FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: CHR/H/CPD 300 SL

Product name(s): Major 300SL, Cloe 300SL, ProSto 300SL

Chemical active substance:

Clopyralid 300g/l

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(renewal of authorization)

Applicant: Innvigo sp. z o.o.

Submission date: 12.2021

MS Finalisation date: 11.2022; 03.2023

Version history

When	What
December 2021	New data for CHR/H/CPD based on the renewal of active substance - clopyralid. New data is highlighted in yellow.
November 2022	zRMS evaluated submitted by Applicant dRR
March 2023	ZRMs made changes according to comenting period.

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on CHR/H/CPD

Product name and code	CHR/H/CPD 300 SL	
Formulation type	SL	
Active substance(s) (incl. content)	Clopyralid 300g/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	Poland: Major 300SL ProSto 300SL Cloe 300SL: Czech republic: Cloe 300SL Major 300SL Hungary: Cloe 300SL Major 300SL Prosto 300SL: Romania: Cloe 300SL Major 300SL Slovakia: Cloe 300SL: Major 300SL: Lithuania: Major 300 SL Slovenia: Major 300 SL Latvia: Major 300 SL	Authorization number: R-237/2017 ;20.11.2017 R-238/2017; 20.11.2017 R-239/2017; 20.11.2017 5546-1;17.04.2008 5546-0; 17.04.2008 6300/142-1/2020 6300/142-1/2020 6300/142-1/2020; 431PC;05.06.2018 431PC;05.06.2018 20-01001-AU; 17.12.2020 20-01000-AU, 17.12.2020 AS2-18H(2020) U34330-15/2021/13 0741

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

Hazard class(es), categories:	Eye Irrit. 2 STOT SE3
Hazard pictograms or Code(s) for hazard pictogram(s):	GHS07
Signal word:	Warning
Hazard statement(s):	H319 Causes serious eye irritation H335 May cause respiratory irritation.
Precautionary statement(s):	**WARNING SECTION OF THE LABEL (first page):** P280: Wear eye/face protection. P305+P351+P338-IF IN EYES: Rinse continuously with water for several minutes. Remove contacts lenses if present and easy to do, continue rinsing. P261: Avoid breathing vapours/spray. P304 + P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing. ~~P301 + P312 – IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.~~ Other section of the label: P261: Avoid breathing spray. P271: Use only outdoors. P264: Wash hands thoroughly after handling. P270: Do no eat, drink or smoke when using this product. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. ~~P362+364: Take off contaminated clothing and wash before reuse.~~ P501: Dispose of contents/container to… And P280 as follows: OPERATOR: ~~See Table 6.1 3~~ „*Stosować rękawice ochronne, ochronę oczu/twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz odzież roboczą w trakcie wykonywania zabiegu*." "Wear protective gloves, eye/face protection and work wear (coverall) during mixing and loading and work wear application." ~~„Stosować ochronę oczu oraz odzież ochronną zabezpieczająca przed oddziaływaniem środków ochrony roślin oczu w trakcie przygotowywania cieczy użytkowej podczas stosowania w mieszaninie".~~ ~~„Wear protective clothing and eye protection during mixing and loading".~~ WORKER: „*Stosować odzież roboczą (długie spodnie, koszula z długim rękawem) w przypadku stosowania pojedynczo i odzież roboczą i rękawice ochronne przypadku stosowania w mieszaninie zbiornikowej".* "Wear work wear (long trousers, long-sleeve shirt) when used solo and work wear and protective gloves when used in tank mix". ~~"Stosować rękawice ochronne oraz odzież roboczą podczas stosowania w mieszaninie".~~ ~~"Wear protective gloves and work wear"~~ Section "First Aid"

	P305+P351+P338 P337+P313 P304+P340 P312 ~~P310~~ ~~P302 + P352~~ ~~P332 + P313~~ ~~P301+P312~~ ~~P330~~ For Polish version: see the label
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, bystanders and residents for CHR/H/CPD 300 SL

	Result	PPE / Risk mitigation measures
Operators	Acceptable	acc. to exposure estimation: protective gloves, ~~protective clothing,~~ work wear acc. to classification: eye/face protection *product used in the tank mix: see above*
Workers	Acceptable	~~protective clothing~~, work wear, protective gloves (recommendation) *product used in the tank mix: work wear, protective gloves*
Bystanders	Acceptable	None
Residents	Acceptable	None

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

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

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

1	2	3	4	5	6	7	8	9	10			
Use-No. *	**Crops and situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Application**		**Application rate**		**PHI (d)**	**Remarks:** **(e.g. safener/synergist (L/ha))** **critical gap for operator, worker, bystander or resident exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind **(incl. application technique ***)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**Max. application rate kg as/ha** **a) a.s. 1** **b) a.s. 2**	**Water L/ha** **min / max**			**Operator**	**Worker**	**Bystander**	**Residents**
1.	Winter oilseed rape Brassica napus,	F	Spray medium sprayer	a) 1 b) 1	a) 0.09-0.12	200-300	N/A	Tank mix: CHR/H/PCR + CHR/H/CPD				

1	2	3	4	5	6	7	8	9	10
	(BRSNW)							(0.0234+0.09) CHR/H/PCR + CHR/H/CPD + CHR/H/MTC (0.0234+0.09+0.75)	
~~2.~~	~~Winter oilseed rape Brassica napus, (BRSNW); CHR/H/PCR + CHR/H/CPD~~	~~F~~	~~Spray medium sprayer~~	~~a) 1 b) 1~~	~~a) 0.0234 b) 0.09~~	~~200-300~~	~~N/A~~		
~~3.~~	~~Winter oilseed rape Brassica napus, (BRSNW); CHR/H/PCR + CHR/H/CPD + CHR/H/MTC~~	~~F~~	~~Spray medium sprayer~~	~~a) 1 b) 1~~	~~a) 0.0234 b) 0.09 c) 0.75~~	~~200-300~~	~~N/A~~		
4.	Winter wheat Triticum aestivum (TRZAW);	F	Spray medium sprayer	a) 1 b) 1	a) 0.09-0.12	200-300	N/A		
5.	Sugar beet Beta vulgaris (BEAVP)	F	Spray medium sprayer	a) 3 (6-10)	a) 0.06	200-300	N/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

Explanation for column 10 "Acceptability of exposure assessment"

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

Data gaps

Noticed data gaps are:

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 300g/l
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:** Eye Dam.1 **Code(s) for hazard pictogram(s):** GHS05 **Signal word**: Danger **Hazard statement(s):** H318 **Precautionary statement(s):** P280 P305 + P351 + P338 P310
Additional C&L proposal	Please insert proposal for additional C&L if no (sufficient) harmonized classification is available
Agreed EU endpoints	
AOEL systemic	0.15 mg/kg bw/d
AAOEL systemic	0.17 mg/kg bw
Reference	EFSA Journal 2018;16(7):5389
Conditions to take into account/critical areas of concern with regard to toxicology	
EFSA Journal 2018;16(7):5389	Operator: Exposure estimates (model): % of AOEL UK POEM Without PPE: 583 PPE (gloves): 82 German model Without PPE: 244 PPE (gloves, coverall, sturdy footwear) 16 EFSA calculator Without PPE: 101 PPE(gloves and work wear) 3 EFSA calculator % of AAOEL Without PPE: 560 PPE(gloves and work wear): 41 Workers: EUROPOEM II % of AOEL Without PPE 15 EFSA calculator Without PPE(work wear-arms, body and

	Clopyralid
	legs covered) 8 Bystander/ Resident **Bystander:** % of AOEL EUROPOEM II: 2 Martin et al. adult: 6 child: 7 Exposure to vapours adult: 0.15 child: 0.7 EFSA calculator % of AAOEL adult: 22 child: 39 **Resident** % of AOEL Martin et al. adult: 0.39 child: 0.64 EFSA calculator adult: 3 child: 12

6.3 Toxicological Evaluation of Plant Protection Product

Comments of zRMS:	The studies of acute toxicity of the product were re-evaluated during re-authorization of the product which followed the renewal of the active substance.

A summary of the toxicological evaluation for 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 CHR/H/CPD 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 / EU Method B.1.BIS)	> 2000 mg/kg bw	Accepted	None	[redacted] 2014
LD_{50} dermal, rat (OECD Guideline No 402 / EU Method B.3)	> 2000 mg/kg bw	Accepted	None	xxx 2014
LC50 inhalation, (calculation method – alternative method)	20mg/L	Accepted	None	Estimation based on the composition of the product (calculation method).
In vitro skin corrosion:(TER) (OECD Guideline No 430 / EU Method B.40.)	No changes in skin discs, Mean TER < 5 kΩ	Accepted	not corrosive; no implications for classification or	xxx 2014

			labelling; skin irritation test is justified	
Skin irritation, (OECD Guideline No 404 / EU Method B.4.)	No general clinical signs. Very slight (barely perceptible) skin erythema.	Accepted	None	xxx 2014
Isolated chicken eye test (OECD Guideline No 438 / EU Method B.48.)	Fluorescein retention score – 2,0; corneal opacity score – 2,0; swelling – 0,2-9,6.	Accepted	not corrosive; no implications for classification or labelling; eye irritation test is justified	xxx 2014
Eye irritation, (OECD Guideline No 405 / EU Method B.5.)	No general clinical signs. Transient changes in the cornea, iris and conjunctivas.	Accepted	Irritant Eye Irrit.2/ H319	xxx 2014
Skin sensitisation, (OECD Guideline No 406 / EU Method B.6.)	5,56 % of animals with allergic reaction - discrete erythema, dryness of the skin	Accepted	weak sensitization - not classified	xxx 2014
Supplementary studies for combinations of plant protection products	No data – not required	-		

Table 6.3-2: Additional toxicological information relevant for classification/labelling of CHR/H/CPD 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 26.45 % (w/w)	Eye Dam. 1 H318	Reg. 1272/2008 /	Eye Irrit. 2, H319
Toxicological properties of non-active substance(s) (relevant for classification of product)	monoethanoloamine (CAS No. 141-43-5 % (w/w))	Acute Tox. 4, H302 Acute Tox. 4, H312 Acute Tox. 4, H332 STOT SE 3, H335 Skin Corr. 1, H314	Reg. 1272/2008	~~Eye Irrit. 2, H319~~ STOT SE 3, H335
Further toxicological information	No data – not required			

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

Clopyralid has no metabolites.

