

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: K-300SL-RR

Product name(s): Faworyt 300 SL

Chemical active substance:

clopyralid, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT- Art. 43

(Renewal of authorisation)

Applicant: CIECH Sarzyna S.A.

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on K-300SL-RR/Faworyt 300 SL *

Product name and code	K-300SL-RR/ Faworyt 300 SL
Formulation type	Soluble concentrate (SL)
Active substance(s) (incl. content)	clopyralid 300 g/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	No, but evaluated and already registered in PL and RO (PL Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments; RO Authorization No: 503PC/14.03.2019)

* Information on the detailed composition of Faworyt 300 SL 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 Faworyt 300 SL according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Eye Irrit. 2
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07
Signal word	Warning
Hazard statement(s)	H319 - Causes serious eye irritation
Precautionary statement(s)	P280 - Wear protective gloves/protective clothing/eye protection/face protection P305 +P351 +P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do continue rinsing P310 - Immediately call a POISON CENTER/doctor
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 Faworyt 300 SL

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) and gloves during mixing and

	Result	PPE / Risk mitigation measures
		loading
Workers	Acceptable	None
Residents	Acceptable	None
Bystanders	Acceptable	None

No unacceptable risk for workers, residents and bystanders was identified when the product is used as intended. No specific PPE is necessary.

In case of the operators, no unacceptable risk 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. safen- er/synergist (L/ha)) critical gap for operator, work- er, resident or bystander expo- sure based on [Exposure mod- el]	Acceptability of exposure as- sessment			
			Method / Kind (incl. applica- tion technique ***)	Max. number (min. interval between applica- tions) a) per use b) per crop/ season	Max. application rate kg as/ha a) a.s. 1	Water L/ha min / max			Operator	Worker	Residents	Bystander
1	Winter Wheat BBCH 21-29 (Spring)	F	Spraying LCTM	a) 1 b) 1	a) 120	200 - 300	-	-				
2	Winter rape BBCH 10-50 (Spring)	F	Spraying LCTM	a) 1 b) 1	a) 120	200 - 300	-	-				
3	Sugar beet BBCH 12-14 (Spring)	F	Spraying LCTM	a) 1 b) 1	a) 90	200 - 300	-	-				

* 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

No data gaps

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 substances 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.	1702-1706
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Eye Dam. 1 Code(s) for hazard pictogram(s): GHS05 Signal word: Danger Hazard statement(s): H318 'Causes serious eye damage' Precautionary statement(s): P280 'Wear protective gloves/protective clothing/eye protection/face protection' P305+P351+P338 'IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.' P310 'Immediately call a POISON CENTER/doctor/...'
Additional C&L proposal	None
Agreed EU endpoints	
AOEL systemic	0.15 mg/kg bw per day
AAOEL	0.17 mg/kg bw per day
Reference	EFSA Journal 2018;16(8):5389, 21 pp.
Conditions to take into account/critical areas of concern with regard to toxicology	
According to Review Report/EFSA Conclusion for clopyralid	Member States should pay particular attention to protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment.

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for Faworyt 300 SL 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.

Results of all studies presented below were already evaluated and accepted by the zRMS (Poland) during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments).

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Faworyt 300 SL

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (OECD Guideline No. 420)	> 2000 mg/kg bw	Yes	None	xxx, 2011a
LD ₅₀ dermal, rat (OECD Guideline No. 402)	> 2000 mg/kg bw	Yes	None	xxx, 2011b
LC ₅₀ inhalation, rat	-	Yes	None	Justification in Appendix 2
Skin irritation (OECD 404)	Non-irritant	Yes	None	xxx, 2011c
Eye irritation (OECD 405)	Irritant	Yes	Eye Irrit.2/H319	xxx, 2011d
Skin sensitisation, guinea pig (OECD 406)	Non-sensitising	Yes	None	xxx, 2011e
Supplementary studies for combinations of plant protection products	No data, not required		-	-

Table 6.3-2: Additional toxicological information relevant for classification/labelling of Faworyt 300 SL

	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 (26.6% (w/w))	No additional H318 'Causes serious eye damage'	- Annex VI CLP table ATP 14, 15, 17 EFSA Journal 2018;16(8):5389, 21 pp	- H319
Toxicological properties of non-active substance(s) (relevant for classification of product)	Co-formulant (<10% (w/w))	H373 (criteria ≥ 10 %)	MSDS	None
	Information concerning toxicological properties of non-active substance are presented can be found in the confidential dossier of this submission (Registration Report - Part C).			
Further toxicological information	No data – not required			

6.4 Toxicological Evaluation of Groundwater Metabolites

There are no relevant groundwater metabolites of clopyralid. As no degradation products other than CO₂ are formed from this active substance, no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in Faworyt 300 SL are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in Faworyt 300 SL

	Clopyralid	
	Value	Reference
Concentrate	10%	Default from EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873)
Dilution	50%	Default from EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873)

6.5.1 Justification for proposed values - clopyralid

No data on dermal absorption for clopyralid in Faworyt 300 SL 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%	Default dermal absorption value from EFSA Journal 2017;15(6):4873 for water based formulation - soluble concentrate	Acceptable
Dilution	50%	Default dermal absorption value from EFSA Journal 2017;15(6):4873 for water based formulation – dilution of soluble concentrate	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	Faworyt 300 SL/ K-300SL-RR
Formulation type	SL
Category	Herbicide
Active substance(s) (incl. content)	clopyralid 300 g/L
AOEL systemic	0.15 mg/kg bw/d
AAOEL	0.17 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	>80%

Dermal absorption	Concentrate: 10% Dilution: 50% (Defaults)
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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 is given in Part B, Section 0.

Justification

Critical GAPs were selected based on the highest application rates recommended for use in crops, i.e. 0.4 L of the product/ha, which is equal to 120 g of clopyralid/ha and the lowest water volumes (L/ha). Since crops to be protected by Faworyt 300 SL (wheat, winter rape and sugar beet) belong to the different types all of them are considered in the separate scenario assessment.

