FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 2619 A

Product name(s): KONARK

Chemical active substances:

Flufenacet, 60 g/L
Pendimethalin, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: March 2021

MS Finalisation date: May 2023; October 2023

Version history

When	What
March 2022	Updated by Applicant
May 2023	zRMS revision after commenting phase – final version of the RR
October 2023	Correction and completing document

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on KONARK *

Product name and code	Flufenacet 6% + pendimethalin 30% EC
Formulation type	Emulsifiable concentrate [Code: EC]
Active substance(s) (incl. content)	Flufenacet; 60 g/L Pendimethalin; 300 g/L
Function	Herbicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of KONARK 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:

The composition of the assessed product has been verified in terms of Regulation 2023/574 of March 2023 and no neutral ingredients prohibited in plant protection products have been identified according in Annex III to Regulation (EC) No 1107/2009.

Table 6.1-2: Justified proposals for classification and labelling for KONARK according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Skin Sens. 1, Repr. 2
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07,GHS08
Signal word	Warning
Hazard statement(s)	H317, H361d
Precautionary statement(s)	P261, P272, P280, P308+P313, P333+P313, P362, P501
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Repeated exposure may cause skin dryness or cracking [EUH066]

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

	Result	PPE / Risk mitigation measures
Operators	Acceptable	~~Work wear (arms, body and legs covered) M/L and A + gloves M/L~~ Wear protective clothing, protective gloves and face/eye protection when mixing, loading and handling
Workers	Acceptable	Work wear (arms, body and legs covered) - ~~time period of 32 days after application~~
Residents & Bystanders	Acceptable	Post -emergence use - ~~dirft reduction technology and 5 m buffer zone~~ None Pre -emergence use – 2-3 m buffer zone

No unacceptable risk for bystanders and residents was identified when the product is used as intended. No specific PPE is necessary.
No unacceptable risk for operators and workers was identified when the product is used as intended and provided that the PPE stated in Table 6.1-3 are applied.
A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders is presented in the following table.

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

1	2	3	4	5	6	7	8	9	10			
Use-No.*	**Crops and situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Application**		**Application rate**		**PHI (d)**	**Remarks:** (e.g. safener/synergist (L/ha)) critical gap for operator, worker, resident or bystander exposure based on [Exposure model]	**Acceptability of exposure assessment**			
			Method / Kind (incl. application technique ***)	**Max. number (min. interval between applications)** a) per use b) per crop/ season	**Max. application rate kg as/ha** a) Flufenacet b) Pendimethalin	**Water L/ha** min / max			**Operator**	**Worker**	**Residents**	**Bystander**
1	Winter wheat, Winter barley Winter rye Triticale Pre emergence (BBCH 00 – 09)	F	Spraying, LCTM	a) 1 1	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stage Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for				
2	Winter wheat, Winter barley Winter rye Triticale	F	Spraying, LCTM	a) 1 b) 1	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufe-	200-400						

1	2	3	4	5	6	7	8	9	10
	Post emergence (BBCH 11 – 25)				nacet + 1.2 pendimethanil			plant protection products; EFSA Journal 2014;12(10):3874	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

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

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)

	Flufenacet	**Pendimethalin**
Common Name	Flufenacet	Pendimethalin
CAS-No.	142459-58-3	40487-42-1
Classification and proposed labelling		
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	**Hazard classes, categories:** Acute Tox. 4, STOT RE 2, Skin Sens. 1 **Codes for hazard pictograms:** GHS07, GHS08 **Signal word:** Warning **Hazard statements:** H302, H373, H317	**Hazard classes, categories:** ~~Skin sens. 1~~ ~~Skin Sens.~~1 Repr.2 **Codes for hazard pictograms:** ~~GHS07~~ GHS08 **Signal word:** Warning **Hazard statements:** ~~H317~~ Repr. 2, H361d
Additional C&L proposal	-	-
Agreed EU endpoints		
AOEL systemic	0.017 mg/kg bw/d	0.17 mg/kg bw/d (corrected for 57% oral absorption
Reference	SANCO 7469/VI/98-Final	SANTE/11656/2016, 18 May 2017 rev.2 the 18th ATP (Regulation (EU) 2022/692) to Regulation (EC) 1272/2008 **ECHA Commttee for Risk Assessment RAC pendimethalin Adopted 8 October 2020**
Conditions to take into account/critical areas of concern with regard to toxicology		

	Flufenacet	Pendimethalin
According to SANCO 7469/VI/98-Final for Flufenacet and SANCO/7477/VI/98-final for Pendimethalin	The review has identified acceptable exposure scenarios for operators, workers and bystanders,which require, however, confirmation for each plant protection product.	The review has identified acceptable exposure scenarios for operators, workers and bystanders,which require, however, confirmation for each plant protection product.

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for KONARK 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 KONARK

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral (calculation)	> 2000 mg/kg bw	Yes	None	Calculated
LD_{50} dermal (calculation)	> 2000 mg/kg bw	Yes	None	Calculated
LC_{50} inhalation (calculation)	None	Yes	None	Calculated
Skin irritation (calculation)	Non-irritant	Yes	None	Calculated
Eye irritation, rabbit (OECD 405)	Non-irritant	Yes	None	xxx
Skin sensitisation, (calculation)	Sensitising	Yes	H317	Calculated
Supplementary studies for combinations of plant protection products	No data – not required			

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

	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)	Flufenacet (6% (w/w))	H302, H373, H317	Reg. 1272/2008	H317
	Pendimethalin (30% (w/w)	~~H317~~ H361d	Reg. 1272/2008	~~H317~~ H361d
Toxicological properties of non-active substance(s) (relevant for classification of product)	-	-	-	-
Further toxicological	No data – not			

	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)
information	required			

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

6.4 Toxicological Evaluation of Groundwater Metabolites

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

Nonetheless, M455H001 was tested for its genotoxic potential in an Ames test, a chromosome aber-ration test, a mouse lymphoma test and an in vivo micronucleus assay. In conclusion, M455H001 is not considered to be a relevant metabolite. : Rrelevance assessment of 455H001 was tested for its gen-otoxic potential in an Ames test, a chromosome aber-ration test, a mouse lymphoma test and an in vivo mic Since the potential exposure to M455H001 is < 0.75, a further assessment in Step 5 is not required. conucleus assay. In conclusion, M455H001 is not considered to be a relevant metabolite

6.4.1 Metabolite - FOE 5043 sulfonic acid

An overview of the results of the accepted toxicological studies for groundwater metabolite FOE 5043 sulfonic acid is given in the following table. Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).

Table 6.4-1: Summary of the results of toxicity studies for FOE 5043 sulfonic acid

Type of test, species (Guideline)	Result	Acceptability	Reference*
Acute oral toxity with FOE 5043 sulfonic acid (OECD 401)	not toxic	Yes	*DAR of Flufenacet* (F. Krötinger, 1998)
Salmonella/microsome with FOE 5043 sulfonic acid	non-genotoxic	Yes	*DAR of Flufenacet* (B. Herbold, 2000)

* indicates that a study was reviewed at EU level

Conclusion:
According to the "*DAR of Flufenacet* - Addendum to Annex B.5: mammalian toxicology – January 2001" the following information on the toxicity of FOE sulfonic acid are available: the acute oral LD50 of FOE sulfonic acid is > 2000 mg/kg bw.
According to the "*DAR of Flufenacet* - Addendum to Annex B.5: mammalian toxicology – January 2001" the following information on the genotoxicity of FOE sulfonic acid are available: FOE sulfonic acid is considered to be non-mutagenic without and with S9 mix in the plate incorporation as well as in the pre-incubation modification of the Salmonella/microsome test.