6.5 Dermal Absorption (KCP 7.3)

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

Table 6.5-1: Dermal absorption rates for active substances in CHR/H/CPD 300 SL

	Clopyralid	
	Value	**Reference**
Concentrate	10 %	EFSA Journal 2017; 15(6): 4873
Dilution	50 %	EFSA Journal 2017; 15(6): 4873

6.5.1 Justification for proposed values – clopyralid

No data on dermal absorption for clopyralid methyl in CHR/H/CPD 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 %	A default dermal absorption value of 10% may be applied for concentrated products that are water-based/dispersed(soluble concentrate).	Accepted
Dilution	50 %	A default dermal absorption value of 50% may be applied for dilutions water-based/ dispersed.	Accepted

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	CHR/H/CPD300SL/Major 300SL, Cloe 300SL, ProSto 300SL
Formulation type	SL
Category	Herbicide
Container size(s), short description	Containers having the size appropriate to hold either 250 - 10000 ml of product. Please refer to Part B1,B2 and B4
Active substance(s) (incl. content)	**Clopyralid** 300 g/L
AOEL systemic	0.15 mg/kg bw/d
AAOEL systemic	0.17 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	Concentrate: 10 % Dilution: 50 % (Default)

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.

6.6.2 Operator exposure (KCP 7.2.1)

Comments of zRMS:	The results of the estimation of operator exposure to clopyralid contained in the product CHR/H/CPD300SL/Major 300SL, Cloe 300SL, ProSto 300SL, presented by the applicant are accepted. The AAOEL and AOEL values used for the estimation of exposure to the active substance are correct. Based on AOEM estimation and assuming the list of intended uses presented in GAP Table, the acute exposure of an **unprotected operator** to clopyralid (potential exposure) **causes unacceptable health risk** because the calculated exposure to this substance significantly exceeds AAOEL value for the active substance. To reduce the acute exposure to the acceptable level, it is necessary that the operator is equipped with protective gloves and work wear (winter oilseed rape, winter wheat) and work wear (sugar beet) during mixing and loading. In the case of systemic long term exposure to clopyralid, the use of the product CHR/H/CPD300SL/Major 300SL, Cloe 300SL, ProSto 300SL is safe for an unprotected operator. Since the Applicant presented the results of combined exposure to all active substances contained in the PPPs used in the tank mix, the reference to the results of estimations is required according to Polish Authorities. The results indicate that the use of the product CHR/H/CPD300SL/Major 300SL, Cloe 300SL, ProSto 300SL in the tank mix with other products proposed in the GAP table causes no health risk (systemic, long term exposure) when operator is equipped with appropriate PPE (protective gloves) during mixing and loading. **Conclusions:** Taking into account the results of exposure estimations (including combine exposure) and classification of the product in regards to eye irritation (Eye Irrit. 2, H319), the use of CHR/H/CPD300SL/Major 300SL, Cloe 300SL, ProSto 300SL causes acceptable exposure risk for an operator equipped with: 1. For the product used solo: a. *Application on winter oilseed rape, winter wheat*: work wear, eye/face protection and protective gloves during mixing and loading and workwear during application. b. *Application on sugar beet:* work wear, eye/face protection during mixing and loading and workwear during application. The protective gloves are strongly recommended during mixing and loading. 2. For the product used in the tank mix: work wear, eye/face protection and protective gloves during mixing and loading and work wear during application. Following sentence regarding the use of PPE is recommended by the evaluator to be placed in the **section of precautions for the operators:** „*Stosować rękawice ochronne, ochronę oczu/twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz odzież roboczą w trakcie wykonywa-*

	nia zabiegu." "Wear protective gloves, eye/face protection and work wear (coverall) during mixing and loading and work wear application."

6.6.2.2 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of CHR/H/CPD300SL according to the critical use(s) is presented in Table 6.6-2. Outcome of the estimation is presented in Table 6.6-3-7. Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Winter wheat (max. 0.12 kg a.s. /ha)
Model(s)	"EFSA Model" ver. 30.03.2015

Table 6.6-3: Estimated operator exposure

		Clopyralid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic ~~A~~AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 0.12 kg a.s./ha			
EFSA Model Long term	~~no PPE~~ Potential exposure	0.0655295	43.69%
	Potential exposure + gloves M/L	0.0335584	22.37%
	no PPE (workwear at mixing/loading)	0.0447744	29.85%
	+PPE (gloves and workwear at mixing/loading)	0.0128032	8.54%
	+ PPE (gloves + workwear at mixing/loading and workwear during application)	0.0087703	5.85%
	+ PPE (gloves + workwear at mixing/loading and gloves during application)	-	-

* no PPE: Operator wearing T-shirt and shorts
** no PPE: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves

		Clopyralid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AAOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 0.12 kg a.s./ha			
EFSA Model acute	~~no PPE~~ Potential exposure	0.4181103	245.95%
	Potential exposure + gloves M/L	0.3003921	176.70%
	no PPE (workwear at	0.2175504	127.97%

	mixing/loading)		
	+PPE (gloves and workwear at mixing/loading)	0.0998323	58.72%
	+ PPE (gloves + workwear at mixing/loading and workwear during application)	0.0787355	46.32%
	+ PPE (gloves + workwear at mixing/loading and gloves during application)	-	-

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Winter oilseed rape (max. 0.12 kg a.s. /ha)
Model(s)	"EFSA Model" ver. 30.03.2015

Table 6.6-5: Estimated operator exposure

Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Clopyralid			
Tractor mounted boom spray application outdoors to low crops Application rate: 0.12 kg a.s./ha			
EFSA Model Long term	~~no PPE~~ Potential exposure	0.0655295	43.69%
	Potential exposure + gloves M/L	0.0335584	22.37%
	no PPE (workwear at mixing/loading)	0.0447744	29.85%
	+PPE (gloves and workwear at mixing/loading)	0.0128032	8.54%
	+ PPE (gloves + workwear at mixing/loading and workwear during application)	0.0087703	5.85%
	+ PPE (gloves + workwear at mixing/loading and gloves during application)	-	-
Picloram			
Tractor mounted boom spray application outdoors to low crops Application rate: 0.0234 kg a.s./ha			
EFSA Model Long term	~~no PPE~~ Potential exposure	0.0182514	6.08%
	Potential exposure + gloves M/L	0.0091801	3.06%
	no PPE (workwear at mixing/loading)	0.0116578	3.89%
	+PPE (gloves and	0.0025865	0.86%

	workwear at mixing/loading)		
	+ PPE (gloves + workwear at mixing/loading and workwear during application)	0.0018001	0.60%
	+ PPE (gloves + workwear at mixing/loading and gloves during application)	-	-
Metazachlor			
Tractor mounted boom spray application outdoors to low crops Application rate: 0.75 kg a.s./ha			
EFSA Model Long term	~~no PPE~~ Potential exposure	0.2847965	142.40%
	Potential exposure + gloves M/L	0.1535946	76.80%
	no PPE (workwear at mixing/loading)	0.2098157	104.91%
	+PPE (gloves and workwear at mixing/loading)	0.0786138	39.31%
	+ PPE (gloves + workwear at mixing/loading and workwear during application)	0.0534083	26.70%
	+ PPE (gloves + workwear at mixing/loading and gloves during application)	-	-

* no PPE: Operator wearing T-shirt and shorts
** no PPE: Operator wearing long sleeved shirt, long trousers (“permeable”) but no gloves

		Clopyralid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AAOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 0.12 kg a.s./ha			
EFSA Model acute	~~no PPE~~ Potential exposure	0.4181103	245.95%
	Potential exposure + gloves M/L	0.3003921	176.70%
	no PPE (workwear at mixing/loading)	0.2175504	127.97%
	+PPE (gloves and workwear at mixing/loading)	0.0998323	58.72%
	+ PPE (gloves + workwear at mixing/loading and workwear during application)	0.0787355	46.32%

	+ PPE (gloves + workwear at mixing/loading and gloves during application)	-	-

For use in a mixture, cumulative exposure will be based on a solo dose calculation as this is a worse case.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Sugar beet(max. 0.06 kg a.s. /ha)
Model(s)	"EFSA Model" ver. 30.03.2015

Table 6.6-7: Estimated operator 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 Application rate: 3x 0.06 kg a.s./ha			
EFSA Model Long term	~~no PPE~~ Potential exposure	0.0379825	25.32%
	Potential exposure + gloves M/L	0.0192411	12.83%
	no PPE (workwear at mixing/loading)	0.0252179	16.81%
	+PPE (gloves and workwear at mixing/loading)	0.0064765	4.32%
	+ PPE (gloves + workwear at mixing/loading and workwear during application)	0.0044601	2.97%
	+ PPE (gloves + workwear at mixing/loading and gloves during application)	-	-

* no PPE: Operator wearing T-shirt and shorts
** no PPE: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves

		Clopyralid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AAOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 3x 0.06 kg a.s./ha			
EFSA Model acute	~~no PPE~~ Potential exposure	0.2906358	170.96%
	Potential exposure + gloves M/L	0.2218527	130.50%
	no PPE (workwear at mixing/loading)	0.1261925	74.23%
	+PPE (gloves and workwear at mixing/loading)	0.0574094	33.77%

	+ PPE (gloves + workwear at mixing/loading and workwear during application)	0.0468610	27.57%
	+ PPE (gloves + workwear at mixing/loading and gloves during application)	-	-