6.6.2 Operator exposure (KCP 7.2.1)

A summary of the exposure models used for estimation of operator exposure to the active substances during application of **Faworyt 300 SL** according to the critical use(s) 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 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Cereals – wheat (max. 0.4 L product/ha) Oilseeds - winter rape (max. 0.4 L product/ha) Root and tuber vegetables – sugar beet (max. 0.3 L product/ha)
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 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
Cereals and oilseeds Tractor mounted boom spray application outdoors to low crops			
Application rate		0.12 kg a.s./ha	
Spray application (AOEM; 95 th percentile) Body weight: 60 kg	No PPE*	0.4181103	245.95
	Work wear (arms, body and legs covered) and gloves M/L	0.0998323	58.72
Root and tuber vegetables Tractor mounted boom spray application outdoors to low crops			
Application rate		0.09 kg a.s./ha	
Spray application	No PPE*	0.3581844	210.80

(AOEM; 95 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves M/L	0.0792664	46.63
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*no PPE, no clothes. Potential exposure

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
Cereals and oilseeds Tractor mounted boom spray application outdoors to low crops			
Application rate		0.12 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	No PPE*	0.0655295	43.69
Root and tuber vegetables Tractor mounted boom spray application outdoors to low crops			
Application rate		0.09 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	No PPE*	0.0522225	34.81

*no PPE, no clothes. Potential exposure

According to the EFSA model, it can be concluded that:
- the risk for operator acute exposure is acceptable with PPE the use of work wear (arms, body and legs covered) M/L and A + gloves during mixing/loading and application,
-the risk for operator longer term exposure is acceptable without PPE

Implication for labelling: P280: Wear protective gloves.

6.6.2.1 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) 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.

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-5: Exposure models for intended uses

shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with **Faworyt 300 SL** according to the critical use(s). Outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.** (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-5: Exposure models for intended uses

Critical use(s)	Cereals – wheat (max. 0.4 L product/ha) Oilseeds - winter rape (max. 0.4 L product/ha) Root and tuber vegetables – sugar beet (max. 0.3 L product/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 EUROPOEM II Model, December 2002

Table 6.6-6: Estimated worker exposure (longer term exposure)

		Clopyralid	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Cereals, oilseeds EFSA calculator Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: n.a.			
Number of applications and application rate		1 x 0.12 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12 500 cm ² /person/h	0.0750000	50.00
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0084000	5.60
	Work wear (arms, body and legs covered) and gloves TC: n.a.	n.a.	n.a.
Root and tuber vegetables EFSA calculator Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: n.a.			

		Clopyralid	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Number of applications and application rate		1 x 0.09 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12 500 cm ² /person/h	0.0562500	37.50
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0063000	4.20
	Work wear (arms, body and legs covered) and gloves TC: n.a.	n.a.	n.a.
Cereals, oilseeds EUROPOEM II model Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: n.a.			
Number of applications and application rate		1 x 0.12 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12 500 cm ² /person/h	0.075	50
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0084	6
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm ² /person/h and an extra reduction factor of 5	0.00168	1
Root and tuber vegetables EUROPOEM II model Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: n.a.			
Number of applications and application rate		1 x 0.09 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12 500 cm ² /person/h	0.056	38
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0063	4
	Work wear (arms, body and legs covered) and gloves TC: : 1400 cm ² /person/h and an extra reduction factor of 5	0.0013	1

It is concluded that there is no unacceptable risk anticipated for the worker exposure (acute and longer term) wearing adequate work clothing, for inspection and irrigation when for re-entering treated with FAWORYT 300 SL

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not relevant, default value 3 µg/cm²/kg a.s./ha was applied for calculations.

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.

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 6.6-6 shows the exposure model(s) used for estimation of resident and bystander exposure to clopyralid. The outcome of the estimation is presented in Table 6.6-8 (longer term resident exposure) and Table 6.6-7 (acute bystander exposure). Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Cereals – wheat (max. 0.4 L product/ha) Oilseeds – winter rape (max. 0.4 L product/ha) Root and tuber vegetables – sugar beet (max. 0.3 L product/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 6.6-7: Estimated resident exposure (longer term exposure)

		Clopyralid	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Cereals, oilseeds			
Tractor mounted boom spray application outdoors to low crops			
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: n.a.			
Number of applications and application rate		1 x 0.12 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0080574	5.37
	Vapour (75 th perc.)	0.0010700	0.71
	Deposits (75 th perc.)	0.0009710	0.65
	Re-entry (75 th perc.)	0.0101250	6.75
	Sum (mean)	0.0142921	9.53
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0019280	1.29
	Vapour (75 th perc.)	0.0002300	0.15
	Deposits (75 th perc.)	0.0004088	0.27
	Re-entry (75 th perc.)	0.0056250	3.75
	Sum (mean)	0.0059302	3.95
Root and tuber vegetables			
Tractor mounted boom spray application outdoors to low crops			
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: n.a.			
Number of applications and application rate		1 x 0.09 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0060431	4.03
	Vapour (75 th perc.)	0.0010700	0.71
	Deposits (75 th perc.)	0.0007283	0.49
	Re-entry (75 th perc.)	0.0075938	5.06
	Sum (mean)	0.0109866	7.32
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0014460	0.96
	Vapour (75 th perc.)	0.0002300	0.15
	Deposits (75 th perc.)	0.0003066	0.20
	Re-entry (75 th perc.)	0.0042188	2.81
	Sum (mean)	0.0045052	3.00

Table 6.6-8: Estimated bystander exposure (acute exposure)

		Clopyralid	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL
Cereals, oilseeds			
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DFR: 3 µg/cm ² /kg a.s./ha			
Application rate		0.12 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95 th perc.)	0.0182712	10.75
	Vapour (95 th perc.)	0.0010700	0.63
	Deposits (95 th perc.)	0.0029070	1.71
	Re-entry (95 th perc.)	0.0101250	5.96
Bystander adult Body weight: 60 kg	Drift (95 th perc.)	0.0049660	2.92
	Vapour (95 th perc.)	0.0002300	0.14
	Deposits (95 th perc.)	0.0012325	0.73
	Re-entry (95 th perc.)	0.0056250	3.31
Root and tuber vegetables			
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DFR: 3 µg/cm ² /kg a.s./ha			
Application rate		0.09 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95 th perc.)	0.0137034	8.06
	Vapour (95 th perc.)	0.0010700	0.63
	Deposits (95 th perc.)	0.0021803	1.28
	Re-entry (95 th perc.)	0.0075938	4.47
Bystander adult Body weight: 60 kg	Drift (95 th perc.)	0.0037245	2.19
	Vapour (95 th perc.)	0.0002300	0.14
	Deposits (95 th perc.)	0.0009244	0.54
	Re-entry (95 th perc.)	0.0042188	2.48

