REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: EF-243

Product name(s): Lontrel 300

Chemical active substance:

Clopyralid-olamine, 395 g/l (300 g ae/l)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Renewal of Authorization under Art.43)

Applicant: Corteva Agriscience

Submission date: 22/12/2021

MS Finalisation date: 05/12/2022

After commenting: 22/02/2023

Version history

When	What
December 2021	Article 43 submission for re-registration of EF-243 following Clopyralid Renewal of approval (Commission Implementing Regulation (EU) 2021/1191)
December 2022	First zRMS assessment
February 2023	After commenting

Table of Contents

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on EF-243 *

Product name and code	EF-243
Formulation type	Soluble concentrate (SL)
Active substance(s) (incl. content)	Clopyralid-olamine, 395 g/l (300 g ae/l)
Function	Herbicide
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 (full list of approvals can be found in Part B, Section 0, point 0.1.4)

* Information on the detailed composition of EF-243 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 EF-243 according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Aquatic Chronic ~~aquatic Cat~~ 1
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS09
Signal word	Warning
Hazard statement(s)	H410
Precautionary statement(s)	P391, ~~P501~~P280
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for EF-243

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) and gloves during mixing/loading
Workers	Acceptable	None
Residents	Acceptable	None

	Result	PPE / Risk mitigation measures
Bystanders	Acceptable	None
Recreational exposure	Acceptable	None

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders 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, resident or bystander 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) Clopyralid (kg.as/ha)**	**Water L/ha min / max**			**Operator**	**Worker**	**Residents**	**Bystander**
9	Bulb (BBCH 12-19)	F	Spraying, LCTM	1 ; 1	a) 0.158 kg as/ha (0.120 kg ae/ha†)	100 - 400	42	Critical GAP for workers, resident, bystander exposure [EFSA Journal 2014;12(10):3874]	R	A	A	A
15	Lawn (March 1st to July 1st)	F	Spraying, LCTM	1 ; 1	a) 0.265 kg as/ha (0.200 kg ae/ha†)	200 - 400	Not applicable	Critical GAP for operators exposure [EFSA Journal 2014;12(10):3874]	R	A	A	A

* 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

† Application rate is expressed as an acid equivalent (a.e.) within the risk assessment to align with the representation of the reference values.

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

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

Noticed data gaps are:

- data gap 1
- data gap 2
- data gap 3

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substance and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

	Clopyralid
Common Name	Clopyralid
CAS-No.	1702-17-6
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	**Hazard classes (s), categories:** Eyes Dam. ~~Cat~~ 1 Aquatic Chronic ~~aquatic Cat~~ 1 **Code(s) for hazard pictogram(s):** GHS05, GHS09 **Signal word:** Danger **Hazard statement(s):** **H318**: Causes serious eye damage. **H410**: Very toxic to aquatic life with long lasting effects. **Precautionary statement(s):** **P273**: Avoid release to the environment **P280**: Wear protective gloves/ protective clothing/ eye protection/ face protection. **P305+351+338**: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P315**: Get immediate medical attention. **P501**: Dispose of contents/container in accordance with applicable regulations.
Additional C&L proposal	**EU specific statements:** **EUH401**: To avoid risks to human health and the environment, comply with the instructions for use.
Agreed EU endpoints	
AOEL systemic	0.15 mg/kg bw/d
AAOEL	0.17 mg/kg bw/d
Reference	EFSA Conclusion (2018;16(~~68~~):5389)
Conditions to take into account/critical areas of concern with regard to toxicology	
According to Review Report/EFSA Conclusion for active substance	~~None~~ Member States should pay particular attention to the protection of operators, ensuring that the conditions of use for operators include the use of appropriate personal protective equipment.

