FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: PP-113H

Product name(s): BARILOCHE

Chemical active substance:

Clopyralid 100 g/L (10% w/v) SL

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: PROPLAN Plant Protection Company, S.L.

Submission date: December 2021

MS Finalisation date: August 2022; April 2023

Version history

When	What
February 2019	Initial version
December 2021	Version 2, Update for the renewal.
August 2022	Assessmeny by expert
April 2023	The final version of RR after commenting period.

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The product BARILOCHE is currently registered in Italy (16096), Spain (ES-00493), UK (Re. No. 17577), Poland (Reg. No. R-26/2018wu), Germany (Reg. No. 008865-00), Czech Republic (Reg. No. 5583-0) and Romania (Reg. No. 466PC) in Sugar beet.

This new dossier has been carried out to support the renewal of the approval of the active substance Clopyralid.

All the changes that have been made in this section, with respect to the original dossier, have been highlighted in yellow. It must be taken into account that the format of the dossier has changed.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on PP-113H / Bariloche*

Product name and code	PP-113H / Bariloche
Formulation type	formulation type [Code: SL]
Active substance(s) (incl. content)	Clopyralid; 100 g/L
Function	herbicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	SP (Bariloche: ES-00493) Italy (Reg. No. 16096) UK: (Reg. No. 17577) Romania: (Reg No: 466PC) Germany (Reg. No: 008865-00) Poland (Reg. No: R-26/2018wu) Czech Republic: (Reg. No: 5583-0)

* Information on the detailed composition of PP-113H 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 PP-113H according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	No classified
Hazard pictograms or Code(s) for hazard pictogram(s):	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	P273, P391, P501, P261, P262
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe1	To protect ground water apply this or any other product contain-ing Clopyralid every two years when the product is applied at BBCH 10-19.

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for PP-113H.

	Result	PPE / Risk mitigation measures
Operators	Acceptable	~~None Gloves~~
Workers	Acceptable	None
Bystanders	Acceptable	None
Residents	Acceptable	None

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

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	Sugar beet (BBCH 10-39)	F	Tractor boom sprayer	1 ; 1	0.125	80-400	None	AOEM model	A	A	A	A

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

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

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

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

N/A

6.2 Toxicological Information on Active Substance(s)

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

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

	Clopyralid
Common Name	Clopyralid
CAS-No.	1702-17-6
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Harmonised classification - Annex VI of Regulation (EC) No 1272/2008: Hazard classes, categories: Eye Dam. 1 Codes for hazard pictograms: GHS05 Signal word: Danger. Hazard statements: H318. Precautionary statements: P280, P305+P351+P338.
Additional C&L proposal	-
Agreed EU endpoints	
Aceptable Operator Exposure Level (AOEL)	0.15 mg/kg bw/day.
Acute Aceptable Operator Exposure Level (AAOEL)	0.17 mg/kg bw/day
Reference	EFSA 2018
Conditions to take into account/critical areas of concern with regard to toxicology	
None	None

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for PP-113H 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 PP-113H

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (OECD 423)	LD_{50} = 2.500 mg/kg bw	Yes	None	xxx 2013 (401-1-01-5762)
LD_{50} dermal, rat (OECD 402)	LD_{50} > 2.000 mg/kg bw	Yes	None	xxx 2013 (403-1-01-5763)
LC_{50} inhalation, rat (OECD 403)	LC_{50} > 6.039 mg/L air	Yes	None	xxx 2013 (405-1-01-5764)
Skin irritation, rabbit (OECD 404)	Non- irritant	Yes	None	xxx 2013 (406-1-01-5765)
Eye irritation, rabbit (OECD 405)	Not irritating to eyes	Yes	None	xxx 2013 (IO-OCDE-PH-13/0217)
Skin sensitisation, ~~mouse~~ guinea pigs (OECD 406-B~~, LLNA: BrdU~~)GPMT	Non-irritant	Yes	None	xxx 2013 (408-1-01-5767)
Supplementary studies for combinations of plant protection products	Not required	Yes	None	