According to the model calculations, it can be concluded that there is no undue risk to any bystander and resident (child and adult) after exposure to FAWORYT 300 SL. Buffer zone: 2-3 (m)

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) 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. Faworyt 300 SL contains only 1 active substance.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.1.1	xxx	2011a	Faworyt 300 SL – Acute oral toxicity study – fixed dose method on rats xxx, Poland Report No.: PO-5/11 GLP Unpublished	Y	CIECH SARZYNA S.A.
KCP 7.1.2	xxx	2011b	Faworyt 300 SL – Acute dermal toxicity study on rats xxx, Poland Report No.: DER-6/11 GLP Unpublished	Y	CIECH SARZYNA S.A.
KCP 7.1.4	xxx	2011c	Faworyt 300 SL – Acute skin irritation/corrosion study on rabbits xxx, Poland Report No.: DDR-5/11 GLP Unpublished	Y	CIECH SARZYNA S.A.
KCP 7.1.5	xxx	2011d	Faworyt 300 SL – Acute eye irritation/corrosion study on rabbits xxx, Poland Report No.: ODR-7/11 GLP Unpublished	Y	CIECH SARZYNA S.A.

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 7.1.6	xxx	2011e	Faworyt 300 SL – Skin sensitization study xxx, Poland Report No.: AI-6/11 GLP Unpublished	Y	CIECH SARZYNA S.A.

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

Bridging is not necessary since toxicological properties of Faworyt 300 SL can be predicted on the basis of toxicological studies available for the whole formulation. The one exception are acute inhalation properties of the product, for which no study is available. However, in this case sufficient data are available for the active substances and co-formulants, and thus bridging is neither necessary.

Please notice that summaries of all studies presented below were already evaluated and accepted by the zRMS (Poland) during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments). For the sake of consistency they are only repeated hereafter.

Comments of zRMS:	N/A
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A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	Under the experimental conditions, the oral LD₅₀ of Faworyt 300 SL is higher than 2000 mg/kg in rats Therefore Faworyt 300 SL is not classified
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Reference	KCP 7.1.1
Report	xxx, 2011a: Faworyt 300 SL – Acute oral toxicity study – fixed dose method on rats; Study Report PO-5/11
Guideline(s)	Yes, OECD Guideline No. 420
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No
Previous evaluation	Yes, study was already evaluated and accepted by the zRMS (Poland) during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments.

Material and Methods:

Test material (Lot/Batch No.)	Faworyt 300 SL (batch No. 1, measured concentration: 311.5 g/L)
Species	rat females with Imp symbol: WIST (outbred)
No. of animals (group size)	5 rats/female
Dose(s)	2000 mg/kg bw
Exposure	Once by gavage

Administration volume	5 mL/kg bw
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table 7.1.1-1: Acute oral toxicity in rats of Faworyt 300 SL

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

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

- No clinical signs and no deaths were observed during the study.
- The body weight gains of females were observed during the study.
- Macroscopic examination revealed that the pathological changes in the form of bloody petechiae in thymus and lung congestion were found in two animals. The changes observed could be caused by an infectious agent or arose after the death as a result of blood stagnation and should not be considered to be related to treatment with test material. No abnormalities in other animals were noted.

Conclusion/endpoint:

Under the experimental conditions, the oral LD₅₀ of Faworyt 300 SL is higher than 2000 mg/kg in rats.

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

Comments of zRMS:	Under the experimental conditions, the dermal LD₅₀ of Faworyt 300 SL is higher than 2000 mg/kg in rats.
	Therefore Faworyt 300 SL is not classified

Reference	KCP 7.1.2
Report	xxx., 2011a: Faworyt 300 SL – Acute dermal toxicity study on rats; Study Report DER-6/11
Guideline(s)	Yes, OECD Guideline No. 402
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No
Previous evaluation	Yes, study was already evaluated and accepted by the zRMS (Poland) during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments.

Material and Methods:

Test material (Lot/Batch No.)	Faworyt 300 SL (batch No. 1, measured concentration: 311.5 g/L)
Species	rat males and females with Imp symbol: WIST (outbred)
No. of animals (group size)	5 males and 5 females
Dose(s)	2000 mg/kg bw
Exposure	24 hours
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table 7.1.2-1: Acute dermal toxicity in rats of Faworyt 300 SL

Dose (mg/kg)	Toxicological results*	Duration of signs	Time of death	LD₅₀ (mg/kg) (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

- No clinical signs and no deaths were observed during the study.
- A slight decrease of body weight of three females was noted in the first week of observation period. After 14 days, the body weight gains of all animals were noted.
- Macroscopic examination revealed no pathological changes in all animals.

Conclusion/endpoint:

Under the experimental conditions, the dermal LD₅₀ of Faworyt 300 SL is higher than 2000 mg/kg in rats.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	Faworyt 300 SL does not need classification related to acute inhalation toxicity. No further studies are also needed
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No studies on acute inhalation toxicity for Faworyt 300 SL were submitted. However, acute inhalation toxicity value (ATE mix) can be estimated according to principles of Regulation 1272/2008, p. 3.1.3.6.1 (additivity formula) as follows:

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$$

Where:

- C_i – concentration of ingredient I (% w/w or % v/v)
 i – the individual ingredient from 1 to n
 n – the number of ingredients
 ATE_i – Acute Toxicity Estimate of ingredient i.

Calculations takes into account data for components which are classified to acute inhalation toxicity class and significant concentration.

Based on MSDS and harmonized CLP classification the active substance and almost all co-formulants are not classified as toxic/harmful if inhaled. The only exception is one ingredient present in concentration of 3.45% which is classified with H332 statement. Therefore this last is considered in the calculation method presented hereafter.