6.4.2 Metabolite - FOE oxalate (M01)

No toxicity studies on FOE oxalate metabolite are reported in DAR of Flufenacet, therefore genotoxicity predictions have been performed with VEGA v1.1.4 for FOE oxalate and provided by applicant Sharda. The predicted endpoints resulted as non-mutagenic, non-carcinogenic and non-developmental toxicant (*VEGA v1.1.4 mutagenicity, carcinogenicity and developmental toxicity evaluation of Flufenacet metabolite FOE Oxalate report*)-see KCP 7.4 report.

6.5 Dermal Absorption (KCP 7.3)

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

Table 6.5-1: Dermal absorption rates for active substances in KONARK

	Flufenacet		Pendimethalin	
	Value	**Reference**	**Value**	**Reference**
~~Concentrate~~	~~25%~~	~~EFSA Journal 2017;15(6):4873~~	~~25%~~	~~EFSA Journal 2017;15(6):4873~~
~~Dilution~~	~~70%~~		~~70%~~	
	Value	**Reference**	**Value**	**Reference**
Concentrate	0.40%	New study reported in Appendix 2 – Nabanita Sam, 2022	0.48%	New study reported in Appendix 2 – Nabanita Sam, 2022
Dilution	9.5%		12%	

6.5.1 Justification for proposed values – Flufenacet

~~No data on dermal absorption for Flufenacet in KONARK 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 Flufenacet

	~~Value~~	~~Justification for value~~	~~Acceptability of justification~~
~~Concentrate~~	~~25%~~	~~EFSA Journal 2017;15(6):4873~~	~~text~~
~~Dilution~~	~~70%~~		~~text~~

Proposed dermal absorption rates for Flufenacet are based on dermal absorption studies on formulation FLUFENACET 6% + PENDIMETHALIN 30% EC. The study results are summarised in the following table. Full summaries of studies on the dermal absorption of FLUFENACET 6% + PENDIMETHALIN 30% EC that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

Table 6.5-3: Summary of in vitro human dermal absorption

Test	Concentrate		Spray dilution (dilution concentration)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference*
In vitro (human)	0.40%		9.5 %	SHA 2619 A / KONARK	Yes / No / Supplementary	Yes (see Appendix A 2.10)	Justification accepted. Endpoint can be used for current product / ~~Justification not accepted. Endpoint cannot be used for current product.~~	Nabanita Sam, 2022

* indicates that a study was reviewed at EU level

6.5.2 Justification for proposed values – Pendimethalin

No data on dermal absorption for Pendimethalin in KONARK 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 6.5-4: Default dermal absorption rates for Pendimethalin

	~~Value~~	~~Justification for value~~	~~Acceptability of justification~~
~~Concentrate~~	~~25%~~	~~EFSA Journal 2017;15(6):4873~~	~~text~~
~~Dilution~~	~~70%~~		~~text~~

Proposed dermal absorption rates for Pendimethalin are based on dermal absorption studies on formulation FLUFENACET 6% + PENDIMETHALIN 30% EC. The study results are summarised in the following table. Full summaries of studies on the dermal absorption of FLUFENACET 6% + PENDIMETHALIN 30% EC that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

Table 6.5-5: Summary of in vitro human dermal absorption

Test	Concentrate	Spray dilution (dilution concentration)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference*
In vitro (human)	0.48%	12 %	SHA 2619 A / KONARK	Yes / No / Supplementary	Yes (see Appendix A 2.10)	Justification accepted. Endpoint can be used for current product / ~~Justification not accepted. Endpoint cannot be used for current product.~~	Nabanita Sam, 2022

* indicates that a study was reviewed at EU leve

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	Flufenacet 6% + pendimethalin 30% EC	
Formulation type	EC	
Category	Herbicide	
Active substance(s) (incl. content)	**Flufenacet** 60 g/L	**Pendimethalin** 300 g/L
AOEL systemic	0.017 mg/kg bw/d	0.17 mg/kg bw/d
Inhalation absorption	100%	100%
Oral absorption	100%	57% ((see EFSA Journal 2016;14(3):4420).
Dermal absorption	Concentrate: ~~25%~~ 0.40% Dilution: ~~70% (Default)~~ 9.5%	Concentrate: ~~25%~~ 0.48% Dilution: ~~70% (Default)~~ 12%

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 southern zone is given in Part B, Section 0.

Justification

All the intended GAP are identical regarding application rate, crops, number of applications, dilution rate, etc. Therefore, only one critical GAP is identified.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure model used for estimation of operator exposure to the active substances during application of KONARK according to the critical use is presented in Table 6.6-2. The outcome of the estimation is presented in
New calculations have been conducted considering endpoints from dermal absorption study conducted with KONARK (Flufenacet 0.40% for concentrate and 9.8% for dilution and Pendimethalin 0.48% for concentrate and 12% for dilution).
Please refer to point A 2.10 for details about dermal absorption values.
Table 6.6-3 (longer term exposure). Detailed calculations are in 0.

Table 6.6-2: Exposure models for intended uses

Critical use	Cereals Pre emergence (max. 4 L product/ha) Cereals Post emergence (max. 4 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

New calculations have been conducted considering endpoints from dermal absorption study conducted

with KONARK (Flufenacet 0.40% for concentrate and 9.8% for dilution and Pendimethalin 0.48% for concentrate and 12% for dilution).
Please refer to point A 2.10 for details about dermal absorption values.

Table 6.6-3: Estimated operator exposure (longer term exposure)

		Flufenacet		Pendimethalin	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops					
Application rate		0.24 kg a.s./ha		1.2 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Without RPE/PPE	~~0.2580282~~ 0.0082562	~~1518~~ 49	~~0.9153750~~ 0.0429718	~~538~~ 25
	Work wear (arms, body and legs covered) M/L and A ~~+ gloves M/L and A~~	~~0.0071456~~ 0.0053740	~~**42**~~ **32**	~~0.0280101~~ 0.0282907	~~**16**~~ **17**

Conclusion
According to the AOEM model, calculations, it can be concluded that the risk for the operator using KONARK is acceptable ~~with~~ without the use of gloves and working clothing (long sleeved shirt and trousers) during mixing/loading and application.

Implication for labelling: ~~P280: Wear protective gloves, protective clothing~~ None

Accepted

6.6.2.2 Measurement of operator exposure

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

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with KONARK according to the critical use. Outcome of the estimation is presented in Table 6.6-5 (longer term exposure). Detailed calculations are in 0.

Table 6.6-4: Exposure models for intended uses

Critical use	Cereals Pre emergence (max. 4 L product/ha) Cereals Post emergence (max. 4 L product/ha)

Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

KONARK is intended to be applied before and after emergence of crop in cereals according to intended GAP. For pre-emergence use, crop has not emerged and, therefore, there is not foliar residue (DFR = 0) and there is not possibility of transference of those residues to workers (TC = 0) when re-entering in the treated crops. In consequence, exposure of worker will be negligible.

Therefore, only calculations for post-emergence use have been conducted.

New calculations have been conducted considering endpoints from dermal absorption study conducted with KONARK (Flufenacet 0.40% for concentrate and 9.8% for dilution and Pendimethalin 0.48% for concentrate and 12% for dilution).
Please refer to point A 2.10 for details about dermal absorption values.