6.6.3 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 considering above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.4 Worker exposure (KCP 7.2.3)

Comments of zRMS:	The results of the estimation of worker exposure to clopyralid contained in the product CHR/H/CPD300SL/Major 300SL, Cloe 300SL, ProSto 300SL presented by the applicant are accepted. Based on AOEM estimation and assuming the list of intended uses presented in GAP Table, the exposure of an unprotected worker to clopyralid causes **no unacceptable health risk** because the calculated exposure is below AOEL values for the active substance (assuming inspection and irrigation in oilseeds, cereals and tuber/roots vegetables, duration: 2h per day). Since the Applicant presented the results of combined exposure to all active substances contained in the tank mix, the reference to the results of estimations is required according to Polish Authorities. The results indicate that the use of the product CHR/H/CPD300SL/Major 300SL, Cloe 300SL, ProSto 300SL in the tank mix with other products proposed in the GAP table causes no health risk when worker is equipped with appropriate PPE (protective gloves) during mixing and loading. <u>Conclusion:</u> The results of the exposure estimations indicate that the use of CHR/H/CPD300SL/Major 300SL, Cloe 300SL, ProSto 300SL causes acceptable exposure risk for a worker equipped with: 1. For the product used solo (application on cereals, oilseeds, tuber/roots vegetables): work wear. However, bearing in minds the hygienic rules, the use of protective gloves is recommended when entering treated area. 2. For the product used in the tank mix (application on oilseeds): work wear and protective gloves is required. Following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label**:** „*Stosować odzież roboczą (długie spodnie, koszula z długim rękawem) w przypadku stosowania pojedynczo i odzież roboczą i rękawice ochronne przypadku stosowania w mieszaninie zbiornikowej”*. “Wear work wear (long trousers, long-sleeve shirt) when used solo and work wear and protective gloves when used in tank mix”.

	Nevertheless, it is forbidden to re-enter area treated with CHR/H/CPD300SL/Major 300SL, Cloe 300SL, ProSto 300SL until spray deposit on plant surfaces has dried.

6.6.4.2 Estimation of worker exposure

Table 6.6-8 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with CHR/H/CPD300SL according to the critical use(s). Outcome of the estimation is presented in Table 6.6-9-13. Detailed calculations are in Appendix 3.

Table 6.6-8: Exposure models for intended uses

Critical use(s)	Winter oilseed rape (max. 0.12 kg a.s./ha)
Model	"EFSA Model" ver. 30.03.2015

Table 6.6-9: Estimated worker exposure

Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Clopyralid			
Number of applications and application rate:		0.12 kg a.s./ha	
2 hours/day (1), TC: 12500cm²/person/h Body weight: 60 kg	~~no PPE~~ Potential exposure (2)	0.0750000	50.00%
	with PPE (3)	0.0084000	5.60%
Picloram			
Number of applications and application rate:		0.0234 kg a.s./ha	
2 hours/day (1), TC: 12500cm²/person/h Body weight: 60 kg	~~no PPE~~ Potential exposure (2)	0.0146250	4.88%
	with PPE (3)	0.0016380	0.55%
Metazachlor			
Number of applications and application rate:		0.75kg a.s./ha	
2 hours/day (1), TC: 12500cm²/person/h Body weight: 60 kg	~~no PPE~~ Potential exposure (2)	0.4687500	234.38%
	with PPE (3)	0.0525000	26.25%

(1) e.g. 8 h/day for professional applications for harvesting, pruning, tying, thinning or weeding activities etc. or 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.
(2) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves
(3) with PPE: *type of PPE* / see 'Instructions for use'

Table 6.6-10: Exposure models for intended uses

Critical use(s)	Winter wheat (max. 0.12 kg a.s./ha)
Model	"EFSA Model" ver. 30.03.2015

Table 6.6-11: Estimated worker exposure

		Clopyralid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate:		0.12 kg a.s./ha	
2 hours/day (1), TC: 12500cm²/person/h Body weight: 60 kg	~~no PPE~~ Potential exposure (2)	0.0750000	50.00%
	with PPE (3)	0.0084000	5.60%

(1) e.g. 8 h/day for professional applications for harvesting, pruning, tying, thinning or weeding activities etc. or 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.
(2) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves
(3) with PPE: *type of PPE* / see 'Instructions for use'

For use in a mixture, cumulative exposure will be based on a solo dose calculation as this is a worse case.

Table 6.6-12: Exposure models for intended uses

Critical use(s)	Sugar beet (max. 0.06 kg a.s./ha)
Model	"EFSA Model" ver. 30.03.2015

Table 6.6-13: Estimated worker exposure

		Clopyralid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate:		0.06 kg a.s./ha	
2 hours/day (1), TC: 12500cm²/person/h Body weight: 60 kg	~~no PPE~~ Potential exposure (2)	0.0985653	65.71%
	with PPE (3)	0.0110393	7.36%

(1) e.g. 8 h/day for professional applications for harvesting, pruning, tying, thinning or weeding activities etc. or 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.
(2) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves
(3) with PPE: *type of PPE* / see 'Instructions for use'

6.6.4.3 Refinement of generic DFR value (KCP 7.2)

Not required.

6.6.4.4 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.

6.6.5 Bystander and resident exposure (KCP 7.2.2)

Comments of	The reference value acutely toxic active substance (RVAAS/AAOEL) for clopyralid is

zRMS:	allocated. Thus, the calculation of bystander exposure has been provided by the Applicant. The presented calculations for bystander and resident exposure are accepted. **Conclusions:** The results of the exposure estimations suggest that the use of CHR/H/CPD300SL/Major 300SL, Cloe 300SL, ProSto 300SL according to the list of intended uses presented in GAP Table, **causes acceptable health risk for bystander and resident, both adult and child.**

6.6.5.1 Estimation of bystander and resident exposure

Table 6.6-14 shows the exposure model(s) used for estimation of bystander and resident exposure to clopyralid. Outcome of the estimation is presented in Table 6.6-15-22. Detailed calculations are in Appendix 3.

Table 6.6-14: Exposure models for intended uses

Critical use(s)	Winter wheat (max. 0.12 kg a.s./ha)
Model	"EFSA Model" ver. 30.03.2015

Table 6.6-15: Estimated bystander exposure

1-3 year old child

Clopyralid				
	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%

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 6.6-16: Estimated resident exposure

1-3 year old child

Clopyralid

	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%

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 6.6-17: Exposure models for intended uses

Critical use(s)	Winter oilseed rape (max. 0.12 kg a.s./ha)
Model	"EFSA Model" ver. 30.03.2015

Table 6.6-18: Estimated bystander exposure

1-3 year old child

Clopyralid				
	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%

Adult

Clopyralid				
	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%

For use in a mixture, cumulative exposure will be based on a solo dose calculation as this is a worse case.

Table 6.6-19: Estimated resident exposure

1-3 year old child

Clopyralid					
	Spray drift (75th per-centile)	**Vapour (75th per-centile)**	**Surface deposits (75th per-centile)**	**Entry into treated crops (75th percentile)**	**All path-ways (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%
Picloram					
	Spray drift (75th per-centile)	**Vapour (75th per-centile)**	**Surface deposits (75th per-centile)**	**Entry into treated crops (75th percentile)**	**All path-ways (mean)**
Total systemic exposure (mg a.s./day)	0.0157119	0.0107000	0.0018935	0.0197438	0.0364832
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0015712	0.0010700	0.0001894	0.0019744	0.0036483
% of RVNAS	0.52%	0.36%	0.06%	0.66%	1.22%
Metazachlor					
	Spray drift (75th per-centile)	**Vapour (75th per-centile)**	**Surface deposits (75th per-centile)**	**Entry into treated crops (75th percentile)**	**All path-ways (mean)**

Total systemic exposure (mg a.s./day)	0.5035875	0.0107000	0.0606900	0.6328125	0.8370838
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0503588	0.0010700	0.0060690	0.0632813	0.0837084
% of RVNAS	25.18%	0.54%	3.03%	31.64%	41.85%

Adult

Clopyralid					
	Spray drift	**Vapour**	**Surface deposits**	**Entry into treated crops**	**All path-ways (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%
Picloram					
	Spray drift	**Vapour**	**Surface deposits**	**Entry into treated crops**	**All path-ways (mean)**
Total systemic exposure (mg a.s./day)	0.0225576	0.0138000	0.0047830	0.0658125	0.0804928
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0003760	0.0002300	0.0000797	0.0010969	0.0013415
% of RVNAS	0.13%	0.08%	0.03%	0.37%	0.45%
Metazachlor					
	Spray drift	**Vapour**	**Surface deposits**	**Entry into treated crops**	**All path-ways (mean)**
Total systemic exposure (mg a.s./day)	0.7230000	0.0138000	0.1533000	2.1093750	2.1513893
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0120500	0.0002300	0.0025550	0.0351563	0.0358565
% of RVNAS	6.03%	0.12%	1.28%	17.58%	17.93%

Table 6.6-20: Exposure models for intended uses

Critical use(s)	Sugar beet (max. 0.06 kg a.s./ha)

Model	"EFSA Model" ver. 30.03.2015

Table 6.6-21: Estimated bystander exposure

1-3 year old child

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0913560	0.0107000	0.0382039	0.1330632
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0091356	0.0010700	0.0038204	0.0133063
% of RVAAS	5.37%	0.63%	2.25%	7.83%

Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.1489800	0.0138000	0.0971854	0.4435440
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0024830	0.0002300	0.0016198	0.0073924
% of RVAAS	1.46%	0.14%	0.95%	4.35%

Table 6.6-22: Estimated resident exposure

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)	0.0402870	0.0107000	0.0127615	0.1330632	0.1483299
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0040287	0.0010700	0.0012761	0.0133063	0.0148330
% of RVNAS	2.69%	0.71%	0.85%	8.87%	9.89%

Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0578400	0.0138000	0.0322348	0.4435440	0.4185310

Total systemic exposure per kg body weight (mg/kg bw/day)	0.0009640	0.0002300	0.0005372	0.0073924	0.0069755
% of RVNAS	0.64%	0.15%	0.36%	4.93%	4.65%

6.6.5.2 Measurement of bystander and/or resident exposure

Since the bystander and resident 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 bystander/resident exposure was not necessary and was therefore not performed.