Taking all above into account the ATE_{mix} for the whole formulation is therefore:

$$\text{The } ATE_{mix} = \frac{100}{\frac{3.45}{11}} = 318 \text{ mg/kg bw}$$

The estimated value ATE_{mix} of acute inhalation toxicity for Faworyt 300 SL is equal to 318 mg/kg bw. Since this value is greater than 20, no classification of the product is needed.

In addition, there are no other concerns which could suggest the inhalation hazard of the product. Faworyt 300 SL is a herbicide in the form of soluble concentrate (SL). The product is to be applied to leaves by using ground equipment (sprayers providing medium-droplet spraying) generating droplets of diameter above 50 µm. Faworyt 300 SL contains an active substance (clopyralid) with a vapour pressure below 1×10^{-2} Pa and is to be used in the field.

Assuming all above, Faworyt 300 SL does not need classification related to acute inhalation toxicity. No further studies are also needed.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Under the experimental conditions, Faworyt 300 SL does not irritate the skin of rabbits.
	Therefore Faworyt 300 SL is not classified

Reference	KCP 7.1.4
Report	xxx 2011c: Faworyt 300 SL – Acute skin irritation/corrosion study on rabbits, Study Report: DDR-5/11
Guideline(s)	Yes, OECD Guideline No. 404
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No
Previous evaluation	Yes, study was already evaluated and accepted by the zRMS (Poland) during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments.

Material and Methods:

Test material (Lot/Batch No.)	Faworyt 300 SL (batch No. 1, measured concentration: 311.5 g/L)
Species	white rabbits of New Zealand strain
No. of animals (group size)	3 males
Exposure	0.5 mL (4 hours)
Vehicle/Dilution	None
Post exposure observation period	72 hours
Remarks	None

Results and discussions

Table 7.1.4-1: Acute skin irritation in rabbits of Faworyt 300 SL

Animal No.	Skin reaction	1hr	24hrs	48hrs	72hrs	Mean
1	Erythema	0	0	0	0	0
	Oedema	0	0	0	0	0
2	Erythema	2	1	0	0	0.3
	Oedema	0	0	0	0	0
3	Erythema	0	0	0	0	0
	Oedema	0	0	0	0	0

- No general clinical signs and no deaths were observed during the study.
- Erythema was noted in one animal. These changes were transient.
- No pathological changes on skin of other animals were observed.

Conclusion/endpoint:

Under the experimental conditions, Faworyt 300 SL does not irritate the skin of rabbits.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	Under the experimental conditions, Faworyt 300 SL is irritating to the rabbit eye . Therefore Faworyt 300 SL is classified H319/Eye Irrit.2
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Reference	KCP 7.1.5
Report	xxx 2011 d: Faworyt 300 SL – Acute eye irritation/corrosion study on rabbits, Study Report: DDR-7/11
Guideline(s)	Yes, OECD Guideline No. 405
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Previous evaluation Yes, study was already evaluated and accepted by the zRMS (Poland) during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments.

Material and Methods:

Test material (Lot/Batch No.)	Faworyt 300 SL (batch No. 1, measured concentration: 311.5 g/L)
Species	white rabbits of New Zealand strain
No. of animals (group size)	3 females
Exposure	0.1 mL (single instillation in conjunctival sac of eye)
Irrigation (time point)	No
Vehicle/Dilution	None
Post exposure observation period	1, 24, 48 and 72 hours as well as 7 and 14 days
Remarks	None

Results and discussions

Table 7.1.5-1: Acute eye irritation in rabbits of Faworyt 300 SL

Animal No.	Part of the eye		1hr	24hrs	48hrs	72hrs	7d	14d	Mean
1	Cornea		1	1	1	1	0	0	1.0
	Iris		1	1	1	1	0	0	1.0
	Conjunctiva	erythema	2	2	2	2	1	0	2.0
		oedema	2	2	2	2	0	0	2.0
2	Cornea		1	1	1	0	0	-	0.7
	Iris		1	1	1	0	0	-	0.7
	Conjunctiva	erythema	2	2	1	1	0	-	1.3
		oedema	2	1	1	0	0	-	0.7
3	Cornea		2	2	2	2	1	0	2.0
	Iris		1	1	1	1	1	0	1.0
	Conjunctiva	erythema	2	3	3	3	1	0	3.0
		oedema	2	2	2	2	0	0	2.0

- No general clinical signs and no deaths were observed during the study.
- The changes in cornea, iris and conjunctiva of eye in all animals were noted. These changes were transient.

Conclusion/endpoint:

Under the experimental conditions, Faworyt 300 SL is irritating to the rabbit eye.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	Under the experimental conditions, Faworyt 300 SL is non-sensitizing to skin of Guinea pigs. Therefore Faworyt 300 SL is not classified
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Reference	KCP 7.1.6
Report	xxx 2011 e: Faworyt 300 SL - Skin sensitization study, Study Report: DDR-6/11
Guideline(s)	Yes, OECD Guideline No. 406
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No
Previous evaluation	Yes, study was already evaluated and accepted by the zRMS (Poland) during the first authorisation process for Faworyt 300 SL (Authorization No: R - 140/2013 from 08.11.2013 r. with further amendments.

Material and Methods:

Test material (Lot/Batch No.)	Faworyt 300 SL (batch No. 1, measured concentration: 311.5 g/L)
Species	Dunkin-Hartley guinea pig (outbred)
No. of animals (group size)	20 animals in treated group and 10 animals in control group (15 males and 15 females)
Exposure	The study consists of three stages: two-stage induction of sensitization and challenge of sensitization. In the first stage, 2% water solution of test material with complete Freund's adjuvant was injected intradermally in the front part of the back of animals exposed to test material. In the second stage, 80% water solution of test material was applied to skin at the place of intradermal injection. The control group was exposed to water. In the third stage, 60% water solution of test material was applied to one side of the trunk of each animal from exposed and control group. Water was applied to the other side.
Post exposure observation period	72 hours
Remarks	None

Results and discussions

Table 7.1.6-1: Skin sensitization in Guinea pigs of Faworyt 300 SL

Sex	No. of animals used	No. of animals with sensitization reaction	% of animals with sensitization reaction
Exposed group			
male	10	1	10
female	10	1	
Control group			
male	5	0	0
female	5	0	

- No general clinical signs and no deaths were observed during the study.