Table 6.6-5: Estimated worker exposure (longer term exposure) using the EFSA Model

		Flufenacet		**Pendimethalin**	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Inspection, irrigation/Outdoor Work rate: 2 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days					
Number of applications and application rate		1 x 0.24 kg a.s./ha		1 x 1.2 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm²/person/h	~~0.2100000~~ 0.0285000	~~1235~~ 168	~~1.0500000~~ 0.1800000	~~618~~ 106
	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	~~0.0235200~~ 0.0031920	~~138~~ 19	~~0.1176000~~ 0.0201600	~~69~~ 12
~~**Proposal of Re-entry period of 32 days**~~ ~~Inspection, irrigation/Outdoor~~ ~~Work rate: 2 hours/day,~~ ~~DT_{50}: 30 days~~ ~~DFR: 1.43 µg/cm2/kg a.s./ha~~ ~~Interval between treatments: 365 days~~					
~~Number of applications and application rate~~		~~1 x 0.24 kg a.s./ha~~		~~1 x 1.2 kg a.s./ha~~	
Body weight: 60 kg	~~Potential~~ ~~TC: 12500 cm²/person/h~~	~~0.1001000~~	~~589~~	~~0.5005000~~	~~294~~
	~~Work wear (arms, body and legs covered)~~ ~~TC: 1400 cm²/person/h~~	~~0.0112112~~	~~66~~	~~0.0560560~~	~~33~~

~~It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and without personal protective equipment, for maintenance activities when for re-entering~~

~~cereals KONARK a time period of 32 days after application is respected.~~

It is concluded that no unacceptable risk is anticipated for the worker re-entering the treated crop even without suitable protective clothing. Implication for labelling **Work wear (arms, body and legs covered**

Accepted

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm2 per kg s.a/ha.

~~**Refinement**~~

~~Proposal of Re-entry period~~

~~The Applicant propose to consider as refinement a re-entry period of 32 days. Therefore we propose to calculate DFR value 32 days for cereals .~~

~~Body weight 60 kg.~~

~~DFR_t is calculated according the following formula:~~

~~$DFR_T = DFR_0 \times e^{-k_i t}$~~

~~Where:~~

~~DFR_T – Dislodgeable foliar residue at the time of re-entry (µg/cm^2)~~

~~DFR_0 – Dislodgeable foliar residue just after application (µg/cm^2)~~

~~k Degradation constant (days $^{-1}$), calculated from the half life time:~~

~~$k = ln(2)/DT_{50}$;~~

~~DT_{50} – Foliar half-life time (days)~~

~~t Re-entry interval (days)~~

~~Dislodgeable foliar residue just after application is calculated as:~~

~~$DFR_0 = DFR_{def} \times MAF$~~

~~Where:~~

~~DFR_{def} default value (If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm^2 per kg s.a/ha)~~

~~MAF_m (multiple application factor for mean residue data for *n* application) is:~~

~~$MAF = (1-e^{-nki})/(1-e^{-ki})$~~

~~where:~~

~~n is the number of applications~~

~~k is the rate constant for foliar dissipation $k = ln(2)/DT_{50}$;~~

~~i is the interval between applications (days)~~

~~DFR factor was calculated for every crop based on above formula and according to the EFSA Journal 2014;12(10):3874[1], corresponding to a half-life $_{foliar}$ of 30 days.~~

~~**Therefore for 32 days of re-entry interval:**~~

~~Flufenacet:~~

~~For cereals, a number of 1 applications and MAF is 1.0. The following DFR value is calculated:~~

~~$DFR_0 = DFR_{def} \times 1.0 = 3.0$ µg/cm² (where $DFR_{def} = 3$ µg/cm² per kg s.a/ha)~~

~~$DFR_T = DFR_0 \times e^{-k,t} = 3.0$ µg/cm² × 0.766 = 1.43 µg/cm²~~

~~Therefore for $DFR_T = DFR_{def\ ref} \times MAF = 1.43$ µg/cm² the $DFR_{def\ ref} = 1.43$ µg/cm² per kg s.a/ha~~

~~Pendimethalin:~~

~~For cereals, a number of 1 applications and MAF is 1.0. The following DFR value is calculated:~~

~~DFR0 = DFRdef × 1.0 = 3.0 µg/cm2 (where DFRdef = 3 µg/cm2 per kg s.a/ha)~~

~~$DFR_T = DFR_0 \times e^{-k,t} = 3.0$ µg/cm2 × 0.766= 1.43 µg/cm2~~

~~Therefore for $DFR_T = DFR_{def\ ref} \times MAF = 1.43$ µg/cm2 the $DFR_{def\ ref} = 1.43$ µg/cm2 per kg s.a/ha~~

6.6.3.3 Measurement of worker exposure

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

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

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

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

Table 6.6-6 shows the exposure model(s) used for estimation of resident and bystander exposure to Flufenacet and Pendimethalin. The outcome of the estimation is presented in
KONARK ~~is intended to be applied before and after emergence of crop in cereals according to intended GAP. For pre-emergence use, crop has not emerged and, therefore, there is not foliar residue (DFR = 0) and there is not possibility of transference of those residues to any person re-entering in the treated crops (TC = 0).~~
~~Thus, resident was estimated with the EFSA AOEM by considering no dermal contact with sprayed crop foliage during re-entry for pre-emergence use~~.

[1] Guidance of EFSA (EFSA Journal 2014;12(10):3874): "Guidance on the assessment of exposure of operators. workers. residents and bystanders in risk assessment for plant protection products"

Table 6.6-7: Estimated resident exposure (longer term exposure) Pre-emergence use

		Flufenacet		Pendimethalin	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to bare soil Buffer zone: 2-3 (m) Drift reduction technology: yes Entry into treated crops : negligeable (pre emergence use) DT_{50}: 30 days DFR: 0 µg/cm^2/kg a.s./ha Interval between treatments: 365 days					
Number of applications and application rate		1 x 0.24 kg a.s./ha		1 x 1.2 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0026988	66.32	0.0563754	33.16
	Vapour (75th perc.)	0.0010700	6.29	0.0010700	0.63
	Deposits (75th perc.)	0.0005723	7.77	0.0063929	3.76
	Re-entry (75th perc.)	0.0000000	0.00	0.0000000	0.00
	Sum (mean)	0.0019310	48.51	0.0367975	21.65
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0026988	15.88	0.0134940	7.94
	Vapour (75th perc.)	0.0002300	1.35	0.0002300	0.14
	Deposits (75th perc.)	0.0005723	3.37	0.0028616	1.68
	Re-entry (75th perc.)	0.0000000	0.00	0.0000000	0.00
	Sum (mean)	0.0019310	11.36	0.0087349	5.14

New calculations have been conducted considering endpoints from dermal absorption study conducted with KONARK (Flufenacet 0.40% for concentrate and 9.8% for dilution and Pendimethalin 0.48% for concentrate and 12% for dilution).
Please refer to point A 2.10 for details about dermal absorption values.
Table 6.6-8 (longer-term bystander exposure). Detailed calculations are in 0.

Table 6.6-6: Exposure models for intended uses

Critical use	Cereals Pre emergence (max. 4 L product/ha) Cereals Post emergence (max. 4 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

KONARK is intended to be applied before and after emergence of crop in cereals according to intended GAP. For pre-emergence use, crop has not emerged and, therefore, there is not foliar residue (DFR = 0) and there is not possibility of transference of those residues to any person re-entering in the treated crops (TC = 0).
Thus, resident was estimated with the EFSA AOEM by considering no dermal contact with sprayed crop foliage during re-entry for pre-emergence use.