6.6.6 Combined exposure

Table 6.6.6-1 Long-term ~~Acute~~ risk assessment from combined exposure of CHR/H/CPD and CHR/H/PCR

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators – wehicle-mounted	picloram	0.06
	clopyralid	0.43
	Cumulative risk Operators (HI)	0.49
Workers – wehicle-mounted	picloram	0.05
	clopyralid	0.5
	Cumulative risk Workers (HI)	0.55
Bystander	picloram	-
	clopyralid	-
	Cumulative risk Bystander – Adult (HI)	-
Resident - Adult	picloram	0.0045
	clopyralid	0.0395
	Cumulative risk Resident – Adult (HI)	0.044
Resident - Child	picloram	0.0122
	clopyralid	0.0953
	Cumulative risk Resident – Child (HI)	0.1075

Table 6.6.6-2 Long-term ~~Acute~~ risk assessment from combined exposure of CHR/H/CPD, CHR/H/PCR and CHR/H/MTC

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators – wehicle-mounted	picloram	0.0086
	clopyralid	0.085
	metazachlor	0.39
	Cumulative risk Operators (HI)	0.49
Workers – wehicle-mounted	picloram	0.05
	clopyralid	0.056
	metazachlor	0.26
	Cumulative risk Workers (HI)	0.366
Bystander	picloram	-
	clopyralid	-

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
	metazachlor	-
	Cumulative risk Bystander – Adult (HI)	-
Resident - Adult	picloram	0.0045
	clopyralid	0.004
	metazachlor	0.18
	Cumulative risk Resident – Adult (HI)	0.19
Resident - Child	picloram	0.0122
	clopyralid	0.095
	metazachlor	0.42
	Cumulative risk Resident – Child (HI)	0.53

Values for bystander are not demanded because of lack of AAOEL.
The Hazard Index is < 1. Thus combined exposure to all active substances in Product Name is not expected to present a risk for operators, workers, bystanders and residents. No further refinement of the assessment is required.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Annex point	**Lead author**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Y/N**	**Owner**
KCP 7.1.1	xxx	2014	CHR/H/CPD Acute oral toxicity study on rats – fixed dose method. [redacted] Study code: PO-15/14 GLP – yes Unpublished	Y	Chemirol
KCP 7.1.2	xxx	2014	CHR/H/CPD Acute dermal toxicity study on rats. [redacted] Study code: DER-9/14 GLP – yes Unpublished	Y	Chemirol

Annex point	**Lead author**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Y/N**	**Owner**
KCP 7.1.4/01	xxx	2014	CHR/H/CPD *In vitro* skin corrosion: Transcutaneous electrical resistance test (TER) [redacted] Study code: OES-9/14 GLP – yes Unpublished	Y	Chemirol
KCP 7.1.4/02	xxx	2014	CHR/H/CPD Acute skin irritation/corrosion study on rabbits. [redacted] Study code: DDR-4/14 GLP – yes Unpublished	Y	Chemirol

Annex point	**Lead author**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Y/N**	**Owner**
KCP 7.1.5/01	xxx	2014	CHR/H/CPD Isolated Chicken Eye Test Method for Identifying i) Chemicals Including Serious Eye Damage and ii) Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage [redacted] Study code: ICE-9/14 GLP – yes Unpublished	Y	Chemirol
KCP 7.1.5/02	xxx	2014	CHR/H/CPD Acute eye irritation/corrosion study on rabbits. [redacted] Study code: ODR-7/14 GLP – yes Unpublished	Y	Chemirol

Annex point	**Lead author**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Y/N**	**Owner**
KCP 7.1.6	xxx	2014	CHR/H/CPD Skin sensitization study. [redacted] Study code: Al-9/14 GLP – yes Unpublished	Y	Chemirol

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

Appendix 2 Detailed evaluation of the studies relied upon

Comments of zRMS:	The studies of acute toxicity of the product was re-assessed during re-authorization of the product which followed the renewal of the active substance.

A 2.1 Statement on bridging possibilities

Not required.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	The study (xxx 2014) is accepted without reservation. Acc. to the results of the study the product CHR/H/CPD 300 SL/Major 300 SL/Cloe 300 SL/ProSto 300 SL does not require classification regarding acute oral toxicity.

Reference:	KCP 7.1.1
Report	CHR/H/CPD An Acute Oral Toxicity Study on Rats – Fixed Dose Method; xxx., 2014
Guideline(s):	OECD Guideline No 420 / EU Method B.1.BIS
Deviations:	-
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Material and methods:

- CHR/H/CPD (batch No. 22.01.2014, date of manufacture 22.01.2014, stabile till 22.01.2016) is in the form of a water-soluble concentrate.
- Active substance – clopyralid 303,63 ± 5,44 g/l.
- In the sighting study the product was administered to one animal at 2000 mg/kg bw. In the main study the product was administered to 4 other animals at 2000 mg/kg bw. (Animal from the sighting study was included in the main study.)
- The test item was administered with the aid of a metal stomach tube of animals in the form of aqueous solution at volume 0.5 mL per 100 g bw.
- Animals – rats Wistar: Crl: WI (Han), outbred; 5 females.
- Time of observation – 14-day observation period.
- Necropsy – yes.
- Deviations from the study plan - no deviations from the Study Plan were found.

Table 7.1.1-1: Acute oral toxicity in rats of CHR/H/CPD

Dose (mg/kg bw)	Toxicological results*	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
female rats				
2000 mg/kg bw	0/0/5	-	-	> 2000

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

Findings:

- Sighting study: following single administration of test item in dose 2000 mg/kg bw to one animal no signs of toxicity were stated.
- Main study: following single administration of test item in dose 2000 mg/kg bw to four animals, no signs of toxicity were stated.
- No clinical signs and no deaths were observed during the study.
- During the 14-day experiment, body weight gain was observed in the animal.
- Macroscopic examination revealed no pathological changes.

Conclusion/endpoint:
Under the experimental conditions, the oral LD_{50} of the CHR/H/CPD for rats is greater than 2000 mg/kg bw.

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

Comments of zRMS:	The study (xxx 2014) provided by the Applicant is accepted. Comments: The study was conducted in accordance with the previous version of the guideline. However, the deviations revealed in relation to the current guideline (2017) do not affect the reliability of the obtained results. **Conclusions:** Acc. to the results of the study the product CHR/H/CPD 300 SL/Major 300 SL/Cloe 300 SL/ProSto 300 SL does not require classification regarding acute dermal toxicity.

A 2.3.1 Study 1

Reference:	KCP 7.1.2/01
Report	CHR/H/CPD Acute dermal toxicity study on rats; xxx., 2014
Guideline(s):	OECD Guideline No 402 / EU Method B.3.
Deviations:	-
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Material and methods:

- CHR/H/CPD (batch No. 22.01.2014, date of manufacture 22.01.2014, stabile till 22.01.2016) is in the form of a water-soluble concentrate.

- Active substance – clopyralid 303,63 ± 5,44 g/l.
- The administration amount of CHR/H/CPD was 2000 mg/kg bw.
- The undiluted test item was applied to gauze patches, at a single dose of 2000 mg/kg b.w. was applied to the dorsal area of the trunks for 24 hours.
- Animals – rats Wistar: Crl: WI (Han), outbred; 5 females and 5 males.
- Time of observation – 14-day observation period.
- Necropsy – yes.
- Deviations from the study plan - Few times during the entire experiment the relative air humidity exceeded 70% The changes were temporary and did not influence study course and results.

Table 7.1.2-1: Acute percutaneous (dermal) toxicity in rats of CHR/H/CPD

Dose (mg/kg bw)	**Toxicological results***	**Duration of signs**	**Time of death**	**LD_{50} (mg/kg bw) (14 days)**
female rats				
2000 mg/kg bw	0/0/5	-	-	> 2000
male rats				
2000 mg/kg bw	0/0/5	-	-	> 2000

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

Findings:

- No general clinical signs and no deaths were observed during the study.
- During the experiment, body weight loss was stated in two females. Body weight gain was stated in the remaining animals.
- Macroscopic examination revealed no pathological changes in any of the animals.

Conclusion/endpoint:
Under the experimental conditions, the dermal LD_{50} of the CHR/H/CPD is higher than 2000 mg/kg bw in rats.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	According to the Regulation 284/2013, the inhalation study shall be carried out where the plant protection product: (a) is a gas or liquefied gas; (b) is a smoke generating plant protection product or fumigant; (c) is used with fogging/misting equipment; (d) is a vapour releasing plant protection product; (e) is supplied in an aerosol dispenser; (f) is in a form of a powder or granules containing a significant proportion of particles of diameter < 50 µm (> 1 % on a weight basis); (g) is to be applied from aircraft in cases where inhalation exposure is relevant;

	(h) contains an active substance with a vapour pressure > 1 × 10–2 Pa and is to be used in enclosed spaces such as warehouses or glasshouses; (i) is to be applied by spraying. However, the study shall not be required if the applicant can justify an alternative approach under Regulation (EC) No 1272/2008, where applicable. Consequently, the inhalation toxicity of CHR/H/CPD 300 SL/Major 300 SL/Cloe 300 SL/ProSto 300 SL was determined by calculation method (additivity formula) based on data for all relevant ingredients. Taking into account the results of calculations, the classification of the product CHR/H/CPD 300 SL/Major 300 SL/Cloe 300 SL/ProSto 300 SL in regards to acute inhalation toxicity **is not required.**

According to point 7.1.3 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:
" A study shall not be required if the applicant can justify an alternative approach under Regulation (EC) No 1272/2008, where applicable. For this purpose, acute inhalation toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture."