- Sensitization skin reactions were noticed in two animals of exposed group (slight erythema and dry skin in one animal and only dry skin in the second one). No pathological changes on skin of control animals were observed.
- After study completion, a decrease in body weight in one animal of exposed and control group was recorded. In other animals a body weight gain was noticed.

Conclusion/endpoint:

Under the experimental conditions, Faworyt 300 SL is non-sensitizing to skin of Guinea pigs.

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

Not relevant.

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)

No study has been submitted. Exposure and risk assessment relies on the default values.

A 2.11 Other/Special Studies

None.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for clopyralid

Table A 1: Input parameters considered for the estimation of operator exposure – cereals

Substance name	CLOPYRALID
Product name	FAWORYT 300 SL
Reference value non acutely toxic active substance (RVNAS)	0,15 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	0,17 mg/kg bw/day
Crop type	Cereals
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	200 L/ha
Maximum application rate of active substance	0,12 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%
Dermal absorption of in-use dilution	50,00%
Oral absorption of active substance	80,00%
Inhalation absorption of active substance	100,00%
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Downward spraying
Application equipment	Vehicle-mounted
Buffer strip	2-3 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Application rate of active substance	0,12 kg a.s./ha	<i>f</i> AppRate
Assumed area treated	50 ha/day	<i>d</i> AreaTreated
Amount of active substance applied	6 kg a.s./day	<i>f</i> AmountAS
Dermal absorption of the product	10,00%	<i>f</i> AbsorpProduct
Dermal absorption of in-use dilution	50,00%	<i>f</i> AbsorInuse
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	19293	71819	AOEM	
	Body	12569	121213	AOEM	
	Head	311	1707	AOEM	
	Protected hands (gloves)	111	1188	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	116	878	AOEM	
	Protected head (hood and face shield)	5	97	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	890	8513	AOEM	
	Body	498	2565	AOEM	
	Head	24	71	AOEM	
	Protected hands (gloves)	112	4107	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	14	33	AOEM	
	Inhalation	3	8	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table A 2: Input parameters considered for the estimation of operator exposure – oilseeds

Substance name	CLOPYRALID
Product name	FAWORYT 300 SL
Reference value non acutely toxic active substance (RVNAS)	0,15 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	0,17 mg/kg bw/day
Crop type	Oilseeds
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	200 L/ha
Maximum application rate of active substance	0,12 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%
Dermal absorption of in-use dilution	50,00%
Oral absorption of active substance	80,00%
Inhalation absorption of active substance	100,00%
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Downward spraying
Application equipment	Vehicle-mounted
Buffer strip	2-3 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Application rate of active substance	0,12 kg a.s./ha	<i>i</i> , AppRate
Assumed area treated	50 ha/day	<i>d</i> , AreaTreated
Amount of active substance applied	6 kg a.s./day	<i>i</i> , AmountAS
Dermal absorption of the product	10,00%	<i>i</i> , AbsorpProduct
Dermal absorption of in-use dilution	50,00%	<i>i</i> , Absorinuse
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	19293	71819	AOEM	
	Body	12569	121213	AOEM	
	Head	311	1707	AOEM	
	Protected hands (gloves)	111	1188	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	116	878	AOEM	
	Protected head (hood and face shield)	5	97	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	890	8513	AOEM	
	Body	498	2565	AOEM	
	Head	24	71	AOEM	
	Protected hands (gloves)	112	4107	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	14	33	AOEM	
	Inhalation	3	8	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table A 3: Estimation of acute operator exposure towards active substance according to EFSA guidance (cereals and oilseeds)

Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	25,0866177	5,9899375
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,4181103	0,0998323
% of RVAAS	245,95%	58,72%

Table A 4: Estimation of longer term operator exposure towards clopyralid according to EFSA guidance (cereals and oilseeds)

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	3,9317712	0,7681931
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0655295	0,0128032
% of RVNAS	43,69%	8,54%

Table A 5: Input parameters considered for the estimation of operator exposure – root and tuber vegetables

Substance name	CLOPYRALID
Product name	FAWORYT 300 SL
Reference value non acutely toxic active substance (RVNAS)	0,15 mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	0,17 mg/kg bw/day
Crop type	Root and tuber vegetables
Substance properties	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Minimum volume water for application (liquids)	200 L/ha
Maximum application rate of active substance	0,09 kg a.s. /ha
50% Dissipation Time DT50	30 days
Initial Dislodgeable Foliar Residue	3 µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%
Dermal absorption of in-use dilution	50,00%
Oral absorption of active substance	80,00%
Inhalation absorption of active substance	100,00%
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	
Indoor or Outdoor application	Outdoor
Application method	Downward spraying
Application equipment	Vehicle-mounted
Buffer strip	2-3 m
Number of applications	1
Interval between multiple applications	365 days
Season (upward spraying orchards only)	not relevant

Application rate of active substance	0,09 kg a.s./ha	<i>I, AppRate</i>
Assumed area treated	50 ha/day	<i>d, AreaTreated</i>
Amount of active substance applied	4,5 kg a.s./day	<i>I, AmountAS</i>
Dermal absorption of the product	10,00%	<i>I, AbsorpProduct</i>
Dermal absorption of in-use dilution	50,00%	<i>I, AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
Mixing and loading	Hands	15460	57406	AOEM	
	Body	10268	111494	AOEM	
	Head	233	1281	AOEM	
	Protected hands (gloves)	92	891	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	90	658	AOEM	
	Protected head (hood and face shield)	4	72	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Application	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	667	6896	AOEM	
	Body	373	1924	AOEM	
	Head	18	53	AOEM	
	Protected hands (gloves)	96	3972	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	10	25	AOEM	
	Inhalation	2	7	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table A 6: Estimation of acute operator exposure towards active substance according to EFSA guidance (root and tuber vegetables)

Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	21,4910662	4,7559826
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,3581844	0,0792664
% of RVAAS	210,70%	46,63%