~~**Table 6.6-7: Estimated resident exposure (longer term exposure) Pre-emergence use**~~

		~~**Flufenacet**~~		~~**Pendimethalin**~~	
~~**Model data**~~		~~**Total absorbed dose (mg/kg bw/day)**~~	~~**% of systemic AOEL**~~	~~**Total absorbed dose (mg/kg bw/day)**~~	~~**% of systemic AOEL**~~
~~Tractor mounted boom spray application outdoors to bare soil~~ ~~Buffer zone: 2-3 (m)~~ ~~Drift reduction technology: yes~~ ~~Entry into treated crops : negligeable (pre-emergence use)~~ ~~DT_{50}: 30 days~~ ~~DFR: 0 µg/cm²/kg a.s./ha~~ ~~Interval between treatments: 365 days~~					
~~Number of applications and application rate~~		~~1 x 0.24 kg a.s./ha~~		~~1 x 1.2 kg a.s./ha~~	
~~Resident child~~ ~~Body weight: 10 kg~~	~~Drift (75th perc.)~~	~~0.0026988~~	~~66.32~~	~~0.0563754~~	~~33.16~~
	~~Vapour (75th perc.)~~	~~0.0010700~~	~~6.29~~	~~0.0010700~~	~~0.63~~
	~~Deposits (75th perc.)~~	~~0.0005723~~	~~7.77~~	~~0.0063929~~	~~3.76~~
	~~Re-entry (75th perc.)~~	~~0.0000000~~	~~0.00~~	~~0.0000000~~	~~0.00~~
	~~**Sum (mean)**~~	~~0.0019310~~	~~48.51~~	~~0.0367975~~	~~21.65~~
~~Resident adult~~ ~~Body weight: 60 kg~~	~~Drift (75th perc.)~~	~~0.0026988~~	~~15.88~~	~~0.0134940~~	~~7.94~~
	~~Vapour (75th perc.)~~	~~0.0002300~~	~~1.35~~	~~0.0002300~~	~~0.14~~
	~~Deposits (75th perc.)~~	~~0.0005723~~	~~3.37~~	~~0.0028616~~	~~1.68~~
	~~Re-entry (75th perc.)~~	~~0.0000000~~	~~0.00~~	~~0.0000000~~	~~0.00~~
	~~**Sum (mean)**~~	~~0.0019310~~	~~11.36~~	~~0.0087349~~	~~5.14~~

New calculations have been conducted considering endpoints from dermal absorption study conducted with KONARK (Flufenacet 0.40% for concentrate and 9.8% for dilution and Pendimethalin 0.48% for concentrate and 12% for dilution).
Please refer to point A 2.10 for details about dermal absorption values.

Table 6.6-8: Estimated resident exposure (longer term exposure) – Post emergence

		Flufenacet		**Pendimethalin**	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to Post emergence and Pre emergence Buffer zone: ~~5 (m)~~ 2-3 m Drift reduction technology: ~~yes~~ no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days					
Number of applications and application rate		1 x 0.24 kg a.s./ha		1 x 1.2 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	~~0.0075009~~ 0.0030832	~~44.12~~ 18.14	~~0.0375045~~ 0.0194381	~~22.06~~ 11.43
	Vapour (75th perc.)	0.0010700	6.29	0.0010700	0.63
	Deposits (75th perc.)	~~0.0005423~~	~~3.19~~	~~0.0026257~~	~~1.54~~

		0.0005268	3.10	0.0026520	1.46
	Re-entry (75th perc.)	~~0.0283500~~ 0.0038475	~~166.76~~ 22.63	~~0.1417500~~ 0.0243000	~~83.38~~ 14.29
	Sum (mean)	~~0.0282400~~ 0.0062265	~~166.12~~ 36.63	~~0.1368529~~ 0.0331161	~~80.50~~ 19.48
Resident adult Body weight: 60 kg	Drift (75th perc.)	~~0.0013669~~ 0.0007343	~~8.04~~ 4.32	~~0.0068345~~ 0.0046348	~~4.02~~ 2.73
	Vapour (75th perc.)	0.0002300	1.35	0.0002300	0.14
	Deposits (75th perc.)	~~0.0002351~~ 0.0001553	~~1.38~~ 0.91	~~0.0011753~~ 0.0009811	~~0.69~~ 0.58
	Re-entry (75th perc.)	~~0.0157500~~ 0.0021375	~~92.65~~ 12.57	~~0.0784500~~ 0.0135000	~~46.32~~ 7.94
	Sum (mean)	~~0.0136775~~ 0.0023975	~~80.46~~ 14.10	~~0.0674676~~ 0.0139174	~~39.69~~ 8.19

~~It is acknowledged, that the TC values considered in the EFSA Guidance/EFSA Calculator (2015) for the estimation of the resident exposure during entry into treated crops, i.e. 7500 cm2/h (75th percentile) and 5980 cm2/h (mean) [the total potential TC value for a worker performing inspection activities] are quite conservative for this case. Therefore, Sharda proposes to refine the risk re-entering the treated crop as follows as a realistic worst case for post-emergence applications:~~
~~It is considered that a child re-entering the treated crop will wear clothes covering arms, body and legs. Therefore, a refinement is proposed, for resident exposure during "entry into treated crops" using the TC values for a worker re-entering the field for inspection/irrigation tasks assuming arms body and legs are covered, i.e. 1400 cm2/h (75th percentiles); 1100 cm2/h (mean). Since there are no TC values available for children, a factor of 0.3 is applied to adult TC values, i.e. 420 cm2/h (75th percentiles); 330 cm2/h (mean).~~

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

		~~Flufenacet~~		**~~Pendimethalin~~**	
~~Model data~~		**~~Total absorbed dose (mg/kg bw/day)~~**	**~~% of systemic AOEL~~**	**~~Total absorbed dose (mg/kg bw/day)~~**	**~~% of systemic AOEL~~**
~~Tractor mounted boom spray application outdoors to low crops (cereals)~~ ~~Buffer zone: 5 (m)~~ ~~Drift reduction technology: yes~~ ~~DT_{50}: 30 days~~ ~~DFR: 3 µg/cm²/kg a.s./ha~~ ~~TC child = 420 cm2/h (75th percentiles)~~ ~~330 cm2/h (mean)~~ ~~TC adult = 1400 cm2/h (75th percentiles)~~ ~~1100 cm2/h (mean)~~ ~~Interval between treatments: 365 days~~					
~~Number of applications and application rate~~		~~1 x 0.24 kg a.s./ha~~		~~1 x 1.2 kg a.s./ha~~	
~~Resident child Body weight: 10 kg~~	~~Drift (75th perc.)~~	~~0.0075009~~	~~44.12~~	~~0.0375045~~	~~22.06~~
	~~Vapour (75th perc.)~~	~~0.0010700~~	~~6.29~~	~~0.0010700~~	~~0.63~~
	~~Deposits (75th perc.)~~	~~0.0005423~~	~~3.19~~	~~0.0026257~~	~~1.54~~
	~~Re-entry (75th perc.)~~	~~0.0052920~~	~~31.13~~	~~0.0264600~~	~~15.56~~
	~~Sum (mean)~~	~~0.0097936~~	~~57.61~~	~~0.0446209~~	~~26.25~~

~~Resident adult Body weight: 60 kg~~	~~Drift (75th perc.)~~	~~0.0013669~~	~~8.04~~	~~0.0068345~~	~~4.02~~
	~~Vapour (75th perc.)~~	~~0.0002300~~	~~1.35~~	~~0.0002300~~	~~0.14~~
	~~Deposits (75th perc.)~~	~~0.0002351~~	~~1.38~~	~~0.0011753~~	~~0.69~~
	~~Re-entry (75th perc.)~~	~~0.0029400~~	~~17.29~~	~~0.0147000~~	~~8.65~~
	~~**Sum (mean)**~~	~~0.0034295~~	~~20.17~~	~~0.0162276~~	~~9.55~~

6.6.4.2 Measurement of resident and/or bystander exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Flufenacet and Pendimethalin will not be exceeded under condi-tions 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.

6.6.5 Combined exposure

The product is a mixture of two active substances.