The complete composition of the formulation with the classification of individual ingredients was already evaluated and available in Core Assessment Part C.
Due to the fact, that all components of the formulation CHR/H/CPD 300 SL are known, the acute inhalation toxicity test is not necessary.
Only one ingredient is classified in this hazard class.

- D – 9.30% (Acute Tox. 4, H332)

$$ATE_{mix} = \frac{100}{\sum_{i=1}^{n} \frac{C_i}{ATE_{mix}}} = \frac{100}{\frac{9.30}{11}} = 118$$

According to the table 3.1.2, result (118mg/L > > 20mg/L) is significantly higher than concentration resulting classification. Therefore the whole formulation is not classified as Acute Tox. 4, H332.

Table 3.1.2
Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for classification for the respective routes of exposure.

Exposure routes	Classification Category or experimentally obtained acute toxicity range estimate	Converted acute toxicity point estimate (see Note 1)
Oral (mg/kg bodyweight)	0 < Category 1 ≤ 5 5 < Category 2 ≤ 50 50 < Category 3 ≤ 300 300 < Category 4 ≤ 2 000	0,5 5 100 500
Dermal (mg/kg bodyweight)	0 < Category 1 ≤ 50 50 < Category 2 ≤ 200 200 < Category 3 ≤ 1 000 1 000 < Category 4 ≤ 2 000	5 50 300 1 100
Gases (ppmV)	0 < Category 1 ≤ 100 100 < Category 2 ≤ 500 500 < Category 3 ≤ 2 500	10 100 700

	2 500 < Category 4 ≤ 20 000	4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5 0,5 < Category 2 ≤ 2,0 2,0 < Category 3 ≤ 10,0 10,0 < Category 4 ≤ 20,0	0,05 0,5 3 11
Dust/mist (mg/l)	0< Category 1 ≤ 0,05 0,05 < Category 2 ≤ 0,5 0,5 < Category 3 ≤ 1,0 1,0 < Category 4 ≤ 5,0	0,005 0,05 0,5 1,5

Note 1
These values are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	The study (xxx 2014) provided by the Applicant is accepted. Comments: The study was conducted in accordance with the previous version of the guideline. However, the deviations disclosed in relation to the current guideline (2015) do not affect the reliability of the obtained results. Acc. to the results of the study the product CHR/H/CPD 300 SL/Major 300 SL/Cloe 300 SL/ProSto 300 SL does not require classification regarding skin corrosion. The examination of irritation properties using *in vivo* test was justified.

A 2.5.1 In vitro skin corrosion

Reference:	KCP 7.1.4/01
Report	CHR/H/CPD In vitro skin corrosion: Transcutaneous electrical resistance test (TER); xxx., 2014 STUDY CODE: OES-9/14
Guideline(s):	OECD Guideline No 430 / EU Method B.40.
Deviations:	-
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Material and methods:

- CHR/H/CPD (batch No. 22.01.2014, date of manufacture 22.01.2014, stabile till 22.01.2016) is in the form of a water-soluble concentrate.
- Active substance – clopyralid 303,63 ± 5,44 g/l.
- Test material – 11 skin discs obtained from each two 28-days old rat females with Imp symbol: WISTAR (outbred) - two of them were used to control the quality of the procedure, whereas the remaining nine were used for the purpose of the experiment.
- The undiluted test item in a volume of 150 µL was applied uniformly to the epidermal surface. Test item was applied for 24 hours at 21-22 °C. The test item were removed by washing with a jet of tap water at up to 30°C and the electrical resistance was measured and made an overall assessment.

- In order to confirm positive results of the TER studies with values lower than 5 kΩ in the absence of visual damage and to determine if the obtained TER value was the result of increased skin permeability, or skin corrosion, a dye-binding assay was included in the study.

- Deviations from the study plan – no deviations from the Study Plan were stated.

Findings:

- Mean TER results were: 1.40 kΩ (animal No. 1) and 1.53 kΩ (animal No. 2).

- Gross examinations of the skin discs treated with the test item did not reveal any pathological changes.

- The mean disc dye content of the skin discs treated with the test item was equal to 39.24 µg/disc (animal no. 1) and 38.57 µg/disc (animal no. 2) - the mean disc Sulforhodamine B dye content of the treated skin discs was lower than the mean disc dye content of the 36% HCl positive control obtained concurrently.

- The test substance is considered to be corrosive to skin, when:

    - the mean TER value is less than or equal to 5 kΩ and the skin disc is obviously damaged, or

    - the mean TER value is less than or equal to 5 kΩ, and the skin disc is showing no obvious damage, but the mean disc dye content is greater than or equal to the mean disc dye content of the 36% HCl positive control obtained concurrently.

Table 2. Results of the transcutaneous electrical resistance test (TER).

Animal number	Tested substance	Skin disc number	TER value (kΩ)	Mean TER value ± SD (kΩ)
1	Positive control – 36% HCl	1	0.81	**0.81 ± 0.02**
		2	0.83	
		3	0.80	
	Negative control – distilled water	1	23.03	**23.04 ± 0.07**
		2	23.12	
		3	22.98	
	Test item	1	1.38	**1.40 ± 0.02**
		2	1.42	
		3	1.39	
2	Positive control – 36% HCl	1	0.78	**0.78 ± 0.02**
		2	0.77	
		3	0.80	
	Negative control – distilled water	1	20.37	**20.52 ± 0.16**
		2	20.49	
		3	20.69	
	Test item	1	1.57	**1.53 ± 0.04**
		2	1.53	
		3	1.49	

Conclusion/endpoint:
Under the experimental conditions, CHR/H/CPD is not corrosive to skin of rat. Performance of skin irritation/corrosion study is justified.

A 2.6 Skin irritation (KCP 7.1.4)

Comments of zRMS:	The study (xxx 2014) provided by the Applicant is accepted. Comments: The study was conducted in accordance with the previous version of the guideline. However, the deviations disclosed in relation to the current guideline (2015) do not affect the reliability of the obtained results. **Conclusions:** Acc. to the results of the study the product CHR/H/CPD 300 SL/Major 300 SL/Cloe 300 SL/ProSto 300 SL does not require classification regarding skin irritation.

A 2.6.1 Study 2

Reference:	KCP 7.1.4/02
Report	CHR/H/CPD Acute skin irritation/corrosion study on rabbits STUDY CODE: DDR-4/14
Guideline(s):	OECD Guideline No 404 / EU Method B.4. , xxx., 2014
Deviations:	-
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Material and methods:

- CHR/H/CPD (batch No. 22.01.2014, date of manufacture 22.01.2014, stabile till 22.01.2016) is in the form of a water-soluble concentrate.
- Active substance – clopyralid 303,63 ± 5,44 g/l.
- The test item in a volume of 0.5 mL was applied to a multilayer gauze patch (2.5 x 2.5 cm), then, the gauze patch was laid on the prepared skin of rabbits. After 4 hours residual test item was removed using water.
- Animals –white rabbits of New Zealand strain: 3 males.
- Time of observation – 72 hours.
- Necropsy – no.
- Deviations from the study plan - during the experiment, air temperature exceeded 23°C once, and the relative air humidity exceeded 70% twice. The changes did not influence the study course

Table 7.1.4-2: Skin irritation in rabbits of CHR/H/CPD

Dose (ml)	**Toxicological results***	**Duration of signs**	**Time of death**	**Conclusion (72 hours)**
male rabbits				
0.5	0/3/3	up to 1/24/48 hours	-	not irritant

* Number of animals which died/number of animals with changes on skin/number of animals used

Volume of the test item	**0.5 mL**		
Animal number	**1**	**2**	3
Sex	male	male	male
Mortality	0	0	0
General clinical signs	none	none	none
Skin erythema	very slight (barely perceptible) after 1 and 24 hours	very slight (barely perceptible) after 1 hour	very slight (barely perceptible) after 1, 24 and 48 hours
Skin edema	none	none	none
Other	none	none	none

Table 1 - Evaluation of skin reactions.

Animal number	Changes	Evaluation after				Average after 24, 48, and 72 hours
		1 hour	24 hours	48 hours	72 hours	
1	erythema	1	1	0	0	0.3
	edema	0	0	0	0	0.0
	other	-	-	-	-	-
2	erythema	1	0	0	0	0.0
	edema	0	0	0	0	0.0
	other	-	-	-	-	-
3	erythema	1	1	1	0	0.7
	edema	0	0	0	0	0.0
	other	-	-	-	-	-

Findings:

- One hour after the application of the test item: very slight erythema (barely perceptible) in three rabbits.
- Twenty-four hours after the application of the test item: very slight erythema (barely perceptible) in rabbits no. 1 and 3, no pathological changes in rabbit no. 2.
- Forty-eight hours after the application of the test item: no pathological changes in rabbits no. 1 and 2, very slight erythema (barely perceptible) in rabbit no. 3.
- Seventy-two hours after the application of the test item: no pathological changes in three rabbits.
- At the beginning of the experiment, animal no. 1 weighed 3.4 kg, animal no. 2 weighed 4.0 kg, and animal no. 3 weighed 3.3 kg. On the last day of the experiment, animal no. 1 weighed 3.5 kg, animal no. 2 weighed 4.0 kg, and animal no. 3 weighed 3.3 kg.

Conclusion/endpoint:
Under the experimental conditions, CHR/H/CPD is not irritant to the skin of rabbits.

A 2.7 Eye irritation (KCP 7.1.5)

Comments of zRMS:	The study (xxx 2014) provided by the Applicant is accepted. However, the deviations disclosed in relation to the current guideline (2018) do not affect the reliability of the obtained results. Acc. to the results of the study the product CHR/H/CPD 300 SL/Major 300 SL/Cloe 300 SL/ProSto 300 SL does not require classification regarding eye corrosion. The examination of irritation properties using *in vivo* test was justified.