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for EF-243 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 EF-243

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (OECD 401)	(>) 5000 mg/kg bw	Yes / ~~No / Supplementary~~	None	[redacted]
LD_{50} oral, rat (None)	(>) 5000 mg/kg bw	~~Yes~~ / ~~No / Supplementary~~	None	[redacted]
LD_{50} dermal, rat (OECD 402)	(>) 2000 mg/kg bw	Yes / ~~No / Supplementary~~	None	[redacted]
LC_{50} inhalation, rat (OECD 403)	(>) 4.27 mg/L air	Yes ~~/ No / Supplementary~~	None	[redacted]
Skin irritation, model system (OECD 404)	Non-irritant	Yes / ~~No / Supplementary~~	None	[redacted]
Eye irritation, model system (OECD 405)	Non-irritant	Yes / ~~No / Supplementary~~	None	[redacted]
Skin sensitisation, guinea pig/mouse (OECD 406)	Non-sensitising	Yes ~~/ No / Supplementary~~	None	[redacted]
Supplementary studies for combinations of plant protection products	No data – not required			

Table 6.3-2: Additional toxicological information relevant for classification/labelling of EF-243

	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)	Clopyralid 300 g/l	H410: Very toxic to aquatic life with long lasting effects.	Reg. 1272/2008	H410: Very toxic to aquatic life with long lasting effects.
Toxicological properties of non-active substance(s) (relevant for classification of product)	See part C	See part C	See part C	See part C
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

In accordance to EFSA conclusion (2018), there are no relevant groundwater metabolites from clopyralid, therefore no assessment is conducted.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substance in EF-243 are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substance in EF-243

	Clopyralid	
	Value	**Reference**
Concentrate	10%	Guidance on dermal absorption (EFSA, 2017)
Dilution	50%	Guidance on dermal absorption (EFSA, 2017)

6.5.1 Justification for proposed values - Clopyralid

No data on dermal absorption for clopyralid in EF-243 is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for clopyralid

	Value	**Justification for value**	**Acceptability of justification**
Concentrate	10%	EFSA default value for concentrated SL formulation (active substance concentration > 50 g/L)	Acceptable
Dilution	50%	EFSA default value for dilute SL formulation (active substance concentration ≤ 50 g/L)	Acceptable

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 name and code	EF-243
Formulation type	SL
Category	Herbicide
Active substance(s)	**Clopyralid**

(incl. content)	300 g/L
AOEL systemic	0.15 mg/kg bw/d
AAOEL	0.17 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption (EFSA Default values)	Concentrate: 10% Dilution: 50%

6.6.1 Selection of critical use(s) and justification

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

Justification

Grassland and Lawn application had the worst-case exposure for operators in the EFSA model, while for workers, residents, and bystanders, bulb vegetable has the worst-case exposure scenario for all supported applications. This is due to the crop-specific differences in working hours, worker task activity and the concentration of the active in-use dilution for liquid application.

6.6.2 Operator exposure (KCP 7.2.1)

Estimated exposures (acute and longer term) from the proposed uses of EF-243 have been evaluated using the EFSA Calculator and do not present a risk for operators. Chronic operator exposure to clopyralid from grasslands and lawns was estimated to be 10% of the AOEL with the use of gloves during mixing/loading and standard work wear. Acute operator exposure to clopyralid from grasslands and lawns was estimated to be 68% of the AAOEL, also based on standard work wear and gloves worn during mixing/loading.

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substance during application of EF-243 according to the critical use is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (acute exposure) and Table 6.6-4 (longer term exposure). Detailed calculations are in Appendix 1.

Table 6.6-2: Exposure models for intended uses

Critical use	Grassland and lawns (max. 0.67 L / kg product/ha); Min water volume = 200 L/ha
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 calculator version: 30/03/2015

Table 6.6-3: Estimated operator exposure (acute exposure)

		Clopyralid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AAOEL**
Tractor mounted boom spray application outdoors to low crops to target weeds in grasslands and lawns			
Application rate		0.200 kg a.e./ha	
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.2906	171
	Work wear (arms, body and legs covered) + Gloves for M/L	0.1157	68

Table 6.6-4: Estimated operator exposure (longer term exposure)

		Clopyralid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops to target weeds in grasslands and lawns			
Application rate		0.200 kg a.e./ha	
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0619	41
	Work wear (arms, body and legs covered) + Gloves for M/L	0.0145	10

6.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) and acute acceptable operator exposure level (AAOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