6.6.5.1 Exposure assessment of Flufenacet and Pendimethalin in KONARK

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

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from Table 6.6 9. converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-10: Risk assessment from combined exposure (longer term exposure)

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Cereals Operators – Work wear (arms, body and legs covered) M/L and A+gloves M/L	Flufenacet	~~0.42~~ 0.32
	Pendimethalin	~~0.16~~ 0.17
	Cumulative risk operators (HI)	**~~0.58~~ 0.49**
Cereals Workers – Work wear (arms, body and legs covered) - ~~time period of 32 days after application~~	Flufenacet	~~0.66~~ 0.19
	Pendimethalin	~~0.33~~ 0.12
	Cumulative risk workers (HI)	**~~0.99~~ 0.31**
Cereals Resident – child Buffer zone: ~~5 (m)~~ 2-3 (m) ~~Drift reduction~~ Post emergence	**Flufenacet**	
	Drift	~~0.44~~ 0.18
	Vapour	0.06
	Deposits	0.03
	Re-entry	~~0.31~~ 0.22

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Sum of all pathways	~~0.58~~ 0.37
	Pendimethalin	
	Drift	~~0.22~~ 0.11
	Vapour	0.01
	Deposits	0.01
	Re-entry	~~0.16~~ 0.14
	Sum of all pathways	~~0.26~~ 0.19
	Cumulative risk resident – child (HI)	
	Drift	~~0.68~~ 0.29
	Vapour	0.07
	Deposits	0.04
	Re-entry	~~0.47~~ 0.36
	Sum of all pathways	~~0.85~~ 0.56
Resident - adult Buffer zone: ~~5(m)~~ 2-3 (m) ~~Drift reduction~~ Post emergence and Pre emergence	**Fluometuron**	
	Drift	~~0.08~~ 0.04
	Vapour	0.01
	Deposits	0.01
	Re-entry	~~0.17~~ 0.13
	Sum of all pathways	~~0.20~~ 0.14
	Pendimethalin	
	Drift	~~0.04~~ 0.03
	Vapour	0.01
	Deposits	~~0.07~~ 0.06
	Re-entry	0.08
	Sum of all pathways	~~0.10~~ 0.08
	Cumulative risk resident – adult (HI)	
	Drift	~~0.12~~ 0.07
	Vapour	0.02
	Deposits	~~0.08~~ 0.07
	Re-entry	~~0.25~~ 0.21
	Sum of all pathways	~~0.30~~ 0.22
~~**Cereals**~~ ~~Resident – child~~ ~~Buffer zone: 2-3 (m)~~ ~~Drift reduction~~ ~~Pre-emergence~~	~~**Flufenacet**~~	
	~~Drift~~	~~0.66~~
	~~Vapour~~	~~0.06~~
	~~Deposits~~	~~0.08~~
	~~Re-entry~~	~~0.00~~
	~~Sum of all pathways~~	~~0.49~~

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	~~**Pendimethalin**~~	
	~~Drift~~	~~0.33~~
	~~Vapour~~	~~0.01~~
	~~Deposits~~	~~0.04~~
	~~Re-entry~~	~~0.00~~
	~~Sum of all pathways~~	~~0.22~~
	~~**Cumulative risk resident – child (HI)**~~	
	~~Drift~~	~~0.99~~
	~~Vapour~~	~~0.07~~
	~~Deposits~~	~~0.12~~
	~~Re-entry~~	~~0.00~~
	~~Sum of all pathways~~	~~0.71~~
~~Resident – adult~~ ~~Buffer zone: 2-3 (m)~~ ~~Drift reduction~~ ~~Pre-emergence~~	~~**Fluometuron**~~	
	~~Drift~~	~~0.16~~
	~~Vapour~~	~~0.01~~
	~~Deposits~~	~~0.03~~
	~~Re-entry~~	~~0.00~~
	~~Sum of all pathways~~	~~0.11~~
	~~**Pendimethalin**~~	
	~~Drift~~	~~0.08~~
	~~Vapour~~	~~0.001~~
	~~Deposits~~	~~0.02~~
	~~Re-entry~~	~~0.00~~
	~~Sum of all pathways~~	~~0.05~~
	~~**Cumulative risk resident – adult (HI)**~~	
	~~Drift~~	~~0.24~~
	~~Vapour~~	~~0.01~~
	~~Deposits~~	~~0.05~~
	~~Re-entry~~	~~0.00~~
	~~Sum of all pathways~~	~~0.16~~

According to the EFSA calculator, when a 2-3 m buffer zone is employed and drift reduction technology is incorporated, the risk for residents(child and adult) can be considered as acceptable.

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 7.1.5	xxx	2017	Flufenacet 6% + Pendimethalin 30% EC: Acute eye irritation/corrosion study in rabbit (OECD guideline No. 405) INTOX PVT. LTD., Company Report No. R/16261/AEI/17 GLP, Unpublished	Y	Sharda Cropchem Limited
KCP 7.6.2	Nabanita Sam	2022	In vitro percutaneous dermal absorption study of FLUFENACET 6% + PENDIMETHALIN 30% EC, through human skin. Eurofins Advinus Limited, Study No. G24217 GLP, Unpublished	N	Sharda Cropchem Limited

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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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**
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Comments of zRMS:	N/A

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	**The acute oral toxicity of Pendimethalin 30% + Flufenacet 6% EC was estimated to be > 2000 mg/kg.** **Therefore, according to the Regulation EC No. 1272/2008, Pendimethalin 30% w/v + Flufenacet 6% w/v EC is not classified.** **No signal word or hazard statement is required for this hazard**

Acute toxicity studies for Pendimethalin 30% + Flufenacet 6% EC were **not** evaluated as part of the EU review of a pendimethalin. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Pendimethalin 30% + Flufenacet 6% EC can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The acute oral toxicity of Pendimethalin 30% + Flufenacet 6% EC was calculated as follow:

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

$$ATE_{mix} = \frac{100}{\frac{5.66}{500} + \frac{xxx}{500}} = 5889\ mg/kg\ bw$$

The acute oral toxicity of Pendimethalin 30% + Flufenacet 6% EC was estimated to be > 2000 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Pendimethalin 30% w/v + Flufenacet 6% w/v EC is **not classified**. No signal word or hazard statement is required for this hazard

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

Comments of zRMS:	**There is no co-formulant in the Pendimethalin 30% + Flufenacet 6% EC recipe classified as danger through dermal contact.** **According to the Regulation EC No. 1272/2008, Pendimethalin 30% + Flufenacet 6% EC is not classified.** **No signal word or hazard statement is required for this hazard.**

Acute toxicity studies for Pendimethalin 30% + Flufenacet 6% EC were **not** evaluated as part of the EU

review of a pendimethalin. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute dermal toxicity of Pendimethalin 30% + Flufenacet 6% EC can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

There is no co-formulant in the Pendimethalin 30% + Flufenacet 6% EC recipe classified as danger through dermal contact.

According to the Regulation EC No. 1272/2008, Pendimethalin 30% + Flufenacet 6% EC is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	**There is no co-formulant in the Pendimethalin 30% + Flufenacet 6% EC recipe classified as danger through inhalation.** **According to the Regulation EC No. 1272/2008, Pendimethalin 30% + Flufenacet 6% EC is not classified.** **No signal word or hazard statement is required for this hazard.**

Acute toxicity studies for Pendimethalin 30% + Flufenacet 6% EC were **not** evaluated as part of the EU review of a pendimethalin. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute inhalation toxicity of Pendimethalin 30% + Flufenacet 6% EC can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

There is no co-formulant in the Pendimethalin 30% + Flufenacet 6% EC recipe classified as danger through inhalation.