Table 6.3-2: Additional toxicological information relevant for classification/labelling of PP-113H

	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 (100% w/v)	Eye Dam. 1, H318	Harmonised classification - Annex VI of Regulation (EC) No 1272/2008	Eye Dam. 1, H318
Toxicological properties of non-active substance(s) (relevant for classification of product)	Refer to part C (confidential information)			
Further toxicological information	Not required			

† EFSA proposal (EFSA Journal 2018;16(8):5389, 21 pp.):
Eye Dam. 1 - H318 'Causes serious eye damage'
Skin Irrit. 2 – H315 'Causes skin irritation'
STOT RE 2 – H373 'May cause damage to organs through pro-longed or repeated exposure'
Repr. 2 – H361d 'Suspected of damaging the unborn child'

Justifications for the proposed classification and labelling (included in the EFSA Peer review of the pesticide risk assessment of

the active substance clopyralid):

"The experts considered that classification as Repr. 2, H361d 'suspected of damaging the unborn child' may be appropriate, based on the malformations observed in rat and rabbit. The basis for no classification with regard to the developmental toxicity in the Annex VI of Regulation (EC) No 1272/2008 is unknown to EFSA. Based on the mortality observed in dams in the developmental toxicity studies in rat and rabbit at 250 mg/kg bw per day, classification as STOT RE 2, H373 'may cause damage to organs through prolonged or repeated exposure' may also be applicable.

No skin irritation was observed after single application of the substance, but clopyralid caused epidermal hyperplasia and inflammation of the dermis at all dose levels (lowest observed adverse effect level (LOAEL) 100 mg/kg body weight (bw) per day) in a 21-day dermal toxicity study in rabbits and caused marked irritation to eyes of rabbit. Accordingly, classification as Skin Irrit. 2, H315 'causes skin irritation' according to Regulation (EU) No 1272/20083 was proposed by the peer review, in addition to the harmonised classification as Eye Dam. 1, H318 'causes serious eye damage'".

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.
** Material safety data sheet by the applicant.

6.4 Toxicological Evaluation of Groundwater Metabolites

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in PP-113H are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in PP-113H

Clopyralid		
	Value	**Reference**
Dermal Absorption	Concentrate: 10% Dilution: 50%	Assessment according to Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp.
	Concentrate: 25% Dilution: 75%	Conclusion on the peer review of the pesticide risk assessment of the active substance clopyralid. EFSA Journal 2018;16(7):5389, 28 pp.*

* Default dermal absorption values according to Guidance on Dermal Absorption (EFSA PPR Panel, 2012).

6.5.1 Justification for proposed values - Clopyralid

No data on dermal absorption for Clopyralid in PP-121H 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%	SL (Soluble concentrate): 21 studies available in EFSA Journal 2017. Details and justification for grouping: Water-based formulation in which a salt of pesticide acid is dissolved in water, together with any other necessary formulants. It should be in the form of a clear or opalescent liquid, free from visible suspended matter and sediment, to be applied as a true solution of the active substance in water.	Yes
Dilution	50%		Yes

6.5.2 Justification for proposed values - Clopyralid

Not required. The product only has one active substance.

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	PP-113H / Bariloche
Formulation type	SL
Category	Herbicide
Container size(s), short description	250, 500, 1000 y 5000 HDPE
Active substance(s) (incl. content)	**Clopyralid** 1000 g/L
AOEL systemic	**0.15 mg/kg bw/d** (Based on the developmental toxicity study in rat with a maternal NOAEL of 15 mg/kg bw per day for reduced maternal body weight gain, applying an UF of 100; no correction for oral absorption is needed)
AAOEL	**0.17 mg/kg bw/day** (Based on the developmental toxicity study in rabbits with a maternal LOAEL at 50 mg/kg bw per day based on early reduction of maternal body weight and an additional UF of 3 (total 300) applied due to the basis of a LOAEL.)
Inhalation absorption	100 %
Oral absorption	**> 80%** (based on urinary excretion after low dose, repeated dose and intravenous administrations (5 mg/kg bw))
Dermal absorption	Concentrate: **10%** Dilution: **50%** (EFSA Journal 2017)

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 Central zone of EU is given in Part B, Section 0.

Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks:
		Method / Kind	Max. number	Max. application rate (kg as/ha) a) a.s. 1 b) a.s. 2	Water L/ha min / max		
Sugar beet (BBCH 10-39)	F	Tractor boom sprayer	1	0.125	80-400	-	Do not use between the 31st August and 1st March

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

The Plant Protection Product PP-113H containing 100 g/L of Clopyralid is intended to be used on sugar beet crops as an herbicide.
Operator exposure to PP-113H was not evaluated as part of the EU review of Clopyralid. Therefore, all relevant data and risk assessments are provided here and are considered adequate
A summary of the exposure models used for estimation of operator exposure to the active substances during application of PP-113H according to the critical use(s) is presented in Table 6.6-2. Outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.**. Detailed calculations are in Appendix 3.

Estimations of potential operator exposure have been undertaken for Clopyralid using the Agricultural Operator Exposure Model (AOEM), (Grosskopf et al. 2013).[1]
The AOEM is a new predictive model recently developed for the estimation of agricultural operator exposure. This model is based on data from 34 unpublished exposure studies conducted between 1994 and 2009 in different European member states, which met a set of quality criteria, e.g. GLP conformity or compliance with OECD guidance, to ensure a very high quality of the data (Grosskopf et al. 2013).
In contrast to the models currently employed to assess agricultural operator exposure in Europe (German model and UK POEM), which were developed more than 20 years ago and are based on old data and do not reflect current application equipment and practices, the AOEM does represent current application techniques and typical work conditions in Europe. Therefore, the AOEM is considered appropriate to assess the operator exposure to the herbicide PP-113H.

The AOEM allows the estimation of overall operator exposure by the models which correspond to the exposure of a professional operator (wearing personal protection equipment or not) during a whole working day comprising mixing and loading (including rinsing the containers or vessels) and application of the plant protection product (including cleaning and maintenance of the equipment). It is composed of the dermal exposure (including head, body and hands) and the inhalation exposure from both tasks. Each systemic exposure term results from the specific dermal exposure or specific inhalation exposure taking account of the dermal or inhalative absorption of the active substance. For the calculation of the overall

[1] Großkopf C, Mielke H, Westphal D, Erdtmann-Vourliotis M, Hamey P, Bouneb F, Rautmann D, Stauber F, Wicke H, Maasfeld W, Salazar JD, Chester G and Martin S, 2013. A new model for the prediction of agricultural operator exposure during professional application of plant protection products in outdoor crops. Journal für Verbraucherschutz und Lebensmittelsicherheit , 8, 143–153.

operator exposure it is assumed that, according to good agricultural practice, the operator is wearing at least one layer of work clothing completely covering the body, arms and legs when mixing and loading or applying pesticides (Grosskopf et al. 2013).
Operator exposure to PP-113H is estimated according to the AOEM model using the calculator provided in the EFSA guidance (2014) with the level of the 75th percentile.

Table 6.6-2: Exposure models for intended uses

Critical use	**Sugar beet (max. 1.25 L/ha)**
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874.

The estimations were compared to following data from the Annex 1 inclusion for Clopyralid:

End-points	**Clopyralid**	
	EU agreed endpoints *(EFSA Journal 2018)*	Endpoints used in risk assessment*
Dermal absorption	Concentrate: 25% Spray dilutions: 75%	Concentrate: **10%** Spray dilutions: **50%**
AOEL	0.15 mg/kg bw/day	**0.15** mg/kg bw/day
AAOEL	0.17 mg/kg bw/day	**0.17** mg/kg bw/day

* Guidance on Dermal Absorption (EFSA Journal 2017).