Study comment 6.6.2:	The applicant presented calculations for the application of Lontrel 300 SL (EF-243) to lawns. It is the worst case and the operator exposure assessment which was performed also covers intended uses for all crop within the zone as were given in Part B, Section 0 of this documentation. The calculations were done correctly.
Agreed endpoint 6.6.2:	According to EFSA AOEM calculations, it can be concluded that the risk of

	operator exposure during mixing & loading and tractor-mounted application on field for all crop within the zone (Part B, Section 0 of this documentation) is acceptable under conditions of intended uses when gloves are used during loading and mixing and work wear is worn during loading, mixing and application. Implication for labelling: P280 Wear protective gloves and protective clothing.

6.6.3 Worker exposure (KCP 7.2.3)

No unacceptable risk for workers from the supported uses of EF-243 was identified based on exposure estimates from the EFSA Model. The predicted worker exposure to clopyralid was 40% of the AOEL, based on normal work wear and no additional PPE.

6.6.3.1 Estimation of worker exposure

Table 6.6-5 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with EF-243 according to the critical use(s). Outcome of the estimation is presented in Table 6.6-6 (acute exposure) and Table 6.6-7 (longer term exposure). Detailed calculations are in Appendix 1.

Table 6.6-5: Exposure models for intended uses

Critical use	Bulb Vegetables (max. 0.40 L / kg product/ha); Min water volume = 100 L/ha
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 calculator version: 30/03/2015

Table 6.6-6: Estimated worker exposure (acute exposure)

There are currently no acute re-entry worker exposure data/scenarios in the EFSA Model.

Table 6.6-7: Estimated worker exposure (longer term exposure)

		Clopyralid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Reaching, picking Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.120 kg a.e./ha	
Body weight: 60 kg	None	0.1392	93
	Work wear (arms, body and legs covered) TC: 2500 cm^2/person/h	0.0600	40
	Work wear (arms, body and legs covered) and gloves TC: 580 cm^2/person/h	0.0139	9

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not applicable, generic value used.

6.6.3.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

Study comment 6.6.3:	The evaluator agrees with estimation of worker exposure after entry into a previously treated area or handling a crop treated with Lontrel 300 SL (EF-243) according to the critical use. The calculations were made for application product to bulb vegetables (onion). This use is the worst case and it covers all crops within the zone which were given in Part B, Section 0 of this documentation. This is due to the crop-specific differences in working hours, worker task activity and the concentration of the active in-use dilution for liquid application. The calculations were done correctly.
Agreed endpoint 6.6.3:	According to calculations, it can be concluded that the risk of worker exposure during re-entry activities in field is acceptable.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

Table 6.6-8 shows the exposure model(s) used for estimation of resident and bystander exposure to clopyralid. The outcome of the estimation is presented in Table 6.6-9 (longer term resident exposure) and Table 6.6-10 (acute bystander exposure). Detailed calculations are in Appendix 1.
Additionally, in Table 6.6-11 there are calculations of the recreational exposure for the intended use: lawn.

Table 6.6-8: Exposure models for intended uses

Critical use	Bulb Vegetables Onions (max. 0.40 L / kg product/ha); Min water volume = 100 L/ha
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 calculator version: 30/03/2015

Table 6.6-9: Estimated resident exposure (longer term exposure)

		Clopyralid	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops to target weeds in bulb vegetables Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		0.120 kg a.e./ha (single application)	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0161	11
	Vapour (75th perc.)	0.0011	0.7
	Deposits (75th perc.)	0.0010	0.7
	Re-entry (75th perc.)	0.0101	7
	Sum (mean)	0.0187	12
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0039	3
	Vapour (75th perc.)	0.0002	0.2
	Deposits (75th perc.)	0.0004	0.3

	Re-entry (75th perc.)	0.0056	4
	Sum (mean)	0.0068	5

Table 6.6-10: Estimated bystander exposure (acute exposure)