According to the Regulation EC No. 1272/2008, Pendimethalin 30% + Flufenacet 6% EC is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	**According to the Regulation EC No. 1272/2008, Pendimethalin 30% + Flufenacet 6% EC is not classified.** **No signal word or hazard statement is required for this hazard**

The product contains < 1% of co-formulants considered as skin corrosive (classified as: Skin Corr. 1; H314) and < 10% of co-formulants considered as skin irritant (classified as: Skin Irrit. 2; H315). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Pendimethalin 30% + Flufenacet 6% EC is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	**Under the experimental conditions, Pendimethalin 30% + Flufenacet 6% EC is not an eye irritant.** **Thus, no classification is required according to Regulation (EC) No. 1272/2008**

In the view of current regulation (EC Regulation 1272/2008, EC Regulation 1107/2009, EC Regulation 1907/2006), in vivo tests on animals should be avoided. Tests on animals within the meaning of Directive 86/609/EEC shall be undertaken only where no other alternatives, which provide adequate reliability and quality of data, are possible. In case of skin irritation, it is possible to classify the product based on validated in vitro tests or the additivity formula if all ingredients are of defined toxicological properties. In case of Pendimethalin 30% + Flufenacet 6% EC the components are of known toxicological classification, thus, the additivity formula was implemented to assess skin irritation potency of the product.
Based on the composition and in accordance with the provisions of the Regulation EC 1272/2008, the formulation Pendimethalin 30% + Flufenacet 6% EC requires classification in regards to eye irritation as Eye Dam. 1 (H318).
However, since the results of eye irritation study on rabbits were available the applicant decided to compare the findings of in vivo testing with calculated result. According to acute eye irritation study (xxx) which was carried out in compliance with OECD Guideline No 405, Pendimethalin 30% + Flufenacet 6% EC does not possess skin irritation potency.
In the opinion of applicant despite the lack of in vitro studies (multi-level approach), if the results of in vivo tests are contrary to the results obtained from calculation method, data generated from animal study should be considered superior.

A 2.6.1 Study 1

Reference	KCP 7.1.5
Report	Flufenacet 6% + Pendimethalin 30% EC: Acute Eye Irritation / Corrosion Study in Rabbit, xxx, report No. R/1626/AEI/17
Guideline(s)	Yes: OECD guideline No. 405
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Pendimethalin 30% + Flufenacet 6% EC (Batch No. SCL-19159)
Species	New Zealand White Rabbit (*Oryctolagus cuniculus*)
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	14 days
Remarks	None

Results and discussions

Table A 1: Eye irritation of SHA Pendimethalin 30% + Flufenacet 6% EC

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Corneal opacity	0.00	0.00	0.00	0.00	0.00	7 days
	Iritis	0.00	0.00	0.00	0.00	0.00	
	Redness conjunctivae	0.00	1.00	2.00	2.00	1.67	
	Chemosis conjunctivae	0.00	1.00	2.00	2.00	1.67	
2	Corneal opacity	0.00	0.00	0.00	0.00	0.00	7 days
	Iritis	0.00	0.00	0.00	0.00	0.00	
	Redness conjunctivae	0.00	1.00	2.00	1.00	1.33	
	Chemosis conjunctivae	0.00	1.00	2.00	1.00	1.33	
3	Corneal opacity	0.00	0.00	0.00	0.00	0.00	7 days
	Iritis	0.00	0.00	0.00	0.00	0.00	
	Redness conjunctivae	0.00	1.00	2.00	1.00	1.33	
	Chemosis conjunctivae	0.00	1.00	2.00	1.00	1.33	

* 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:	No signs of systemic toxicity were observed.

Conclusion

Under the experimental conditions, Pendimethalin 30% + Flufenacet 6% EC is not an eye irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	**According to the Regulation EC No. 1272/2008, Pendimethalin 30% + Flufenacet 6% EC is classified as skin sensitiser.** **The product contains > 1% of co-formulants considered as skin sensitiser (classified as: Skin Sens. 1; H317).** **Therefore H317 with pictogram GHS07 and signal word "Warning" is proposed**

The product contains > 1% of co-formulants considered as skin sensitiser (classified as: Skin Sens. 1; H317). Under the GHS classification system this component gets the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Pendimethalin 30% + Flufenacet 6% EC is classified as skin sensitiser, therefore **H317** with pictogram GHS07 and signal word "Warning" is proposed.

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

No supplementary studies are necessary.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

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

A 2.9.2 Available toxicological data for each co-formulant

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

A 2.10 Studies on dermal absorption (KCP 7.3)

Comments of zRMS:	**Acceptable** **In vitro (human Concentrate: 0.48% and Spray dilution(dilution concentration 12%**

~~According to the new EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 adopted: 24 May 2017) a default dermal absorption value of 25 % (concentrate) and 70% (diluted) of may be applied for products that are organic solvent based [(a)] or other [(b)]~~

~~[(a)]: Formulation types: emulsifiable concentrate (EC), emulsion, oil in water (EW), suspo-emulsion (SE), dispersible concentrate (DC), oil miscible liquids (OL/OF), oil-based suspension concentrates (OD), emulsion for seed treatment (ES), microemulsion (ME).~~

~~[(b)]: Formulation types: bait concentrate (CB), capsule suspension (CS), gel for direct application (GEL/GD), bait, ready for use (RB), mixture of capsule suspension and suspension concentrate (ZC), seed coated with a pesticide (PS), experimental solution of active substances in solvent (AI).~~

A 2.10.1 Study 1 – FLUFENACET AND PENDIMETHALIN in FLUFENACET 6% + PENDIMETHALIN 30% EC

A 2.10.2 Comparative dermal absorption, in vitro human skin

Reference	KCP 7.6.2
Report	In vitro percutaneous dermal absorption study of FLUFENACET 6% + PENDIMETHALIN 30% EC, through human skin, Nabanita Sam., 2022. Study No.: G24217
Guideline(s)	OECD Guideline 428 “Skin Absortion: in vitro Method” April 2004
Deviations	No
GLP	Yes
Acceptability	Yes

Duplication (if vertebrate study) No

Materials and methods

Test material	Name (Lot/Batch No.)	^{14}C-Flufenacet (XXVII/9/C/1)
	Test preparation	radioformulation
	Specific activity	4.279 MBq/mg
	Radiochemical purity	100 %
Product	Name (Lot/Batch No.)	Flufenacet 6% + Pendimethalin 30% EC (SCL-44652)
	Company code	Flufenacet
	Concentration a.s.	(%w/v): 6.01
	Formulation type	Flufenacet 6% + Pendimethalin 30% EC
Blank product	Name (Lot/Batch No.)	Flufenacet 6% + Pendimethalin 30% EC Blank (SCL-33665)
	Concentration a.s.	0 g/kg
	Name (Lot/Batch No.)	14C-Pendimethalin (TJBIOS-NB67-170-30)
	Test preparation	radioformulation
	Specific activity	28.6 mCi/mmol
	Radiochemical purity	100 %
	Name (Lot/Batch No.)	Flufenacet 6% + Pendimethalin 30% EC (SCL-44652)
	Company code	Pendimethalin
	Concentration a.s.	(%w/v): 30.20
	Formulation type	Flufenacet 6% + Pendimethalin 30% EC
	Name (Lot/Batch No.)	Flufenacet 6% + Pendimethalin 30% EC Blank (SCL-33665)
	Concentration a.s.	0 g/kg