Table 6.6-3 Estimated operator exposure

Model data	**Level of PPE**	**Clopyralid**			
		Long term		**Acute**	
		Total absorbed dose (mg/kg bw/day)	**% AOEL (0.15 mg/kg bw/day)**	**Total absorbed dose (mg/kg bw/day)**	**% AAOEL (0.17 mg/kg bw/day)**
Tractor-mounted, downward spraying application to root and tuber vegetables (sugar beet), outdoor					
EFSA model 50 ha/d	No PPE (potential exposure)	0.0676796	45.12	0.4275771	251.52
	Gloves during mixing and loading + Workwear – during mixing, loading and application	0.0091281	**6.09**	0.0811906	**47.76**

Conclusion

According to the model calculations, it can be concluded that the acute risk for the operator using the PP-113H product with the tractor mounted is acceptable with the use of gloves during mixing / loading and with workwear (covered arms, body and legs) during mixing, loading and application (AAOEL wynosi 47.76%).
Long term risk for the operator using the PP-113H product with the tractor mounted is acceptable even without PPE (AOEL wynosi 45.12%)

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)

6.6.4.1 Estimation of worker exposure

Table 6.6-3 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with PP-113H according to the critical use(s). Outcome of the estimation is presented in

Critical use 1	**Sugar beet (max. 1.25 L/ha)**
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874.

Table 6.6-4. Detailed calculations are in Appendix 3.

Table 6.6-3: Exposure models for intended uses

Critical use 1	**Sugar beet (max. 1.25 L/ha)**
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874.

Table 6.6-4: Estimated worker exposure

Crop	**TC (cm^2/h)**	**Duration exposure (hours)**	**Nº Applic.** (interval- days)	**Clopyralid** Total systemic exposure(mg/kg bw/d) **% AOEL (0,15 mg/kg bw/day)**
Root and tuber vegetables (Sugar beet)	12.500 (potential exposure)	2	1	**52.08**
	1.400 (arms, body and legs covered)	2	1	**5.83**

Conclusion: 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 It is concluded that there is no risk for workers re-entering sugar beet' fields for inspection and harvesting activities after application of PP-113H.

New evaluation of the formulation taking into account these comments:
The following parameters have been modified in the model spreadsheet to adapt it to the requests of the evaluators.

- Potential: 18600 cm^2/h
- Work wear: 4400 cm^2/h
- Work wear + gloves: 430 cm^2/h
-Working rate of 8 hours per day

Worker exposure from residues on foliage for PP-121H			
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	0,125	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)	0,375	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	18600	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	4400	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	430	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)	27,9000000	6,6000000	0,6450000	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,4650000	0,1100000	0,0107500	
% of RVNAS	310,00%	73,33%	7,17%	

2. Details

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
Dermal - Potential	27,9000000	0,4650000	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*	
Dermal - Work wear - arms, body and legs covered	6,6000000	0,1100000	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Dermal - Working wear and gloves	0,6450000	0,0107500	*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Inhalation				Na for outdoor activities

Conclusions:
Taking into account the results obtained, it is observed that the use of the Bariloche product is safe for workers who wear work wear (arms, body and legs covered).

6.6.4.2 Refinement of generic DFR value (KCP 7.2)

Not required.

6.6.4.3 Measurement of worker exposure

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

6.6.5 Bystander and resident exposure (KCP 7.2.2)

6.6.5.1 Estimation of bystander and resident exposure

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

Table 6.6-5: Exposure models for intended uses

Critical use(s)	**Sugar beet (max. 1.25 L/ha)**
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874.