		Clopyralid	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AAOEL**
Tractor mounted boom spray application outdoors to low crops to target weeds in bulb vegetables Buffer zone: 2-3(m) Drift reduction technology: no DFR: 3 µg/cm²/kg a.s./ha			
Application rate		0.120 kg a.e./ha	
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.0365	22
	Vapour (95th perc.)	0.0011	0.6
	Deposits (95th perc.)	0.0029	2
	Re-entry (95th perc.)	0.0101	6
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.0099	6
	Vapour (95th perc.)	0.0002	0.1
	Deposits (95th perc.)	0.0012	0.7
	Re-entry (95th perc.)	0.0056	3

Table 6.6-11: Recreational exposure for Lontrel

		Clopyralid	
Model data		**Total systemic exposure (mg/kg bw/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to lawn DFR: 3 µg/cm²/kg a.s./ha			
Application rate		0.120 kg a.e./ha	
Child Body weight: 10 kg		0.0173	11.56
Adult Body weight: 60 kg		0.0073	4.87

6.6.4.2 Measurement of resident and/or bystander exposure

Since the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) and AAOEL, respectively for clopyralid will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements

of resident/bystander exposure was not necessary and was therefore not performed.

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

Study comment 6.6.4:	The evaluator agrees with estimation of resident and/or bystander exposure after application of Lontrel 300 SL (EF-243) according to the critical use. The calculations were made for the application of the product to bulb vegetables (onion) as the worst case. The risk for residents and bystanders from application on all crops within the zone which were given in Part B, Section 0 of this documentation is addressed through the risk assessment which has been performed for application to onion. The calculations were done correctly. Addionally zRMS has calculated the recreational exposure for the intended use: lawn. The estimation of child and adult exposure after application of Lontrel 300 SL (EF-243) to the lawn was provided in Table 6.6-11.
Agreed endpoint 6.6.4:	According to EFSA AOEM calculations, it can be concluded that there is no unacceptable risk for any bystander and resident (child and adult) after in field application product to all crops within the zone which were given in Part B, Section 0 of this documentation.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	**Owner**
KCP 7.1.1/1	[redacted]	1990	EF-243: Acute Oral Toxicity (Limit Test) in the Rat [redacted] GLP Unpublished	Y	Corteva Agriscience
KCP 7.1.1/2	[redacted]	1981	EF-243: Acute Oral Toxicity Study (LD_{50}) in the Rat [redacted] GLP Unpublished	Y	Corteva Agriscience
KCP 7.1.2/1	[redacted]	1990	EF-243: Acute Dermal Toxicity (Limit Test) in the Rat [redacted] GLP Unpublished	Y	Corteva Agriscience

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
KCP 7.1.3/1	[redacted]	1990	EF-243: Acute Inhalation Toxicity Study Four-Hour Exposure (Nose-Only) in the Rat [redacted] GLP Unpublished	Y	Corteva Agriscience
KCP 7.1.4/1	[redacted]	1990	EF-243: Acute Dermal Irritation Test in the Rabbit [redacted] GLP Unpublished	Y	Corteva Agriscience
KCP 7.1.5/1	[redacted]	1990	EF-243: Acute Eye Irritation Test in the Rabbit [redacted] GLP Unpublished	Y	Corteva Agriscience
KCP 7.1.6/1	[redacted]	1990	EF-243: Modified Nine-Induction Buehler Contact Sensitisation Study in the Guinea Pig [redacted] GLP Unpublished	Y	Corteva Agriscience

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Comments of zRMS:	Not required.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	The study was evaluated and assessed as acceptable at EU level.

A 2.2.1 Study 1

Reference	KCP 7.1.1/1
Report	EF-243: Acute Oral Toxicity (Limit Test) in the Rat, [redacted] 1990, [redacted]
Guideline(s)	OECD 401 (1981)
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	EF-243 (DB 940-89-40)
Species	Rat, Sprague-Dawley
No. of animals (group size)	5 rats/sex for LD50 study:
Dose(s)	5000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of EF-243

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
Male rats				
5000	0/0/5	NA[a]	NA	> 5000
Female rats				
5000	0/0/5	NA	NA	> 5000

* Number of animals which died/number of animals with clinical signs/number of animals used
[a] Not applicable

Table A 1: Summary of findings of acute oral toxicity study in rats of EF-243

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 oral LD_{50} of EF-243 is higher than 5000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

Comments of zRMS:	The study was evaluated and assessed at EU level. Moreover the study was assessed by zRMS as acceptable and considered as additional information during previous authorisation of the product.