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1.8 mL/hr
	Exposed skin area	0.64 cm^2
Membrane	Skin type	isolated epidermis
	Skin thickness range	0.2-0.4 mm
	Skin donors age	34, 51, 41, 44 years
	Skin donors sex	female
	Location	abdomen
	Source	post-mortem
	Integrity test	yes
Receptor	Receptor medium	Phosphate buffered saline (PBS) + 0.01% sodium azide +6% polyoxybutylene-20-oleyl ether (PEG), pH:7.4 ± 0.2
	Solubility in receptor medium	Yes
Sample Time	Exposure time	8 h
	Observation time	16 h
Sampling	Sample intervals	At 0-1 h, 1-2 h, followed by 2-h intervals until 24 hours after application
Washing		At 8 h using water and a mild soap solution (3% Dove)
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	y

Tested doses	Concentrate	Spray dilution
Target concentration	Flufenacet - 61.03 $g.L^{-1}$ Pendimethalin - 301.29 $g.L^{-1}$	Flufenacet - 0.376 $g.L^{-1}$ Pendimethalin - 1.874 $g.L^{-1}$

Area dose	Flufenacet - 610.29 µg.cm^{-2} Pendimethalin - 3012.90 µg.cm^{-2}	Flufenacet - 3.76 µg.cm^{-2} Pendimethalin - 18.74 µg.cm^{-2}
Specific activity	Flufenacet - 3.6894 MBq.mL^{-1} Pendimethalin - 3.7151 MBq.mL^{-1}	Flufenacet - 1.6108 MBq.mL^{-1} Pendimethalin - 6.9999MBq.mL^{-1}
No. of donors	4	4
No of cells used/valid cells*	8/8	8/8

Results and discussions - Flufenacet

Dose group	High dose (Formulation concentrate)		Low dose (Spray dilution 1:160)	
Target concentration	60 g.L^{-1}		0.375 g.L^{-1}	
Mean actual applied dose	610.29 µg.cm-2		3.76 µg.cm-2	
Number of replicates (n)	8		8	
	Mean	S.D.	Mean	S.D.
Dislodgeable dose				
Skin wash	98.15	1.10	85.29	1.18
Donor chamber wash	1.73	0.18	3.65	0.55
Dose associated to skin				
Tape strips: 1st sample, strips 1 + 2	0.06	0.02	1.18	0.08
Tape strips: 2nd sample; strips 3 - n	0.16	0.02	2.80	0.34
Skin preparation	0.02	0.01	2.45	0.32
Absorbed dose				
Receptor fluid	0.19	0.01	3.90	0.17
Receptor chamber wash	0.01	0.01	0.20	0.04
Total recovery[1]	100.33	1.06	99.47	0.66
Absorption essentially complete at end of study (>75% absorption within half the study duration) [%Absorption at $t_{0.5}$]	No [62.55%]		No [61.08%]	
If no: Absorption estimates = absorbed dose + skin preparation + tape strips sample 2)[2]	0.38	0.02	9.35	0.18
If yes: Absorption estimates = absorbed dose + skin preparation	N/A	N/A	N/A	N/A
Absorption estimate normalised[3]	0.38 ± 0.84 × 0.02		9.35 ± 0.84 × 0.18	
Relevant absorption estimate	0.39		9.50	
Absorption estimates [4]	**0.40**		**9.5**	

[1] Values may not calculate exactly due to rounding of figures

[2] In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study (see Table 7.6.2-1) Finally, the skin preparation is also considered potentially absorbable.

[3] In accordance with the EFSA Guidance on Dermal Absorption (2017), dermal absorption should be calculated as follows: Absorption (mean value) + ks, where s is the sample standard deviation. The multiplication factor required depends on the number of replicates and is given in Table 1 of EFSA Guidance.

[4] Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

Results and discussions - Pendimethalin

Dose group	High dose (Formulation concentrate)		Low dose (Spray dilution 1:160)	
Target concentration	300 g.L^{-1}		1.875 g.L^{-1}	
Mean actual applied dose	3012.90 µg.cm-2		18.74 µg.cm-2	
Number of replicates (n)	8		8	
	Mean	S.D.	Mean	S.D.
Dislodgeable dose				
Skin wash	97.17	0.080	83.39	1.07
Donor chamber wash	1.59	0.20	1.97	0.14
Dose associated to skin				
Tape strips: 1st sample, strips 1 + 2	0.12	0.02	3.60	0.33
Tape strips: 2nd sample; strips 3 - n	0.22	0.02	4.62	0.22
Skin preparation	0.02	0.01	4.68	0.27
Absorbed dose				
Receptor fluid	0.20	0.03	1.93	0.16
Receptor chamber wash	0.01	0.00	0.36	0.03
Total recovery[1]	99.33	0.89	100.55	1.11
Absorption essentially complete at end of study (>75% absorption within half the study duration) [%Absorption at $t_{0.5}$]	No [60.33%]		No [59.89%]	
If no: Absorption estimates = absorbed dose + skin preparation + tape strips sample 2)[2]	0.45	0.03	11.58	0.19
If yes: Absorption estimates = absorbed dose + skin preparation	N/A	N/A	N/A	N/A
Absorption estimate normalised[3]	0.45 ± 0.84 × 0.03		11.58 ± 0.84 × 0.18	
Relevant absorption estimate	0.475		11.73	
Absorption estimates [4]	**0.48**		**12**	

[1] Values may not calculate exactly due to rounding of figures

[2] In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study (see Table 7.6.2-1) Finally, the skin preparation is also considered potentially absorbable.

[3] In accordance with the EFSA Guidance on Dermal Absorption (2017), dermal absorption should be calculated as follows: Absorption (mean value) + ks, where s is the sample standard deviation. The multiplication factor required depends on the number of replicates and is given in Table 1 of EFSA Guidance.

[4] Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

A 2.11 Other/Special Studies

No data submitted.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Flufenacet

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

Substance	flufenacet	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,24 kg a.s. /ha	Spray dilution = 1,2 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 25	Dermal for in use diluation = 70	Oral = 100	Inhalation = 100	
RVNAS	0,017 mg/kg bw/day		RVAAS	0,017 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,2580	% of RVNAS	1517,81%
	Acute systemic exposure mg/kg bw/day		1,3725	% of RVAAS	8073,82%
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Substance	flufenacet	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,24 kg a.s. /ha	Spray dilution = 1,2 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 0,4	Dermal for in use diluation = 9,5	Oral = 100	Inhalation = 100	
RVNAS	0,017 mg/kg bw/day		RVAAS	0,017 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0083	% of RVNAS	48,57%
	Acute systemic exposure mg/kg bw/day		0,0498	% of RVAAS	292,81%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Table A 3: Estimation of longer term operator exposure towards Flufenacet according to EFSA guidance

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**15,4816909**	**0,4305384**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,2580282**	**0,0071756**	
% of RVNAS	**1517,81%**	**42,21%**	

1. Total			
	Without RPE/PPE	**With RPE/PPE**	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**0,4953692**	**0,3224371**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,0082562**	**0,0053740**	
% of RVNAS	**48,57%**	**31,61%**	

A 3.1.2 Calculations for Pendimethalin

Table A 4: Input parameters considered for the estimation of operator exposure

Substance	pendimethalina	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-1,2 kg a.s. /ha	Spray dilution = 6 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 25	Dermal for in use diluation = 70	Oral = 57	Inhalation = 100	
RVNAS	0,17 mg/kg bw/day		RVAAS	0,17 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,9154	% of RVNAS	538,46%
	Acute systemic exposure mg/kg bw/day		3,6996	% of RVAAS	2176,25%
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Substance	pendimethalina	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-1,2 kg a.s. /ha	Spray dilution = 6 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 0,48	Dermal for in use diluation = 12	Oral = 57	Inhalation = 100	
RVNAS	0,17 mg/kg bw/day		RVAAS	0,17 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0430	% of RVNAS	25,28%
	Acute systemic exposure mg/kg bw/day		0,2005	% of RVAAS	117,95%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Table A 5: Estimation of longer term operator exposure towards Pendimethalin according to EFSA guidance