Table A 7: Estimation of longer term operator exposure towards clopyralid according to EFSA guidance (root and tuber vegetables)

1. Total		
	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	3,1333475	0,5786644
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0522225	0,0096444
% of RVNAS	34,81%	6,43%

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for clopyralid – EFSA model

Table A 8: Input parameters considered for the estimation of worker exposure – EFSA model (cereals)

Crop type	Cereals	
Indoor or outdoor	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Inspection, irrigation	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0,12 kg a.s./ha	i_AppRate
Number of applications	1	i_AppNo
Interval between multiple applications	365 days	i_AppInt
Half-life of active substance	30 days	d_HalfLifeAS
Multiple application factor	1,0	d_MAF
Dermal absorption of the product	10,00%	i_AbsorpProduct
Dermal absorption of the in-use dilution	50,00%	i_AbsorpInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,36 µg a.s./cm ²	d_DFR
Working hours	2 hr	d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr	d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr	d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ⁻³	d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ⁻³	d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ⁻³	d_InhalTcSort

Table A 8: Input parameters considered for the estimation of worker exposure – EFSA model (oil seeds)

Crop type	Oilseeds	
Indoor or outdoor	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Inspection, irrigation	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0,12 kg a.s./ha	i_AppRate
Number of applications	1	i_AppNo
Interval between multiple applications	365 days	i_AppInt
Half-life of active substance	30 days	d_HalfLifeAS
Multiple application factor	1,0	d_MAF
Dermal absorption of the product	10,00%	i_AbsorpProduct
Dermal absorption of the in-use dilution	50,00%	i_AbsorpInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,36 µg a.s./cm ²	d_DFR
Working hours	2 hr	d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr	d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr	d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA ha/hr*10 [^] (-3)	d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 [^] (-3)	d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 [^] (-3)	d_InhalTcSort

Table A 9: Estimation of worker exposure towards active substance according to EFSA guidance (cereals and oilseeds)

1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	4,5000000	0,5040000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0750000	0,0084000		
% of RVNAS	50,00%	5,60%		
2. Details				
	Systemic exposure		Formula	Comments
	[mg a.s. /day]	[mg a.s./kg bw/day]		
Dermal - Potential	4,5000000	0,0750000	$d_DermTcUCV * d_WorkHr * i_DFR * i_MAF / 1000 * i_AbsorpInuse$	
Dermal - Work wear - arms, body and legs covered	0,5040000	0,0084000	$d_DermTcCV1 * d_WorkHr * d_DFR * d_MAF / 1000 * i_AbsorpInuse$	
Dermal - Working wear and gloves	no TC available for this assessment		$d_DermTcCV2 * d_WorkHr * d_DFR * d_MAF / 1000 * i_AbsorpInuse$	
Inhalation				Na for outdoor activities

Table A 10: Input parameters considered for the estimation of worker exposure – EFSA model (root and tuber vegetables)

Crop type	Root and tuber vegetables	
Indoor or outdoor	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Inspection, irrigation	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0,09 kg a.s./ha	i_AppRate
Number of applications	1	i_AppNo
Interval between multiple applications	365 days	i_AppInt
Half-life of active substance	30 days	d_HalfLifeAS
Multiple application factor	1,0	d_MAF
Dermal absorption of the product	10,00%	i_AbsorpProduct
Dermal absorption of the in-use dilution	50,00%	i_AbsorpInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,27 µg a.s./cm ²	d_DFR
Working hours	2 hr	d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr	d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr	d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA ha/hr*10 [^] (-3)	d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 [^] (-3)	d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 [^] (-3)	d_InhalTcSort

1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	3,3750000	0,3780000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0562500	0,0063000		
% of RVNAS	37,50%	4,20%		
2. Details				
	Systemic exposure		Formula	Comments
	[mg a.s. /day]	[mg a.s./kg bw/day]		
Dermal - Potential	3,3750000	0,0562500	$d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_Absorplnuse$	
Dermal - Work wear - arms, body and legs covered	0,3780000	0,0063000	$d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_Absorplnuse$	
Dermal - Working wear and gloves	no TC available for this assessment		$d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_Absorplnuse$	
Inhalation				Na for outdoor activities

Table A 12: Estimation of worker exposure towards active substance according to EU-ROPOEM II mode (cereals and oilseeds) – potential exposure

WORKER EXPOSURE		EUROPEM II MODEL		
form	FAWORYT 300 SL	Re-entry in the field		
a.s.	clpyralid			
Parameter		Value	Unit	References, comments
Re-entry activities in the field				
AR	Application rate	0.12	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europeoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europeoem II)
TC	Transfer coefficient	1.25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 DE = DFR x AR x TC x T
Dermal Exposure		9	mg a.s./ day	
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	9	mg a.s./ day	based on 70 kg bw
		Without PPE [mg a.s./ day]	With PPE [mg a.s./ day]	
	Internal exposure			
	Inhalation	-	-	no model available
	Dermal	4,500	0,900	DE(int) = DE x (DA/100)
	Total	4,500	0,900	sum
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	50	10	%AOEL = 100 x DE(int)/ AOEL
	Total	50	10	sum
* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.				

Table A 13: Estimation of worker exposure towards active substance according to EUROPOEM II mode (cereals and oilseeds) – workwear and gloves

WORKER EXPOSURE		EUROPOEM II MODEL	
form	FAWORYT 300 SL	Re-entry in the field	
a.s.	clodpyralid		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0,12	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	2	hours / day	default: 8 h (Europoem II)
Inhalation Exposure			
no model available	-		without PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0,14	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45
Dermal Exposure	1,008	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	9	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	0,504	0,101	DE(int) = DE x (DA/100)
Total	0,504	0,101	sum
	% AOEL		
Inhalation	-	-	no model available
Dermal	6	1	%AOEL = 100 x DE(int) / AOEL
Total	6	1	sum
* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.			