A 2.2.2 Study 2

Reference	KCP 7.1.1/2
Report	EF-243: Acute Oral Toxicity Study (LD_{50}) in the Rat, [redacted]., 1981, [redacted]
Guideline(s)	None
Deviations	No
GLP	No. this study was conducted pre-GLP
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	EF-243 (EF-243)
Species	Rat, Sprague-Dawley
No. of animals (group size)	5 rats/sex
Dose(s)	5000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 2: Results of acute oral toxicity study in rats of EF-243

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
Male rats				
5000	0/0/5	NA[a]	NA	> 5000
Female rats				
5000	0/0/5	NA	NA	> 5000

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

[a] Not applicable

Table A 3: Summary of findings of acute oral toxicity study in rats of EF-243

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 oral LD_{50} of EF-243 is higher than 5000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

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

Comments of zRMS:	The study was evaluated and assessed as acceptable at EU level.

Reference	KCP 7.1.2/1
Report	EF-243: Acute Dermal Toxicity (Limit Test) in the Rat, [redacted]., 1990, [redacted]
Guideline(s)	OECD 402 (1981)
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	EF-243 (DB 940-89-40)
Species	Rat, Sprague-Dawley
No. of animals (group size)	5 rats/sex
Dose(s)	2000 mg/kg bw
Exposure	24 hours (dermal, occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 4: Results of acute dermal toxicity study in rats of EF-243

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
Male rats				
2000	0/0/5	NA[a]	NA	> 2000
Female rats				
2000	0/0/5	NA	NA	> 2000

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

[a] Not applicable

Table A 5: Summary of findings of acute dermal toxicity study in rats of EF-243

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 EF-243 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:	The study was evaluated and assessed as acceptable at EU level.

Reference	KCP 7.1.3/1
Report	EF-243: Acute Inhalation Toxicity Study Four-Hour Exposure (Nose-Only) in the Rat. [redacted]., 1990, [redacted]
Guideline(s)	OECD 403 (1981)
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	EF-243 (DB 940-89-40)
Species	Rat, Sprague-Dawley
No. of animals (group size)	5 rats/sex/dose
Concentration(s)	4.27 mg/L air
Exposure	4 hours (nose only)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 6: Concentration(s) and exposure conditions

Target conc. (mg/L air)	Actual conc. (mg/L air)	MMAD * (µm)	GSD ** (µm)
5.0	4.27	2.5	0.46

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

Table A 7: Results of acute inhalation toxicity study in rats of EF-243

Concentration (mg/L air)	Toxicological results *	Duration of signs	Time of death	LC_{50} (mg/L air) (14 days)
Male rats				
4.27	0/5/5	One day	NA[a]	> 4.27
Female rats				
4.27	0/5/5	One day	NA	> 4.27

* Number of animals which died/number of animals with clinical signs/number of animals used
[a] Not applicable

Table A 8: Summary of findings of acute inhalation toxicity study in rats of EF-243

Mortality	No mortality occurred.
Clinical signs	Yes. Hunched posture, piloerection, lethargy, and decreased respiratory rate were observed immediately on removal from the restraining tubes and one hour later. All animals continued to show hunched posture and piloerection one day after exposure but appeared normal two days after exposure and for the rest of the study period.
Body weight	Small loss in body weight was noted in all females and one male over the first week and in one femle over the second week
Macroscopic examination	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the inhalation LC_{50} of EF-243 is higher than 4.27 mg/L air 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:	The study was evaluated and assessed as acceptable at EU level.