Table 6.6-6: 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 per kg body weight (mg/kg bw/day)	0.0209828	0.0010700	0.0010115	0.0105469	0.0217778
% of RVNAS	13.99%	0.71%	0.67%	7.03%	**14.52%**
Adult					
	Spray drift	**Vapour**	**Surface deposits**	**Entry into treated crops**	**All pathways (mean)**
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0050208	0.0002300	0.0004258	0.0058594	0.0075989
% of RVNAS	3.35%	0.15%	0.28%	3.91%	**5.07%**

Table 6.6-8: Estimated bystander exposure

1-3 year old child				
	Spray drift	**Vapour**	**Surface deposits**	**Entry into treated crops**
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0475813	0.0010700	0.0030281	0.0105469
% of RVNAS	**27.99%**	**0.63%**	**1.78%**	**6.20%**
Adult				
	Spray drift	**Vapour**	**Surface deposits**	**Entry into treated crops**
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0129323	0.0002300	0.0012839	0.0058594
% of RVNAS	**7.61%**	**0.14%**	**0.76%**	**3.45%**

Conclusion:
According EFSA model, resident and bystander exposure to Clopyralid from vehicle-mounted application outdoor to low crops (sugar beet) is below the combined AOEL. Buffer zone 2-3 m

6.6.5.2 Measurement of bystander and/or resident exposure

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

6.6.6 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	Owner
KCP 7.1.1	xxx	2013	Acute oral toxicity study of PP-113H (Clopyralid 10 % w/v) in rats xxx Report Nº: 401-1-01-5762 GLP, Unpublished	Y	PROPLAN
KCP 7.1.2	xxx	2013	Acute dermal toxicity study of PP-113H (Clopyralid 10 % w/v) in rats XXX Report Nº: 403-1-01-5763 GLP, Unpublished	Y	PROPLAN
KCP 7.1.3	xxx	2013	Acute inhalation toxicity study of PP-113H (Clopyralid 10 % w/v) in rats XXX Report Nº: 405-1-01-5764 GLP, Unpublished	Y	PROPLAN
KCP 7.1.4	xxx	2013	Acute dermal irritation study of PP-113H (Clopyralid 10 % w/v) in rabbits XXX Report Nº: 406-1-01-5765 GLP, Unpublished	Y	PROPLAN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.1.5	xxx	2013	Assessment of acute eye irritation xxx Report Nº: IO-OCDE-PH-13/0217 GLP, Unpublished	Y	PROPLAN
KCP 7.1.6	xxx	2013	Skin sensitization study of PP-113H (Clopyralid 10% w/v SL) in guinea pigs (Guinea Pig Maximization Test) xxx Report Nº: 408-1-01-5767 GLP, Unpublished	Y	PROPLAN

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Comments of zRMS:	N/A

A 2.2 Acute oral toxicity (KCP 7.1.1)

Reference:	**KCP 7.1.1**
Report	Acute oral toxicity study of PP-113H (Clopyralid 10 % w/v SL) in rats. xxx. 2012/13. **Report No. 401-1-5762.**
Guideline(s):	Yes (OECD No. 423, December 2001, EC B.1 tris, May 2008)
Deviations:	No.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No.

Materials and methods

Test material (Lot/Batch No.)	PP-113H, Bariloche (Batch No. 20110713)
Species	Rat (*Rattus norvegicus*), Wistar
No. of animals (group size)	3 females per set (total 6 rats)
Dose(s)	10 ml/kg bw
Exposure	Once by gavage, using a metal cannula attached to a syringe
Vehicle/Dilution	Distilled water
Post exposure observation period	Signs of toxicity and mortality at 30 minutes, 1, 2, 3, 4 and 6 h post dosing on the day of dosing. Twice a day for morbidity and mortality for a period of 14 days following oral dosing. The clinical signs were recorded once a day. Individual body weight was recorded prior to dosing on day 0 and on days 7 and 14 following oral dosing and at death.
Remarks	None

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of PP-113H

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD50 (mg/kg bw) (14 days)
Female rats (Set I)				
2000	0/2/3	2 and 4h on day 0	-	2500
Female rats (Set II)				
2000	1/2/3	2 h (day 0)	½-4 h (day 0)	2500