A 2.7.1 In vitro eye corrosion

Reference:	KCP 7.1.5/01
Report	CHR/H/CPD Isolated Chicken Eye Test Method for Identifying i) Chemicals Including Serious Eye Damage and ii) Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage; xxx., 2014 STUDY CODE: ICE-9/14
Guideline(s):	OECD Guideline No 438 / EU Method B.48.
Deviations:	-
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Material and methods:

- CHR/H/CPD (batch No. 22.01.2014, date of manufacture 22.01.2014, stabile till 22.01.2016) is in the form of a water-soluble concentrate.
- Active substance – clopyralid 303,63 ± 5,44 g/l.
- Animals – chickens
- Test material – 9 eyeballs; three eyeballs were used for negative control, positive control and for the test item.
- The test item and the items used in the positive (10% acetic acid) and negative (physiological salt) controls were uniformly applied to the corneal surface in a volume of 0.03 mL., for 10 second, then, they were rinsed from the eye with 20 mL of physiological salt at ambient temperature.
- Time of observation – the corneas treated with the test item and the control items were evaluated pretreatment and 4 hour after the end of the exposure.
- At all observation times points, corneal opacity and swelling were evaluated, whereas morphological changes of the corneal surface were recorded. The quantitative determination of fluorescein retention was performed only once, i.e. 30 minutes after the end of the exposure.
- Deviations from the study plan – none.

Table 7.1.5-1: Eye irritation in Isolated Chicken Eye Test of CHR/H/CPD

Dose (ml)	Fluorescein retention score	Corneal opacity score	Corneal swelling score	Gross evaluation of cornea	Histopathological evaluation of cornea	Conclusion
Isolated chicken eyes						
0.03	2.0	2,0	0,2-9,6	No pathological	No pathological	Not irritating to eye

				changes	changes	

Findings:

- The mean fluorescein retention value for the eyeballs treated with the test item was equal to 2.0 (III ICE class); for the positive control (10% acetic acid) were 3.0 (ICE class IV).

- The mean corneal opacity value for the eyeballs treated with the test item was equal to 2.0 (III ICE class); for the positive control were 4.0 (ICE class IV).

- The mean corneal swelling value for the eyeballs treated with the test item were from 0.2 (I ICE class) to 9.6 (II ICE class); for the positive control were from 6.6 (ICE class II) to 40.1 (ICE class IV).

- Gross examinations of the eyeballs treated with the test item did not reveal any changes on the corneal surface. During the gross examination of the positive control eyeballs, roughening of the corneal surface was observed.

- Histopathological examinations of the corneas treated with the test item showed a normal histological structure (eyeballs no. 1, 2, and 3). Histopathological examinations of the positive control corneas revealed exfoliation of the anterior corneal epithelium (eyeballs no. 4); detachment of the posterior corneal epithelium (eyeballs no. 4); dissection of the corneal stroma (eyeball no. 6). The cornea (eyeball no. 5) had a normal histological structure.

Conclusion/endpoint:
Under the experimental conditions, CHR/H/CPD did not show definite eye corrosion/irritation. These results serve as a basis for performing an acute eye irritation/corrosion study on rabbits based on the OECD Guideline for the Testing of Chemicals No. 405/EU Method B.5.

A 2.7.2 Eye irritation

Comments of zRMS:	The study (xxx 2014) provided by the Applicant is accepted. However, the deviations revealed in relation to the current guideline (2021) do not affect the reliability of the obtained results. The mean score (24-72h) value of conjunctival erythema for each animal amounted to 2.0. Acc. to the Regulation 1272/2008 (table 3.3.2) the product is irritating to the eyes. **Conclusions:** Acc. to the results of the study the product CHR/H/CPD 300 SL/Major 300 SL/Cloe 300 SL/ProSto 300 SL requires classification regarding eye irritation (**Eye Irrit.2, H319**).

Reference:	KCP 7.1.5/02
Report	CHR/H/CPD Acute eye irritation/corrosion study on rabbits; xxx, 2014 STUDY CODE: ODR-7/14
Guideline(s):	OECD Guideline No 405 / EU Method B.5.
Deviations:	-
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Material and methods:

- CHR/H/CPD (batch No. 22.01.2014, date of manufacture 22.01.2014, stabile till 22.01.2016) is in the form of a water-soluble concentrate.
- Active substance – clopyralid 303,63 ± 5,44 g/l.
- The test item in a volume of 0.1 mL was applied to the conjunctival sac of one eye of the animals after gently pulling the lower lid away from the eyeball. The lids were then gently held together for a moment in order to prevent loss of the material.
- Animals – white rabbits of New Zealand strain: 2 females, 1 male.
- Time of observation – animals 1 and 3 - 14 days, animal 2 – 7 days.
- Necropsy – no.
- Deviations from the study plan - few times the relative air humidity exceeded 70%. The changes did not influence study course.

Table 7.1.5-2: Eye irritation in rabbits of CHR/H/CPD

Dose (ml)	**Toxicological results***	**Duration of signs**	**Time of death**	**Conclusion (14 days)**
2 females/1 male rabbits				
0.1	0/3/3	up to 7 days	-	not irritant

* Number of animals which died/number of animals with changes in eye/number of animals used

Volume of the test item		**0.1 mL**		
Rabbit number		**1**	**2**	**3**
Sex		male	female	female
Mortality		0/1	0/1	0/1
General clinical signs		none	none	none
PART OF THE EYE		Ocular lesions		
CORNEA		Transient: opacity – details of iris clearly visible	none	none
IRIS		Transient: congestion-sluggish reaction to light, congestion-normal reaction to light	Transient: congestion – normal reaction to light	Transient: congestion – normal reaction to light
CONJUNCTIVA	**erythema**	Transient: diffuse beefy red, diffuse crimson colour; congestion of some	Transient: diffuse beefy red, diffuse crimson colour; congestion of some	Transient: diffuse beefy red, diffuse crimson colour; congestion of some

		blood vessels; congestion of the nictitating membrane; circumcorneal injection	blood vessels; congestion of the nictitating membrane; circumcorneal injection	blood vessels; congestion of the nictitating membrane; circumcorneal injection
	swelling	Transient: obvious swelling with partial eversion of lids, some swelling, swelling of the nictitating membrane	Transient: swelling with lids about hal f closed, some swelling, swelling of the nictitating membrane	Transient: obvious swelling with partial eversion of lids, some swelling, swelling of the nictitating membrane
	other	Transient: discharge on the lids, lids' hair and a considerable part of the ocular area, discharge on the lids and lids' hair	Transient: discharge on the lids, lids' hair and a considerable part of the ocular area, discharge on the lids and lids' hair	Transient: discharge on the lids, lids' hair and a considerable part of the ocular area, discharge on the lids and lids' hair

Table – Evaluation of the animal`s ocular lesions.

Animal number	Part of the eye		Readings after						Average after 24, 48, and 72 hours
			1 hour	24 hours	48 hours	72 hours	7 days	14 days	
1	Cornea		0	1	1	0	0	0	0.7
	Iris		1	1	1	0	0	0	0.7
	Conjunctiva	erythema	2	3	2	1	1	0	2.0
		swelling	2	1	1	1	0	0	1.0
2	Cornea		0	0	0	0	0	-	0.0
	Iris		1	1	0	0	0	-	0.3
	Conjunctiva	erythema	2	3	2	1	0	-	2.0
		swelling	3	1	1	1	0	-	1.0
3	Cornea		0	0	0	0	0	0	0.0
	Iris		1	1	0	0	0	0	0.3
	Conjunctiva	erythema	2	3	2	1	1	0	2.0
		swelling	2	1	1	1	0	0	1.0

Findings:

- No general clinical signs and no deaths were observed during the study.
- After the application of the test item, pathological changes in the cornea, iris and conjunctiva were stated. Changes were transient.
- In conjunctiva changes included: erythema (e.g. injection of blood vessels, circumcorneal injection), swelling and discharge on the lids, lids' hair and a considerable part of the ocular area (all animals); opacity of cornea (male); congestion of iris (all animals).
- At the beginning of the experiment, rabbit no. 1 weighed 3.6 kg, rabbit no. 2 weighed 3.9 kg, and

rabbit no. 3 weighed 3.0 kg. On the last day of the experiment, the animals weighed 3.6 kg, 4.0 kg and 2.9 kg, respectively.

Conclusion/endpoint:
~~Under the experimental conditions, CHR/H/CPD is not irritant to the eye of rabbits~~. Acc. to the results of the study the product CHR/H/CPD 300 SL/Major 300 SL/Cloe 300 SL/ProSto 300 SL requires classification regarding eye irritation (Eye Irrit.2, H319)

A 2.8 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	The study (xxx 2014) provided by the Applicant is accepted. Comments: The study was conducted in accordance with the previous version of the guideline. However, the deviations disclosed in relation to the current guideline at the time of report submission (2021) do not affect the reliability of the obtained results. **Conclusions:** Acc. to the results of the study the product CHR/H/CPD 300 SL/Major 300 SL/Cloe 300 SL/ProSto 300 SL does not require classification regarding skin sensitization.

