislodged control samples were fortified with trifloxystrobin and AE C656948 at the LOQ and at a level of 10 to 100 times of the LOQ. Field spikes were performed by the field technician (PI field) prior to the 1st application. The field recovery samples were treated in the same manner as the field residue samples until analysis. LOQ was set to 0.01 µg/cm² (corresponding to 20 µg/L). Spiking levels were: 0.01 µg/cm² (corresponds to 20 µg/L), 0.1 µg/cm² (corresponds to 200 µg/L) and 1 µg/cm² (corresponds to 2000 µg/L). For each level (unspiked control, 20 µg/L, 200 µg/L and 2000 µg/L) three replicates were performed.

Forty leaf disks representing a total area of 400 cm² (double-sided surface) were collected out of the potential worker contact zone including upper, middle, lower, interior and exterior portions of raspberry foliage after the spray application was dry, according to study schedule. The application equipment used in the study was representative for the crop, the region and the task.

Control samples were collected prior to the first application. Field fortification samples were also generated at the field test site.

Leaf discs were dislodged with a 0.01 % Aerosol OT surfactant solution yielding a total amount of 200 mL of dislodging solution. The dislodging of the leaf samples was performed as soon as possible, but not later than 4 hours after sample collection.

Sampling information is given in Chapter 4.3 and Appendix 3 of the report.

Absolut (µg/cm²) DFR of trifloxystrobin and AE C656948 are summarised in the following table. No residues above the LOQ were found in the control samples. Results were neither corrected for laboratory nor for field spike recoveries.

Table A 73: Dislodgeable Foliar Residue summary in/on raspberry

Trial No. Country	DAT	Residues [µg/cm²]	
		a.s. trifloxystrobin	a.s. AE C656948
18-2905-01 Italy	-0	<0.01	<0.01
	0	0.496	1.02
	3	0.408	0.832
	7/-0	0.136	0.558
	0	0.528	1.46
	1	0.658	1.41
	3	0.587	1.11
	5	0.325	0.149
	7	0.137	0.0435

DAT = Days After Treatment; a.s. = active substance; "-0" = before the application

The maximum DFR value of 1.46 µg FLU/cm² (7.3 µg/kg a.s. applied/ha/cm²) was determined after the second application and 0.658 µg TFS/cm² (3.29 µg/kg a.s. applied/ha/cm²) was determined after the second application day 1 after application.

A 4.1.3 DFR study for for fluopyram & trifloxystrobin in/on lily, conducted in the Netherlands, with an application rate of 0.8 L/ha (200 g FLU/ha & 200 g TFS/ha)

Reference:	**KCA 6.10/03**
Title:	Determination of the dislodgeable foliar residues (DFR) of trifloxystrobin and AE C656948 in/on lily after spraying of AE C656948 & CGA279202 SC 500 in the field in the Netherlands
Report:	Stuke, S.; van Berkum, S.; 2016; 15-2925; M-558518-01-1
Authority registration No:	
Guideline(s):	US EPA OPPTS 875.2100 Foliar Dislodgeable Residue Dissipation
Deviations:	not specified
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

The magnitude of the dislodgeable foliar residues (DFR) of the substances AE C656948 (fluopyram, FLU) and CGA279202 (trifloxystrobin, TFS) in washings from lily leaf punches was determined after two spray applications with AE C656948 & CGA279202 SC 500 (containing 250 g/L fluopyram and 250 g/L trifloxystrobin).

The study included one supervised residue trial conducted in the field in northern Europe (The Netherlands) during the 2015 season.

The actual application data are presented in the following table. These data reflect the intended application scheme, or, if minor deviations occurred, these were within the acceptable range.

Table A 74: Application summary

Trial Number / Country	Crop	Appl. Number	Interval (days)	Growth Stage (BBCH)	Dose rate (L/ha)	Water rate (L/ha)	Appl. rate (kg a.s./ha)	
							FLU	TFS
15-2925-01 The Netherlands	lily	1	-	35	0.8	500	0.2	0.2
		2	7	37	0.8	500	0.2	0.2

Appl. = Application; a.s. = active substance.

Representative leaf punch samples were obtained, prepared, identified, transported and stored following the corresponding study plan and EPA OPPTS Guideline 875.2100 (1996).

Preparation of Control and Field Recovery Samples

Field fortification samples were used to demonstrate the stability of the samples during storage period of the study and the ability of the analytical laboratory to recover an analyte fortified into a sample at the field test site. The solutions from dislodged control samples were fortified with a mixture of AE C656948 and trifloxystrobin at the LOQ and at a level of 10 to 100 times of the LOQ. Field spikes were performed by the field technician (PI field) prior to the 1st application. The field recovery samples were treated in the same manner as the field residue samples until analysis. LOQ was set to 0.01 µg/cm² (corresponding to 20 µg/L). Spiking levels were: 0.01 µg/cm² (corresponds to 20 µg/L), 0.1 µg/cm² (corresponds to 200 µg/L) and 1 µg/cm² (corresponds to 2000 µg/L). For each level (unspiked control, 20 µg/L, 200 µg/L and 2000 µg/L) three replicates were performed.

Forty or eighty leaf disks representing a total area of 400 cm² (double-sided surface) were collected out of the potential worker contact zone including upper, middle, lower, interior and exterior portions of lily foliage after the spray application was dry, according to study schedule. The application equipment used in the study was representative for the crop, the region and the task.

Control samples were collected prior to the first application. Field fortification samples were also generated at the field test site.

Leaf discs were dislodged with a 0.01 % Aerosol OT surfactant solution yielding a total amount of 200 mL of dislodging solution. The dislodging of the leaf samples was performed as soon as possible, but not later than 4 hours after sample collection.

Sampling information is given in Chapter 4.3 and Appendix 3 of the report. No residues above the LOQ were found in the control samples.

Absolut (µg/cm²) DFR of fluopyram and trifloxystrobin are summarised in the following table. No residues above the LOQ were found in the control samples. Results were neither corrected for laboratory nor for field spike recoveries.

Table A 75: Dislodgeable Foliar Residue summary in/on lily

Trial No. / Country	DALT	Residues [µg/cm²]*	
		a.s. fluopyram	a.s. trifloxystrobin
15-2925-01 The Netherlands	-1	< 0.01	< 0.01
	0	0.514	0.457
	3	0.362	0.222
	7/-0	0.0356	0.117
	0	0.577	0.335
	1	0.468	0.241
	3	0.174	0.131
	7	0.0246	0.0479

DALT = Days After Last Treatment; a.s. = active substance; "-" = before the last application; * = average values of sub-plots T1, T2 and T3

The maximum DFR value of 0.577 µg FLU/cm² (2.885 µg/kg a.s. applied/ha/cm²) was determined after the

second application and 0.457 µg TFS/cm² (2.285 µg/kg a.s. applied/ha/cm²) was determined after the initial application after application.