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

Table A 2: Summary of findings of acute oral toxicity study in rats of PP-113H

Mortality:	Yes (Only one mortality was observed in set II at the dose level of 2000 mg PP-113H (clopyralid 10% w/v SL)/kg body weight)
Clinical signs:	Yes / (Signs of toxicity like lethargy was observed in rats from set I and set II treated at the dose level of 2000 mg PP-113H (clopyralid 10% w/v SL)/kg body weight).
Body weight:	All the surviving rats treated at the dose level of 2000 mg PP-113H (clopyralid 10% w/v SL)/kg body weight showed normal gain in the body weight at the end of experiment.
Macroscopic examination:	**External** External examination of the terminally sacrificed and found dead rats did not reveal any abnormality of pathological significance. **Internal** Visceral examination of found dead rat revealed lungs: congestion (rat N° 4) and liver: congestion (rat N° 4) whereas the terminally sacrificed rats did not reveal any lesion of pathological significance. Lesions observed in the terminally sacrificed rats could be correlated with the test item used in the present study.

Conclusion

Under the experimental conditions, the oral LD50 of PP-113H is 2500 mg/kg bw in rats. Thus, classification is required according to Regulation (EC) No. 1272/2008.
Globally Harmonized System of Classification and Labelling of Chemicals (GHS 2011): **Category 5.**

Comments of zRMS:	**Under the experimental conditions, the oral LD50 of PP-113H is 2500 mg/kg bw in rats and then is not classified**

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

Reference:	**KCP 7.1.2**
Report	Acute dermal toxicity study of PP-113H (Clopyralid 10 % w/v SL) in rats. xxx. 2012/13. Report No. **403-1-01-5763**.
Guideline(s):	Yes ((OECD N° 402 (February 1987), EC B.3 (May 2008)).
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	PP-113H, Bariloche (Batch No. 20110713)
Species	wistar rats
No. of animals (group size)	Two groups of rats, comprising 5 males and 5 females per group. (Total: Twenty (10 males and 10 females)).
Dose(s)	2000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)

Vehicle/Dilution	Distiled water in group II.
Post exposure observation period	Signs of toxicity and mortalities at 1, 2, 3 and 5 h post dermal application on day 0. Twice a day for morbidity and mortality for a period of 14 days following dermal application . The clinical signs were recorded once a day. Individual body weight was recorded prior to dermal application on day 0 and on days 7 and 14 following dermal application.
Remarks	None

Results and discussions

Table A 3: Results of acute dermal toxicity study in rats of PP-113H

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD50 (mg/kg bw) (14 days)
5 Male rats				
Control (0.55 mL Distilled Water)	0/0/5	No signs	No death	-
2000 mg/kg bw	0/0/5	No signs	No death	> 2000
5 Female rats				
Control (0.55 mL Distilled Water)	0/0/5	No signs	No death	-
2000 mg/kg bw	0/0/5	No signs	No death	> 2000

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

Table A 4: Summary of findings of acute dermal toxicity study in rats of PP-113H

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

Conclusion

Under the experimental conditions, the dermal LD_{50} of PP-113H is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

Comments of zRMS:	**Under the experimental conditions, the dermal LD_{50} of PP-113H is higher than 2000 mg/kg bw in rats and then is not classified**

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Reference:	**KCP 7.1.3**
Report	Acute inhalation toxicity study of PP-113H (Clopyralid 10 % w/v SL) in rats. xxx. 2012/13. Report No. **405-1-01-5764.**
Guideline(s):	Yes, OECD N° 403 (September 2009) and Commission Regulation (EC) No 440/2008, No B. 2 (May 2008).
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	PP-113H, Bariloche (Batch No. 20110713)
Species	Wistar rats
No. of animals (group size)	10 rats (5 rat/sex)
Concentration(s)	6.039 mg/L air
Exposure	4 hours (nose only)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 5: Concentration(s) and exposure conditions

Nominal conc. (mg/L air)	Actual conc. (mg/L air)	MMAD * (µm)	GSD ** (µm)
46.738	6.039	-	2.73