A 2.8.1 Study 1

Reference:	KCP 7.1.6/01
Report	CHR/H/CPD Skin sensitization study; xxx., 2014 STUDY CODE: Al-9/14
Guideline(s):	OECD Guideline No 406 / EU Method B.6.
Deviations:	-
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

Material and methods:

- CHR/H/CPD (batch No. 22.01.2014, date of manufacture 22.01.2014, stabile till 22.01.2016) is in the form of a water-soluble concentrate.
- Active substance – clopyralid 303,63 ± 5,44 g/l.
- Animals – Dunkin-Hartley guinea pigs (outbred).
- Sighting study was performed in order to determine concentrations of product to be used in the main study.
- Main study:
    - 20 animals in the test group: 10 females and 10 males (the control group included 4 males and 5 females),
    - in order to prepare appropriate concent rations of the test item, aqua pro injectione was used as a medium,

- induction: intradermal injections – three pairs of intradermal injections of 0.1 mL volume were given to all 20 animals so that one of each pair of injections laid on each side of the midline,

- induction: topical application – in order to create local skin irritation one day before application 10% sodium lauryl sulfate in vaseline was applied on skin of animals in site of intradermal injections; the undiluted test item in a volume of about 1 mL was applied to multilayered gauze patches in the place of intradermal injection, for 48 hours,

- challenge: topical application – the undiluted test item in a volume of 0.5 mL was applied for 24 hours to the skin of right flank of animals.

- Time of observation – 72 hours

- Necropsy – the animal which died spontaneously during the experiment was subjected to a gross necropsy.

- Deviations from the study plan – during the experiment, the relative air humidity exceeded 70% a few times. The changes were temporary and did not influence the study course and results.

Table 7.1.6-1: Skin sensitization in guinea pigs of CHR/H/CPD

Dose (mL)/ concentration	**Toxicological results***	**Duration of signs**	**Time of death**	**Sensitization ratio (72 hours)**
female guinea pigs				
0.5	2/0/10	-	24 h	5,56%
male guinea pigs				
0.5	0/1/10	24-72 h	-	

* Number of animals which died/number of animals with allergic reaction/number of animals used

Findings:

- Two animals died during the study (females no. 19/171 and 20/173). It could have been caused by a mechanical injury resulting from the test item administration.

- CHR/H/CPD caused sensitization in 1 of 20 animals (male no. 6/20 , which is 5,56%) in the form of mild erythema and dry skin.

- During the experiment the treated animals did not exhibit any changes in behaviour or general clinical changes.

- During the main study, body weight gain was stated in all animals (the average body weight gain was 82.6 g for males and 62.8 g for females).

On the ground of the study the test item CHR/H/CPD can be classified to:
- agents causing weak sensitization – according to classification of Magnusson and Kligman
- agents beyond categorization – according to the Commission Regulation (EU) No. 286/2011 of March 10, 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No. 1272/2008 of the European Parliament and of the Council on classification, labelling, and packaging of substances and mixtures.

Conclusion/endpoint:
Under the experimental conditions, CHR/H/CPD causes no sensitization of skin of guinea pig.

A 2.9 Specific target organ toxicity

Comments of zRMS:	Only one ingredient has been taken into account for the purpose of classification (see dRR part C, table 1.3.2): D – 9.3 % (STOT SE 3, H335) with the specific concentration limit: ≥5%. **Conclusions:** Acc. to the Regulation 1272/2008, the concentration of the relevant ingredient is above the specific concentration limit that triggers classification of the mixture in regards to specific target organ toxicity. Taking into account the composition of the product, the formulation CHR/H/CPD 300 SL/Major 300 SL/Cloe 300 SL/ProSto 300 SL should be classified as STOT SE 3, H335).

For consideration of specific target organ toxicity the following table applies:

Table 2.9-1 Generic concentration limits of ingredients of a mixture classified as a specific target organ toxicant that trigger classification of the mixture as Category 1 or 2.

Ingredient classified as:	Generic concentration limits triggering classification of the mixture as:	
	Category 1	Category 2
Category 1 Specific Target Organ Toxicant	Concentration ≥ 10 %	1,0 % ≤ concentration < 10 %
Category 2 Specific Target Organ Toxicant		Concentration ≥ 10 % [(Note 1)]

Note 1
If a Category 2 specific target organ toxicant is present in the mixture as an ingredient at a concentration ≥ 1,0 % a SDS shall be available for the mixture upon request.

We also took into account the point 3.8.3.4.5.: "Care shall be exercised when extrapolating toxicity of a mixture that contains Category 3 ingredient(s). A generic concentration limit of 20 % is appropriate; however, it shall be recognised that this concentration limit may be higher or lower depending on the Category 3 ingredient(s) and that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20 % value. Expert judgement shall be exercised."

We consider only ingredient D. The concentration of ingredient D (9.30%) exceeds the specific concentration limit (5%) according to Regulation (EC) 1272/2008. Therefore the plant protection product is classified as STOT SE 3, H335.

Reproductive toxicity

Comments of zRMS:	Taking into account the composition of the product, the formulation CHR/H/CPD 300 SL/Major 300 SL/Cloe 300 SL/ProSto 300 SL does not require the classification regarding reproductive toxicity.

Table 2.9-2 Generic concentration limits of ingredients of a mixture classified as reproduction toxicants or for effects on or via lactation that trigger classification of the mixture

Ingredient classified as:	Generic concentration limits triggering classification of a mixture as:			
	Category 1 reproductive toxicant		Category 2 reproductive toxicant	Additional category for effects on or via lactation
	Category 1A	Category 1B		
Category 1A reproductive toxicant	≥ 0,3 % [Note 1]	-	-	-
Category 1B reproductive toxicant	-	≥ 0,3 % [Note 1]	-	-
Category 2 reproductive toxicant	-	-	≥ 3,0 % [Note 1]	-
Additional category for effects on or via lactation	-	-	-	≥ 0,3 % [Note 1]

Note
The concentration limits in the table above apply to solids and liquids (w/w units) as well as gases (v/v units).
Note 1
If a Category 1 or Category 2 reproductive toxicant or a substance classified for effects on or via lactation is present in the mixture as an ingredient at a concentration ≥ 0,1 % a SDS shall be available for the mixture upon request.

Only one ingredient H (Repr. 2, H361f) is relevant at the concentration of 10^{-4} %. The content of ingredient H is significantly lower than concentration triggering classification (3.0%). Therefore according to table 3.6.2 the formulation is not classified as Repr. 2, H361f.

A 2.10 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

Not required.

A 2.11 Data on co-formulants (KCP 7.4)

A 2.11.1 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 2.11.2 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 2.12 Studies on dermal absorption (KCP 7.3)

For the dermal absorption of the active substances the Applicant refers to Guidance on Dermal Absorption1 EFSA, EFSA Journal 2017;15(6):4873.
Based on an evaluation of agreed dermal absorption values for a range of concentrated pesticide formulations and their dilutions, the following default values are recommended (see opinion section 4.1.1.for details).
A default dermal absorption value of 10% may be applied for concentrated products that are water-based/dispersed or solid-formulated.
A default dermal absorption value of 50% may be applied for (in use) dilutions water-based/ dispersed or solid-formulated.

A 2.13 Other/Special Studies

Not required.

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: Estimation of operator exposure towards clopyralid without PPE using EFSA Model ver. 30.03.3015

- **For winter wheat:**

Operator exposure for CHR/H/CPD outdoor spray applications

Application rate of active substance	0.12 kg a.s./ha	*i_AppRate*
Assumed area treated	50 ha/day	*d_AreaTreated*
Amount of active substance applied	6 kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%	*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	

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	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	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	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	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	3.9317712	3.9317712	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0655295	0.0655295	
% of RVNAS	43.69%	43.69%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	25.0866177	25.0866177	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.4181103	0.4181103	
% of RVAAS	245.95%	245.95%	

- **For winter oilseed rape**:

Operator exposure for CHR/H/CPD outdoor spray applications

Application rate of active substance	0.12	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	6	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*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		

Outdoor|Soluble concentrates, emulsifiable concentrate, etc.|Downward spraying|Vehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	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	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	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	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	3.9317712	3.9317712
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0655295	0.0655295
% of RVNAS	43.69%	43.69%
Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	25.0866177	25.0866177
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.4181103	0.4181103
% of RVAAS	245.95%	245.95%

- **For sugar beet**:

Operator exposure for CHR/H/CPD outdoor spray applications

Application rate of active substance	0.06	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	3	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*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		

Outdoor/Soluble concentrates, emulsifiable concentrate, etc./Downward spraying/Vehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	11315	41864	AOEM	
	Body	7722	99105	AOEM	
	Head	156	854	AOEM	
	Protected hands (gloves)	70	594	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	63	439	AOEM	
	Protected head (hood and face shield)	2	48	AOEM	
	Inhalation	5	29	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
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	445	5124	AOEM	
	Body	249	1283	AOEM	
	Head	12	35	AOEM	
	Protected hands (gloves)	77	3789	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	17	AOEM	
	Inhalation	2	5	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	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	2.2789475	2.2789475	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0379825	0.0379825	
% of RVNAS	25.32%	25.32%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	17.4381457	17.4381457	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2906358	0.2906358	
% of RVAAS	170.96%	170.96%	

Table A 2: Estimation of operator exposure towards clopyralid with gloves at mixing and loading using EFSA Model ver. 30.03.3015

- **For winter wheat**:

Operator exposure for CHR/H/CPD outdoor spray applications

Application rate of active substance	0.12	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	6	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*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		

Outdoor|soluble concentrates, emulsifiable concentrate, etc.|Downward spraying|Vehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	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	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	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	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	3.9317712	2.0135032
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0655295	0.0335584
% of RVNAS	43.69%	22.37%
Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	25.0866177	18.0235286
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.4181103	0.3003921
% of RVAAS	245.95%	176.70%

- For winter oilseed rape

Operator exposure for CHR/H/CPD outdoor spray applications

Application rate of active substance	0.12	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	6	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*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		

Outdoor|Soluble concentrates, emulsifiable concentrate, etc.|Downward spraying|Vehicle-mounted

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	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	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	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	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	3.9317712	2.0135032
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0655295	0.0335584
% of RVNAS	43.69%	22.37%
Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	25.0866177	18.0235286
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.4181103	0.3003921
% of RVAAS	245.95%	176.70%

- For sugar beet

Operator exposure for CHR/H/CPD outdoor spray applications

Application rate of active substance	0.06	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	3	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*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		