Table A 14: Estimation of worker exposure towards active substance according to EUROPOEM II mode (root and tuber vegetables) – potential exposure

WORKER EXPOSURE		EUROPOEM II MODEL	
form	FAWORYT 300 SL	Re-entry in the field	
a.s.	clodpyralid		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0,09	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	2	hours / day	default: 8 h (Europoem II)
Inhalation Exposure			
no model available	-		without PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC Transfer coefficient	1,25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45
Dermal Exposure	6,75	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	9	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	3,375	0,675	DE(int) = DE x (DA/100)
Total	3,375	0,675	sum
	% AOEL		
Inhalation	-	-	no model available
Dermal	38	8	%AOEL = 100 x DE(int) / AOEL
Total	38	8	sum
* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.			

Table A 15: Estimation of worker exposure towards active substance according to EURO-POEM II mode (root and tuber vegetables) – workwear and gloves

WORKER EXPOSURE		EUROPOEM II MODEL	
form	FAWORYT 300 SL	Re-entry in the field	
a.s.	clopyralid		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0,09	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		without PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0,14	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45
Dermal Exposure	0,756	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	9	mg a.s./ day	based on 70 kg bw
		Without PPE	With PPE
Internal exposure		[mg a.s./ day]	[mg a.s./ day]
Inhalation	-	-	no model available
Dermal	0,378	0,076	DE(int) = DE x (DA/100)
Total	0,378	0,076	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	4	1	%AOEL = 100 x DE(int) / AOEL
Total	4	1	sum
* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.			

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for clopyralid

Table A 16: Input parameters considered for the estimation of longer term resident exposure (cereals)

Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	<i>i_FormVal</i>
Buffer strip	2-3 m	<i>i_Buffer</i>
Application rate of the product	0,12 kg a.s./ha	<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	0,6 g a.s./l	<i>d_ConcAS</i>
Dermal absorption of product	10,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50,00%	<i>i_Absorplnuse</i>
Oral absorption	80,00%	<i>i_AbsorpOrallnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0,36 µg a.s./cm ²	<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa	<i>i_Volat</i>
Concentration in air	0,001 mg/m ³	<i>d_AirCon</i>
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	<i>d_ReExpDur</i>
Exposure duration inhalation	24 hours	<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops	0,25 hours	<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18,0%	<i>d_ClothAF</i>
Breathing rate adult	0,23 m ³ /day/kg	<i>d_BreathRAD</i>
Breathing rate child (1-3 year old)	1,07 m ³ /day/kg	<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)	5,60%	
Drift percentage on surface (mean)	4,10%	
Turf transferable residues percentage	5,00%	<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm ² /hour	<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour	<i>d_ReTCCh</i>
Saliva extraction percentage	50,00%	<i>d_SalExt</i>
Surface area of hands mouthed	20 cm ²	<i>d_AreaHM</i>
Frequency of hand to mouth activity	9,5 events/hour	<i>d_ReFreqHM</i>
Ingestion rate for mouth of grass per day	25 cm ²	<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20,00%	<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h	<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h	<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h	<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h	<i>d_TcEntryCh</i>

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

Croptype	Oilseeds	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	<i>i_FormVal</i>
Buffer strip	2-3 m	<i>i_Buffer</i>
Application rate of the product	0,12 kg a.s./ha	<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	0,6 g a.s./l	<i>d_ConcAS</i>
Dermal absorption of product	10,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50,00%	<i>i_Absorplnuse</i>
Oral absorption	80,00%	<i>i_AbsorpOrallnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0,36 µg a.s./cm ²	<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa	<i>i_Volat</i>
Concentration in air	0,001 mg/m ³	<i>d_AirCon</i>
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	<i>d_ReExpDur</i>
Exposure duration inhalation	24 hours	<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops	0,25 hours	<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18,0%	<i>d_ClothAF</i>
Breathing rate adult	0,23 m ³ /day/kg	<i>d_BreathRAD</i>
Breathing rate child (1-3 year old)	1,07 m ³ /day/kg	<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)	5,60%	
Drift percentage on surface (mean)	4,10%	
Turf transferable residues percentage	5,00%	<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm ² /hour	<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour	<i>d_ReTCCh</i>
Saliva extraction percentage	50,00%	<i>d_SalExt</i>
Surface area of hands mouthed	20 cm ²	<i>d_AreaHM</i>
Frequency of hand to mouth activity	9,5 events/hour	<i>d_ReFreqHM</i>
Ingestion rate for mouth of grass per day	25 cm ²	<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20,00%	<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h	<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h	<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h	<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h	<i>d_TcEntryCh</i>

Table A 1: Estimation of longer term resident exposure towards clopyralid according to EFSA guidance (cereals and oilseeds)

1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0805740	0,0107000	0,0097104	0,1012500	0,1429214
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0080574	0,0010700	0,0009710	0,0101250	0,0142921
% of RVNAS	5,37%	0,71%	0,65%	6,75%	9,53%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1156800	0,0138000	0,0245280	0,3375000	0,3558143
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0019280	0,0002300	0,0004088	0,0056250	0,0059302
% of RVNAS	1,29%	0,15%	0,27%	3,75%	3,95%

Table A 19: Input parameters considered for the estimation of longer term resident exposure (root and tuber vegetables)

Croptype	Root and tuber vegetables	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	i_FarmVal
Buffer strip	2-3 m	i_Buffer
Application rate of the product	0,09 kg a.s./ha	i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,45 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	80,00%	i_AbsorpOralinuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,27 µg a.s./cm ²	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa	i_Volat
Concentration in air	0,001 mg/m ³	d_AirCon
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	d_ReExpDur
Exposure duration inhalation	24 hours	d_ReExpDurInhal
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 /day/kg	d_BreathRAD
Breathing rate child (1-3 year old)	1,07 m ³ /day/kg	d_BreathRCh
Drift percentage on surface (75th percentile)	5,60%	
Drift percentage on surface (mean)	4,10%	
Turf transferable residues percentage	5,00%	d_Turf
Transfer coeff. of surface deposits-adult	7300 cm ² /hour	d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour	d_ReTCCh
Saliva extraction percentage	50,00%	d_SalExt
Surface area of hands mouthed	20 cm ²	d_AreaHM
Frequency of hand to mouth activity	9,5 events/hour	d_ReFreqHM
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 (75th percentile) - adult	7500 cm ² /h	d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h	d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h	d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h	d_TcEntryCh

Table A 20: Estimation of longer term resident exposure towards clopyralid according to EFSA guidance (root and tuber vegetables)