Reference	KCP 7.1.4/1
Report	EF-243: Acute Dermal Irritation Test in the Rabbit, [redacted]., 1990, [redacted]
Guideline(s)	OECD 404 (1981)
Deviations	Yes. Test area only 2.5 cm^2, instead of 6 cm^2

GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	EF-243 (DB 940-89-40)
Species	Rabbit, New Zealand White
No. of animals (group size)	2 females, 1 male
Initial test using one animal	No
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	72 hours
Remarks	None

Results and discussions

Table A 9: Skin irritation of EF-243

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
76 Female	Erythema Oedema	0 0	0 0	0 0	0 0	0 0	0 0
99 Female	Erythema Oedema	1 0	0 0	0 0	0 0	0 0	0 0
111 Male	Erythema Oedema	1 0	0 0	0 0	0 0	0 0	0 0

* scores in the range of 0 to 4

Clinical signs:	No clinical signs of toxicity were observed.

Conclusion

Under the experimental conditions, EF-243 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:	The study was evaluated and assessed as acceptable at EU level.

Reference	KCP 7.1.5/1
Report	EF-243: Acute Eye Irritation Test in the Rabbit, [redacted] 1990, [redacted] 248, 30141
Guideline(s)	OECD 405 (1987)
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	EF-243 (DB 940-89-40)
Species	Rabbit, New Zealand White
No. of animals (group size)	2 females, 1 male
Initial test using one animal	No
Exposure	0.1 mL (single instillation in conjunctival sac of right eye)
Irrigation (time point)	No
Vehicle/Dilution	None
Post exposure observation period	72 hours
Remarks	None

Results and discussions

Table A 10: Eye irritation of EF-243

Animal No.		Scores after treatment *				Reversible (day)
		1 h	24 h	48 h	72 h	
94 Female	Corneal opacity	0	0	0	0	2
	Iritis	1	0	0	0	
	Redness conjunctivae	1	0	0	0	
	Chemosis conjunctivae	1	0	0	0	
	Discharge conjunctivae	2	0	0	0	
54 Female	Corneal opacity	0	0	0	0	2
	Iritis	1	0	0	0	
	Redness conjunctivae	1	1	0	0	
	Chemosis conjunctivae	1	0	0	0	
	Discharge conjunctivae	1	0	0	0	
51 Male	Corneal opacity	0	0	0	0	2
	Iritis	1	1	0	0	
	Redness conjunctivae	1	1	0	0	
	Chemosis conjunctivae	1	1	0	0	
	Discharge conjunctivae	2	0	0	0	

* Draiz scale scoring was conducted

Clinical signs:	No clinical signs of toxicity were observed. (If yes, describe kind of signs)

Conclusion

Under the experimental conditions, EF-243 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:	The study was evaluated and assessed as acceptable at EU level.

Reference	KCP 7.1.6/1
Report	EF-243: Modified Nine-Induction Buehler Contact Sensitisation Study in the Guinea Pig, [redacted]., 1990, [redacted]
Guideline(s)	OECD 406 (1987)
Deviations	Yes. Only 12 animals treated, instead of 20. In the absence of a reaction in any of these animals together with the need for 15% of animals to have a positive response to trigger classification in the EU this study was considered to have adequately filled this data requirement
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	EF-243 (DB 940-89-40)
Species	Guinea pig, Dunkin-Hartley
No. of animals (group size)	Test substance group: 12 female guinea pigs Vehicle control goup: 12 female guinea pigs
Range finding	Yes
Exposure (concentration(s), no. of applications)	Topical induction: 0.5 mL. Undiluted (9x / 6 hours) Challenge: 0.2 mL. Undiluted
Vehicle	None
Pretreatment prior to topical application	No
Reliability check	None
Remarks	None

Results and discussions

Table A 11: Results of skin sensitisation study of EF-243

	24 hours	**48 hours**	**Total number of animals affected**
	After challenge		
EF-243	0*	0*	0
Test vehicle control group	0*	0*	0

* Number of animals with positive dermal response (scores of 1-3) /number of animals in dose group

Clinical signs:	No clinical signs of toxicity were observed.

Conclusion

Under the experimental conditions, EF-243 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 new or additional data submitted.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Safety data sheet for each co-formulant

Information regarding 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)

No new or additional data submitted.