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

Table A 6: Results of acute inhalation toxicity study in rats of PP-113H

Concentration (mg/L air)	Toxicological results *	Duration of signs	Time of death	LC_{50} (mg/L air) (14 days)
Male rats				
6.039	0/0/5	No signs	No death	> 6.039
Female rats				
6.039	0/0/5	No signs	No death	> 6.039

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

Table A 7: Summary of findings of acute inhalation toxicity study in rats of PP-113H

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed. (If yes, describe kind of signs)
Body weight:	Decrease in mean body weight was observed on day 1 while increase in the mean body weight was observed on days 3, 7 and 14 in both the sexes of rats when compared to day 0 mean body weight.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the inhalation LC_{50} of PP-113H is higher than 6.039 mg/L air in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

Comments of zRMS:	**Under the experimental conditions, the inhalation LC_{50} of PP-113H is higher than 6.039 mg/L air in rats and then is not classified**

A 2.5 Skin irritation (KCP 7.1.4)

Reference:	**KCP 7.1.4**
Report	Acute dermal irritation study of PP-113H (Clopyralid 10 % w/v SL) in rabbits. xxx 2012/13. Report No. **405-1-01-5765.**
Guideline(s):	Yes, OECD N° 404(April 2002) and (EC) No 440/2008, No B. 4 (May 2008).
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	PP-113H, Bariloche (Batch No. 20110713)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 males
Initial test using one animal	No
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None

Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 8: Skin irritation of PP-113H

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

* scores in the range of 0 to 4.

Clinical signs:	No clinical signs of toxicity were observed.

Conclusion

Under the experimental conditions, PP-113H is not a skin irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

Comments of zRMS:	**Under the experimental conditions, PP-113H is not a skin irritant and then is not Skin Irrit.2**

A 2.6 Eye irritation (KCP 7.1.5)

Reference:	**KCP 7.1.5**
Report	Assessment of acute eye irritation. xxx 2013. Report No. **IO-OCDE-PH-13/0217**.
Guideline(s):	Yes (OECD guideline No. 405 dated April 24th, 2002 and the test method B.5 of the council regulation No. 440/2008).
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	PP-113H, Bariloche (Batch No. 20110713)
Species	Rabbit, New Zealand White
No. of animals (group size)	3 males
Initial test using one animal	Yes
Exposure	0.1 mL (single instillation in conjunctival sac)
Irrigation (time point)	No
Vehicle/Dilution	None
Post exposure observation period	21 days
Remarks	None

Results and discussions

Table A 9: Eye irritation of PP-113H

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Corneal opacity	0	0	0	0	0.0	-
	Iritis	0	0	0	0	0.0	-
	Redness conjunctivae	1	1	0	0	0.3	days 1 and 2
	Chemosis conjunctivae	0	0	0	0	0.0	-
2	Corneal opacity	0	0	0	0	0.0	-
	Iritis	0	0	0	0	0.0	-
	Redness conjunctivae	1	1	0	0	0.3	days 1 and 2
	Chemosis conjunctivae	0	0	0	0	0.0	-
3	Corneal opacity	0	0	0	0	0.0	-
	Iritis	0	0	0	0	0.0	-
	Redness conjunctivae	1	0	0	0	0.0	-
	Chemosis conjunctivae	0	0	0	0	0.0	-

* scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 3 for redness of conjunctivae and 0 to 2 for iritis

Clinical signs:	Yes (a slight redness noted 1 hor after the test item instillation and totally reversible between days 1 and 2).