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	11315	41864	AOEM	
	Body	7722	99105	AOEM	
	Head	156	854	AOEM	
	Protected hands (gloves)	70	594	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	63	439	AOEM	
	Protected head (hood and face shield)	2	48	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	445	5124	AOEM	
	Body	249	1283	AOEM	
	Head	12	35	AOEM	
	Protected hands (gloves)	77	3789	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	17	AOEM	
	Inhalation	2	5	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	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	2.2789475	1.1544661
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0379825	0.0192411
% of RVNAS	25.32%	12.83%
Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	17.4381457	13.3111626
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2906358	0.2218527
% of RVAAS	170.96%	130.50%

Table A 3: Estimation of operator exposure towards clopyralid with gloves and work-wear at mixing and loading and gloves during application using EFSA Model ver. 30.03.3015

- For winter wheat

Operator exposure for CHR/H/CPD outdoor spray applications

Application rate of active substance	0.12	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	6	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*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		

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	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	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	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	

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%
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%

- for winter oilseed rape

Operator exposure for CHR/H/CPD outdoor spray applications

Application rate of active substance	0.12	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	6	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*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		

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Downward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	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	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	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	

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%
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%

- For sugar beet

Operator exposure for CHR/H/CPD outdoor spray applications

Application rate of active substance	0.06	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	3	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*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		

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Downward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	11315	41864	AOEM	
	Body	7722	99105	AOEM	
	Head	156	854	AOEM	
	Protected hands (gloves)	70	594	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	63	439	AOEM	
	Protected head (hood and face shield)	2	48	AOEM	
	Inhalation	5	29	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	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	445	5124	AOEM	
	Body	249	1283	AOEM	
	Head	12	35	AOEM	
	Protected hands (gloves)	77	3789	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	17	AOEM	
	Inhalation	2	5	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	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	2.2789475	0.3885898
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0379825	0.0064765
% of RVNAS	25.32%	4.32%
Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	17.4381457	3.4445652
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2906358	0.0574094
% of RVAAS	170.96%	33.77%

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for clopyralid

Table A 4: Estimation of worker exposure towards clopyralid using EFSA Model ver. 30.03.3015

- **for winter wheat**

Worker exposure from residues on foliage for CHR/H/CPD			
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	cm^2/hr	*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)	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%		

- **for winter oilseed rape**

Worker exposure from residues on foliage for CHR/H/CPD			
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	cm^2/hr	*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)	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%		

- **For sugar beet**

Worker exposure from residues on foliage for CHR/H/CPD			
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	0.06	kg a.s./ha	*i_AppRate*
Number of applications	3		*i_AppNo*
Interval between multiple applications	6	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	2.6		*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)	0.18	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	cm^2/hr	*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)	5.9139199	0.6623590	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0985653	0.0110393		
% of RVNAS	65.71%	7.36%		

A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for clopyralid

Table A 5: Estimation of bystander exposure towards clopyralid using EFSA Model

- **for winter wheat**

Bystander exposure for CHR/H/CPD			
Croptype	Cereals		
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	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*

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%

- For winter oilseed rape

Bystander exposure for CHR/H/CPD			
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	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*

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%

- For sugar beet

Bystander exposure for CHR/H/CPD

Croptype	Root and tuber vegetables		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	0.06	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	0.3	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)	0.18	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*

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)	0.0913560	0.0107000	0.0382039	0.1330632
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0091356	0.0010700	0.0038204	0.0133063
% of RVAAS	5.37%	0.63%	2.25%	7.83%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.1489800	0.0138000	0.0971854	0.4435440
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0024830	0.0002300	0.0016198	0.0073924
% of RVAAS	1.46%	0.14%	0.95%	4.35%

Table A 6: Estimation of resident exposure towards clopyralid using EFSA Model

- For winter wheat

Resident exposure for CHR/H/CPD			
Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		i_FormVal
Buffer strip	2-3	m	i_Buffer
Application rate of the product	0.12	kg a.s./ha	i_AppRate
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	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
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

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)	0.0805740	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%

- For winter oilseed rape

Resident exposure for CHR/H/CPD			
Croptype	Oilseeds		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		i_FormVal
Buffer strip	2-3	m	i_Buffer
Application rate of the product	0.12	kg a.s./ha	i_AppRate
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	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
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

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)	0.0805740	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%

- For sugar beet

Resident exposure for CHR/H/CPD				
Croptype	Root and tuber vegetables			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			*i_FormVal*
Buffer strip	2-3	m		*i_Buffer*
Application rate of the product	0.06	kg a.s./ha		*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	0.3	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)	0.18	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*
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*

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)	0.0402870	0.0107000	0.0127615	0.1330632	0.1483299
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0040287	0.0010700	0.0012761	0.0133063	0.0148330
% of RVNAS	2.69%	0.71%	0.85%	8.87%	9.89%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0578400	0.0138000	0.0322348	0.4435440	0.4185310
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0009640	0.0002300	0.0005372	0.0073924	0.0069755
% of RVNAS	0.64%	0.15%	0.36%	4.93%	4.65%

A 3.4 Combined exposure calculations for clopyralid

Table A 6: Estimation of worker exposure towards clopyralid, picloram and metazachlor using EFSA Model ver. 30.03.3015

Operator exposure for CHR/H/CPD outdoor spray applications

Application rate of active substance	0.09	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	4.5	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*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		

Outdoor|Soluble concentrates, emulsifiable concentrate, etc.|Downward spraying|Vehicle-mounted

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
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	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	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	

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%
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%

Operator exposure for CHR/H/PCR outdoor spray applications

Application rate of active substance	0.0234	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	1.17	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*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
	75th centile	95th centile		
Hands	5481	20110	AOEM	
Body	3983	75386	AOEM	
Head	61	333	AOEM	
Protected hands (gloves)	38	232	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	27	171	AOEM	
Protected head (hood and face shield)	1	19	AOEM	
Inhalation	4	29	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
Water soluble bag	No		1	

Application

Exposure values	µg exposure/day applied		Reference	Comment
	75th centile	95th centile		
Hands	174	2571	AOEM	
Body	97	500	AOEM	
Head	5	14	AOEM	
Protected hands (gloves)	46	3395	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	3	7	AOEM	
Inhalation	1	3	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	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.0950823	1.0950823
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0182514	0.0182514
% of RVNAS	6.08%	6.08%
Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	11.1573738	11.1573738
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1859562	0.1859562
% of RVAAS	#DZIEL/0!	#DZIEL/0!

Operator exposure for CHR/H/MTC outdoor spray applications

Application rate of active substance	0.75	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	37.5	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*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		

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Downward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	79085	299200	AOEM	
	Body	45579	206430	AOEM	
	Head	1946	10671	AOEM	
	Protected hands (gloves)	364	7428	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	590	5484	AOEM	
	Protected head (hood and face shield)	31	604	AOEM	
	Inhalation	11	31	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	5562	32584	AOEM	
	Body	3110	16032	AOEM	
	Head	147	443	AOEM	
	Protected hands (gloves)	303	5086	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	85	209	AOEM	
	Inhalation	6	23	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	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	17.0877910	9.2156767	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2847965	0.1535946	
% of RVNAS	142.40%	76.80%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	76.2141138	47.0368930	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	1.2702352	0.7839482	
% of RVAAS	#DZIEL/0!	#DZIEL/0!	

Table A 7: Estimation of worker exposure towards clopyralid, picloram and metazachlor using EFSA Model ver. 30.03.3015

Worker exposure from residues on foliage for CHR/H/CPD			
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	0.09	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	cm^2/hr	*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%		

Worker exposure from residues on foliage for CHR/H/PCR			
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	0.0234	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)	0.0702	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	cm^2/hr	*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)	0.8775000	0.0982800	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0146250	0.0016380		
% of RVNAS	4.88%	0.55%		

Worker exposure from residues on foliage for CHR/H/MTC			
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	0.75	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)	2.25	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	cm^2/hr	*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)	28.1250000	3.1500000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.4687500	0.0525000		
% of RVNAS	234.38%	26.25%		

Table A 8: Estimation of bystander exposure towards clopyralid using EFSA Model

Bystander exposure for CHR/H/CPD			
Croptype	Oilseeds		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	0.09	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
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	100.00%		*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*10-3Pa	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*

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)	0.1370340	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%

Table A 9: Estimation of resident exposure towards clopyralid, picloram and metazachlor using EFSA Model

Resident exposure for CHR/H/CPD			
Croptype	Oilseeds		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		*i_FormVal*
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	100.00%		*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*10-3Pa	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*

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%

Resident exposure for CHR/H/PCR			
Croptype	Oilseeds		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		*i_FormVal*
Buffer strip	2-3	m	*i_Buffer*
Application rate of the product	0.0234	kg a.s./ha	*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	0.117	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)	0.0702	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*
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*

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)	0.0157119	0.0107000	0.0018935	0.0197438	0.0364832
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0015712	0.0010700	0.0001894	0.0019744	0.0036483
% of RVNAS	0.52%	0.36%	0.06%	0.66%	1.22%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0225576	0.0138000	0.0047830	0.0658125	0.0804928
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0003760	0.0002300	0.0000797	0.0010969	0.0013415
% of RVNAS	0.13%	0.08%	0.03%	0.37%	0.45%

Resident exposure for CHR/H/MTC			
Croptype	Oilseeds		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		*i_FormVal*
Buffer strip	2-3	m	*i_Buffer*
Application rate of the product	0.75	kg a.s./ha	*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	3.75	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)	2.25	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*
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*

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)	0.5035875	0.0107000	0.0606900	0.6328125	0.8370838
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0503588	0.0010700	0.0060690	0.0632813	0.0837084
% of RVNAS	25.18%	0.54%	3.03%	31.64%	41.85%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.7230000	0.0138000	0.1533000	2.1093750	2.1513893
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0120500	0.0002300	0.0025550	0.0351563	0.0358565
% of RVNAS	6.03%	0.12%	1.28%	17.58%	17.93%

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 required.