1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0604305	0,0107000	0,0072828	0,0759375	0,1098661
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0060431	0,0010700	0,0007283	0,0075938	0,0109866
% of RVNAS	4,03%	0,71%	0,49%	5,06%	7,32%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0867600	0,0138000	0,0183960	0,2531250	0,2703107
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0014460	0,0002300	0,0003066	0,0042188	0,0045052
% of RVNAS	0,96%	0,15%	0,20%	2,81%	3,00%

Table A 21: Input parameters considered for the estimation of acute bystander exposure (cereals)

Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Application rate of the product	0,12 kg a.s./ha	<i>i_AppRate</i>
Buffer strip	2-3 m	<i>i_Buffer</i>
Concentration of active substance (in-use dilution for liquid applications)	0,6 g a.s./l	<i>d_ConcAS</i>
Dermal absorption of product	10,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50,00%	<i>i_AbsorpInuse</i>
Oral absorption	80,00%	<i>i_AbsorpOralinuse</i>
Dislodgeable foliar residue ($i_AppRate * i_DFR$)	0,36 µg a.s./cm ²	<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa	<i>i_Volat</i>
Concentration in air	0,001 mg/m ³	<i>d_AirCon</i>
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	<i>d_ByExpDur</i>
Exposure duration entry into treated crops	0,25 hours	<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18,0%	<i>d_ClothAF</i>
Breathing rate adult	0,23 m ³ /kg bw/day	<i>d_BreathRAd</i>
Breathing rate child (1-3 year old)	1,07 m ³ /kg bw/day	<i>d_BreathRCh</i>
Drift percentage on surface (90th percentile)	8,50%	
Turf transferable residues percentage	5,00%	<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	14500 cm ² /hour	<i>d_ByTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	5200 cm ² /hour	<i>d_ByTCCh</i>
Saliva extraction percentage	50,00%	<i>d_SalExt</i>
Surface area of hands mouthed	20 cm ²	<i>d_AreaHM</i>
Frequency of hand to mouth activity	20 events/hour	<i>d_ByFreqHM</i>
Ingestion rate for mouthing of grass per day	25 cm ²	<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20,00%	<i>d_DRP</i>
Transfer coefficient for entry into treated crops - adult	7500 cm ² /h	<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops - child	2250 cm ² /h	<i>d_TcEntryCh</i>

Table A 22: Input parameters considered for the estimation of acute bystander exposure (oilseeds)

Croptype	Oilseeds	
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)	0,6 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	80,00%	i_AbsorpOrallnuse
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 ⁻³ 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_ExpDurTreatCrap
Light clothing adjustment factor	18,0%	d_ClothAF
Breathing rate adult	0,23 m ³ /kg bw/day	d_BreathRAAd
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 mouthed 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 2: Estimation of acute bystander exposure towards active substance according to EFSA guidance (cereals and oilseeds)

1. Total					
1.1 1-3 year old child					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	
Total systemic exposure (mg a.s./day)	0,1827120	0,0107000	0,0290700	0,1012500	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0182712	0,0010700	0,0029070	0,0101250	
% of RVAAS	10,75%	0,63%	1,71%	5,96%	
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	
Total systemic exposure (mg a.s./day)	0,2979600	0,0138000	0,0739500	0,3375000	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0049660	0,0002300	0,0012325	0,0056250	
% of RVAAS	2,92%	0,14%	0,73%	3,31%	

Table A 24: Input parameters considered for the estimation of acute bystander exposure (root and tuber vegetables)

Croptype	Root and tuber vegetables	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Application rate of the product	0,09 kg a.s./ha	<i>i_AppRate</i>
Buffer strip	2-3 m	<i>i_Buffer</i>
Concentration of active substance (in-use dilution for liquid applications)	0,45 g a.s./l	<i>d_ConcAS</i>
Dermal absorption of product	10,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50,00%	<i>i_AbsorpInuse</i>
Oral absorption	80,00%	<i>i_AbsorpOrallInuse</i>
Dislodgeable foliar residue ($i_AppRate * i_DFR$)	0,27 µg a.s./cm ²	<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa	<i>i_Volat</i>
Concentration in air	0,001 mg/m ³	<i>d_AirCon</i>
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	<i>d_ByExpDur</i>
Exposure duration entry into treated crops	0,25 hours	<i>d_ExpDurTreatCrap</i>
Light clothing adjustment factor	18,0%	<i>d_ClothAF</i>
Breathing rate adult	0,23 m ³ /kg bw/day	<i>d_BreathRAd</i>
Breathing rate child (1-3 year old)	1,07 m ³ /kg bw/day	<i>d_BreathRCh</i>
Drift percentage on surface (90th percentile)	8,50%	
Turf transferable residues percentage	5,00%	<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	14500 cm ² /hour	<i>d_ByTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	5200 cm ² /hour	<i>d_ByTCCh</i>
Saliva extraction percentage	50,00%	<i>d_SalExt</i>
Surface area of hands mouthed	20 cm ²	<i>d_AreaHM</i>
Frequency of hand to mouth activity	20 events/hour	<i>d_ByFreqHM</i>
Ingestion rate for mouthing of grass per day	25 cm ²	<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20,00%	<i>d_DRP</i>
Transfer coefficient for entry into treated crops - adult	7500 cm ² /h	<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops - child	2250 cm ² /h	<i>d_TcEntryCh</i>

Table A 35: Estimation of acute bystander exposure towards active substance according to EFSA guidance (root and tuber vegetables)

1.1 1-3 year old child					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	
Total systemic exposure (mg a.s./day)	0,1370340	0,0107000	0,0218025	0,0759375	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0137034	0,0010700	0,0021803	0,0075938	
% of RVAAS	8,06%	0,63%	1,28%	4,47%	
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	
Total systemic exposure (mg a.s./day)	0,2234700	0,0138000	0,0554625	0,2531250	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0037245	0,0002300	0,0009244	0,0042188	
% of RVAAS	2,19%	0,14%	0,54%	2,48%	

A 3.4 Combined exposure

Not relevant. Faworyt 300 SL contains only 1 active substance.

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)

No data submitted.