Conclusion

Under the experimental conditions, PP-113H is not an eye irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

Comments of zRMS:	**Under the experimental conditions, PP-113H is not an eye irritant and then is not Eye Irrit.**

A 2.7 Skin sensitisation (KCP 7.1.6)

Reference: **KCP 7.1.6**

Report	Acute dermal irritation study of PP-113H (Clopyralid 10 % w/v SL) in rabbits. xxx, 2013, Report No. **408-1-01-5767**.
Guideline(s):	Yes (OECD N° 406 (July 1992) and EC No 440/2008, B. 6 (May 2008))
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	PP-113H, Bariloche (Batch No. 20110713)
Species	Guinea pig, Hartley
No. of animals (group size)	Test substance group: 10 female guinea pigs Vehicle control goup: 5 female guinea pigs
Range finding:	Yes
Exposure (concentration(s), no. of applications)	Intradermal inductione Undiluted Topical inductione.Undiluted
Vehicle	Distilled water for intradermal injection and for topical application.
Pretreatment prior to topical application	Yes (sodium lauryl sulfate)
Reliability check	Yes
Remarks	None

Results and discussions

Table A 10: Results of skin sensitisation study of product PP-113H

	24 hours	**48 hours**	**Total number of animals affected**
	After challenge		
PP-113H	0/10	0/10	0
Test Vehicle Control Group	0/5	0/5	0

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

Clinical signs:	No clinical signs of toxicity were observed.

Conclusion

Under the experimental conditions, PP-113H is not a skin sensitiser. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

Comments of zRMS:	**Under the experimental conditions, PP-113H is not a skin sensitiser Skin.Sens.**

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

This is not an EC data requirement by Directive 91/414/EEC.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co- formulant

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

A 2.9.2 Available toxicological data for each co-formulant

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

A 2.10 Studies on dermal absorption (KCP 7.3)

Not required.

Comments of zRMS:	N/A

A 2.11 Other/Special Studies

Not required.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

Substance name	CLOPYRALID	
Product name	PP-121H	
Reference value non acutely toxic active substance (RVNAS)	0,15	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	0,17	mg/kg bw/day
Crop type	Root and tuber vegetables	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	80	L/ha
Maximum application rate of active substance	0,125	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	100,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Operator exposure for PP-121H outdoor spray applications

Application rate of active substance	0,125	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	6,25	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	19909	74139	AOEM	
	Body	12935	122660	AOEM	
	Head	324	1778	AOEM	
	Protected hands (gloves)	113	1238	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	121	914	AOEM	
	Protected head (hood and face shield)	5	101	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	927	8771	AOEM	
	Body	518	2672	AOEM	
	Head	24	74	AOEM	
	Protected hands (gloves)	115	4127	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	14	35	AOEM	
	Inhalation	3	8	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		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)	4,0607789	0,5476878	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0676796	0,0091281	
% of RVNAS	45,12%	6,09%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	25,6546242	4,8714363	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,4275771	0,0811906	
% of RVAAS	251,52%	47,76%	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

Worker exposure from residues on foliage for PP-121H			
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	0,125	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)	0,375	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)	4,6875000	0,5250000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0781250	0,0087500		
% of RVNAS	52,08%	5,83%		

A 3.3 Resident exposure calculations (KCP 7.2.2.1)

Resident exposure for PP-121H			
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	0,125	kg a.s./ha	*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	1,5625	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)	0,375	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)	0,2098281	0,0107000	0,0101150	0,1054688	0,2177775
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0209828	0,0010700	0,0010115	0,0105469	0,0217778
% of RVNAS	13,99%	0,71%	0,67%	7,03%	14,52%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,3012500	0,0138000	0,0255500	0,3515625	0,4559341
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0050208	0,0002300	0,0004258	0,0058594	0,0075989
% of RVNAS	3,35%	0,15%	0,28%	3,91%	5,07%

A 3.4 Bystander exposure calculations (KCP 7.2.2.1)

Bystander exposure for PP-121H				
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	0,125	kg a.s./ha		*i_AppRate*
Buffer strip	2-3	m		*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	1,5625	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)	0,375	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 - adul	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)	0,4758125	0,0107000	0,0302813	0,1054688
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0475813	0,0010700	0,0030281	0,0105469
% of RVAAS	27,99%	0,63%	1,78%	6,20%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0,7759375	0,0138000	0,0770313	0,3515625
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0129323	0,0002300	0,0012839	0,0058594
% of RVAAS	7,61%	0,14%	0,76%	3,45%

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)