A 2.11 Other/Special Studies

No new or additional data submitted.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for clopyralid

Table A 12: Input parameters considered for the estimation of operator exposure

Substance	Clopyralid	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	Grassland and lawns / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 10	Dermal for in use diluation = 50	Oral = 100	Inhalation = 100	
RVNAS	0.15 mg/kg bw/day		RVAAS	0.17 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Table A 13: Estimation of acute and long-term operator exposure towards clopyralid according to EFSA guidance (without PPE)

Operator Model	Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day	0.0983	% of RVNAS	65.52%

	Acute systemic exposure mg/kg bw/day		0.5577	% of RVAAS	328.05%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day		0.0619	% of RVNAS	41.25%
	Acute systemic exposure mg/kg bw/day		0.2906	% of RVAAS	170.95%

Table A 14: Estimation of acute and long-term operator exposure towards clopyralid according to EFSA guidance (with PPE)

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0.0983	% of RVNAS	65.52%
	Acute systemic exposure mg/kg bw/day		0.5577	% of RVAAS	328.05%
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day		0.0145	% of RVNAS	9.65%
	Acute systemic exposure mg/kg bw/day		0.1157	% of RVAAS	68.09%

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for clopyralid

Table A 15: Input parameters considered for the estimation of worker exposure

Crop type	**Bulb vegetables**	
Indoor or outdoor	**Outdoor**	
Application method	**Downward spraying**	
Application equipment	**Vehicle-mounted**	
Worker's task	**Reaching, picking**	
Main body parts in contact with foliage	**Hand and body**	
Application rate of active substance	**0.12**	kg a.s./ha
Number of applications	**1**	
Interval between multiple applications	**365**	days
Half-life of active substance	**30**	days
Multiple application factor	**1.0**	
Dermal absorption of the product	**10.00%**	
Dermal absorption of the in-use dilution	**50.00%**	
Dislodgeable foliar residue (i_AppRate*i_DFR)	**0.36**	µg a.s./cm^2
Working hours	**8**	hr
Dermal transfer coefficient - Total potential exposure	**5800**	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	**2500**	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	**580**	cm^2/hr
Inhalation transfer coefficient for automated applications	**NA**	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	**NA**	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	**NA**	ha/hr*10^(-3)

Table A 16: Estimation of longer-term worker exposure towards clopyralid according to EFSA guidance

Worker - Reaching, picking	Potential exposure mg/kg bw/day	0.1392	% of RVNAS	92.80%
	Working clothing mg/kg bw/day	0.0600	% of RVNAS	40.00%
	Working clothing and gloves mg/kg bw/day	0.0139	% of RVNAS	9.28%

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for clopyralid

Table A 17: Input parameters considered for the estimation of longer term resident exposure

Croptype	**Bulb vegetables**	
Application method	**Downward spraying**	
Application equipment	**Vehicle-mounted**	
Formulation type	**Soluble concentrates, emulsifiable concentrate, etc.**	
Buffer strip	**2-3**	m
Application rate of the product	**0.12**	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	**1.2**	g a.s./l
Dermal absorption of product	**10.00%**	
Dermal absorption of in-use dilution	**50.00%**	
Oral absorption	**100.00%**	
Dislodgeable foliar residue (i_AppRate*i_DFR)	**0.36**	µg a.s./cm^2
Vapour pressure of in-use dilution	**low volatile substances having a vapour pressure of <5*10-3Pa**	Pa
Concentration in air	**0.001**	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	**0.47**	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	**0.327**	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	**0.00010**	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	**0.00022**	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	**0.22318**	ml spray dilution/person
Resident dermal spray drift exposure mean - child	**0.18**	ml spray dilution/person

Resident inhal. spray drift exposure mean - adult	**0.00009**	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	**0.00017**	ml spray dilution/person
Exposure duration dermal	**2**	hours
Exposure duration inhalation	**24**	hours
Exposure duration entry into treated crops	**0.25**	hours
Light clothing adjustment factor	**18.0%**	
Breathing rate adult	**0.23**	m^3/day/kg
Breathing rate child (1-3 year old)	**1.07**	m^3/day/kg
Drift percentage on surface (75th percentile)	**5.60%**	
Drift percentage on surface (mean)	**4.10%**	
Turf transferable residues percentage	**5.00%**	
Transfer coeff. of surface deposits-adult	**7300**	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	**2600**	cm^2/hour
Saliva extraction percentage	**50.00%**	
Surface area of hands mouthed	**20**	cm^2
Frequency of hand to mouth activity	**9.5**	events/hour
Ingestion rate for mouthing of grass per day	**25**	cm^2
Dislodgeable residues percentage transferability for object to mouth	**20.00%**	
Transfer coefficient for entry into treated crops (75th percentile) - adult	**7500**	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	**2250**	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	**5980**	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	**1794**	cm^2/h

Table A 18: Estimation of longer term resident exposure towards clopyralid according to EFSA guidance

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.0161	% of RVNAS	10.74%
	Vapour (75th percentile) mg/kg bw/day	0.0011	% of RVNAS	0.71%
	Surface deposits (75th percentile) mg/kg bw/day	0.0010	% of RVNAS	0.65%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0101	% of RVNAS	6.75%
	All pathways (mean) mg/kg bw/day	0.0187	% of RVNAS	12.49%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.0039	% of RVNAS	2.57%
	Vapour (75th percentile) mg/kg bw/day	0.0002	% of RVNAS	0.15%
	Surface deposits (75th percentile) mg/kg bw/day	0.0004	% of RVNAS	0.27%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0056	% of RVNAS	3.75%
	All pathways (mean) mg/kg bw/day	0.0068	% of RVNAS	4.56%

Table A 19: Input parameters considered for the estimation of acute bystander exposure

Croptype	**Bulb vegetables**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		*i_AppEquip*
Formulation type	**Soluble concentrates, emulsifiable concentrate, etc.**		
Application rate of the product	**0.12**	kg a.s./ha	*i_AppRate*
Buffer strip	**2-3**	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	**1.2**	g a.s./l	*d_ConcAS*
Dermal absorption of product	**10.00%**		*i_AbsorpProduct*

Dermal absorption of in-use dilution	**50.00%**		*i_AbsorpInuse*
Oral absorption	**100.00%**		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	**0.36**	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	**low volatile substances having a vapour pressure of <5*10-3Pa**	Pa	*i_Volat*
Concentration in air	**0.001**	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	**1.21**	ml spray dilution/person	
Bystander dermal spray drift exposure - child	**0.74**	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	**0.00050**	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	**0.00112**	ml spray dilution/person	
Exposure duration	**2**	hours	*d_ByExpDur*
Exposure duration entry into treated crops	**0.25**	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	**18.0%**		*d_ClothAF*
Breathing rate adult	**0.23**	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	**1.07**	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	**8.50%**		
Turf transferable residues percentage	**5.00%**		*d_Turf*
Transfer coeff. of surface deposits-adult	**14500**	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	**5200**	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	**50.00%**		*d_SalExt*
Surface area of hands mouthed	**20**	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	**20**	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	**25**	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	**20.00%**		*d_DRP*

Transfer coefficient for entry into treated crops - adult	**7500**	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - child	**2250**	cm^2/h	*d_TcEntryCh*

Table A 20: Estimation of acute bystander exposure towards clopyralid according to EFSA guidance

Bystander - child	Spray drift (95th percentile) mg/kg bw/day	0.0365	% of RVAAS	21.50%
	Vapour (95th percentile) mg/kg bw/day	0.0011	% of RVAAS	0.63%
	Surface deposits (95th percentile) mg/kg bw/day	0.0029	% of RVAAS	1.71%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.0101	% of RVAAS	5.96%
Bystander - adult	Spray drift (95th percentile) mg/kg bw/day	0.0099	% of RVAAS	5.84%
	Vapour (95th percentile) mg/kg bw/day	0.0002	% of RVAAS	0.14%
	Surface deposits (95th percentile) mg/kg bw/day	0.0012	% of RVAAS	0.73%
	Entry into treated crops (95th percentile) mg/kg bw/day	0.0056	% of RVAAS	3.31%

A 3.4 Combined exposure calculations for clopyralid

Not relevant.

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)

Not applicable. No higher tier studies were used.