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**54,9224996**	**1,6806074**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,9153750**	**0,0280101**	
% of RVNAS	**538,46%**	**16,48%**	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	**2,5783104**	**1,6974439**	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0,0429718**	**0,0282907**	
% of RVNAS	**25,28%**	**16,64%**	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Flufenacet

Table A 6: Input parameters considered for the estimation of worker exposure

Worker exposure from residues on foliage for		
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	0,24	kg a.s./ha
Number of applications	1	
Interval between multiple applications	365	days
Half-life of active substance	30	days
Multiple application factor	1,0	
Dermal absorption of the product	25,00%	
Dermal absorption of the in-use dilution	70,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,72	µg a.s./cm^2
Working hours	2	hr
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

Worker exposure from residues on foliage for		
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	0,24	kg a.s./ha
Number of applications	1	
Interval between multiple applications	365	days
Half-life of active substance	30	days
Multiple application factor	1,0	
Dermal absorption of the product	0,40%	
Dermal absorption of the in-use dilution	9,50%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,72	µg a.s./cm^2
Working hours	2	hr
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

Table A 7: Estimation of longer term worker exposure towards Flufenacet according to EFSA guidance

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	12,6000000	1,4112000	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,2100000	0,0235200	
% of RVNAS	1235,29%	138,35%	

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	1,7100000	0,1915200	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0285000	0,0031920	
% of RVNAS	167,65%	18,78%	

~~**Table A 8: Input parameters considered for the estimation of worker exposure for re-entry period of 32 days**~~

Worker exposure from residues on foliage for		
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	0,24	kg a.s./ha
Number of applications	1	
Interval between multiple applications	365	days
Half-life of active substance	30	days
Multiple application factor	1,0	
Dermal absorption of the product	25,00%	
Dermal absorption of the in-use dilution	70,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,3432	µg a.s./cm^2
Working hours	2	hr
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

~~**Table A 9: Estimation of worker exposure towards Flufenacet according to EFSA guidance for re-entry period of 32 days**~~

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	6,0060000	0,6726720	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1001000	0,0112112	
% of RVNAS	588,82%	65,95%	

A 3.2.2 Calculations for Pendimethalin

Table A 10: Input parameters considered for the estimation of worker exposure

Worker exposure from residues on foliage for		
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	1,2	kg a.s./ha
Number of applications	1	
Interval between multiple applications	365	days
Half-life of active substance	30	days
Multiple application factor	1,0	
Dermal absorption of the product	25,00%	
Dermal absorption of the in-use dilution	70,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	3,6	µg a.s./cm^2
Working hours	2	hr
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

Worker exposure from residues on foliage for		
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	1,2	kg a.s./ha
Number of applications	1	
Interval between multiple applications	365	days
Half-life of active substance	30	days
Multiple application factor	1,0	
Dermal absorption of the product	0,48%	
Dermal absorption of the in-use dilution	12,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	3,6	µg a.s./cm^2
Working hours	2	hr
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

Table A 11: Estimation of longer term worker exposure towards Pendimethalin according to EFSA guidance

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	63,0000000	7,0560000	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	1,0500000	0,1176000	
% of RVNAS	617,65%	69,18%	

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	10,8000000	1,2096000	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1800000	0,0201600	
% of RVNAS	105,88%	11,86%	

~~Table A 12: Input parameters considered for the estimation of worker exposure for re-entry period of 32 days~~

Worker exposure from residues on foliage for		
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	1,2	kg a.s./ha
Number of applications	1	
Interval between multiple applications	365	days
Half-life of active substance	30	days
Multiple application factor	1,0	
Dermal absorption of the product	25,00%	
Dermal absorption of the in-use dilution	70,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	1,716	µg a.s./cm^2
Working hours	2	hr
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

~~Table A 13: Estimation of worker exposure towards Pendimethalin according to EFSA guidance for re-entry period of 32 days~~

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	30,0300000	3,3633600	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,5005000	0,0560560	
% of RVNAS	294,41%	32,97%	

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Flufenacet

Table A 14: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for		
Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted-Drift Reduction	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Buffer strip	5	m
Application rate of the product	0,24	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	1,2	g a.s./l
Dermal absorption of product	25,00%	
Dermal absorption of in-use dilution	70,00%	
Oral absorption	100,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,72	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	0,23798	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0,2175	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00009	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00017	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0,12278	ml spray dilution/person
Resident dermal spray drift exposure mean - child	0,12	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00008	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00014	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0,25	hours
Light clothing adjustment factor	18,0%	
Breathing rate adult	0,23	m^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/day/kg
Drift percentage on surface (75th percentile)	2,30%	
Drift percentage on surface (mean)	1,80%	
Turf transferable residues percentage	5,00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

Resident exposure for		
Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Buffer strip	2-3	m
Application rate of the product	0,24	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	1,2	g a.s./l
Dermal absorption of product	0,40%	
Dermal absorption of in-use dilution	9,50%	
Oral absorption	100,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,72	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0,25	hours
Light clothing adjustment factor	18,0%	
Breathing rate adult	0,23	m^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/day/kg
Drift percentage on surface (75th percentile)	5,60%	
Drift percentage on surface (mean)	4,10%	
Turf transferable residues percentage	5,00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

Table A 15: Estimation of longer term resident exposure towards Flufenacet according to EFSA guidance

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)	0,0750090	0,0107000	0,0054234	0,2835000	0,2824004
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0075009	0,0010700	0,0005423	0,0283500	0,0282400
% of RVNAS	44,12%	6,29%	3,19%	166,76%	166,12%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0820143	0,0138000	0,0141036	0,9450000	0,8206510
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0013669	0,0002300	0,0002351	0,0157500	0,0136775
% of RVNAS	8,04%	1,35%	1,38%	92,65%	80,46%

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)	0,0308320	0,0107000	0,0052685	0,0384750	0,0622651
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0030832	0,0010700	0,0005268	0,0038475	0,0062265
% of RVNAS	18,14%	6,29%	3,10%	22,63%	36,63%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0440556	0,0138000	0,0093206	0,1282500	0,1438529
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0007343	0,0002300	0,0001553	0,0021375	0,0023975
% of RVNAS	4,32%	1,35%	0,91%	12,57%	14,10%

~~Table A 16: Input parameters considered for the refinement of the estimation of longer term resident exposure~~

Resident exposure for		
Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted-Drift Reduction	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Buffer strip	5	m
Application rate of the product	0,24	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	1,2	g a.s./l
Dermal absorption of product	25,00%	
Dermal absorption of in-use dilution	70,00%	
Oral absorption	100,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,72	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	0,23798	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0,2175	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00009	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00017	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0,12278	ml spray dilution/person
Resident dermal spray drift exposure mean - child	0,12	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00008	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00014	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0,25	hours
Light clothing adjustment factor	18,0%	
Breathing rate adult	0,23	m^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/day/kg
Drift percentage on surface (75th percentile)	2,30%	
Drift percentage on surface (mean)	1,80%	
Turf transferable residues percentage	5,00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	1400	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	420	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	1100	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	330	cm^2/h

~~Table A 17: Estimation of longer term resident exposure towards Flufenacet according to EFSA guidance refinement to reduce the Transfer Coefficient~~

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)	0,0750090	0,0107000	0,0054234	0,0529200	0,0979364
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0075009	0,0010700	0,0005423	0,0052920	0,0097936
% of RVNAS	44,12%	6,29%	3,19%	31,13%	57,61%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0820143	0,0138000	0,0141036	0,1764000	0,2057710
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0013669	0,0002300	0,0002351	0,0029400	0,0034295
% of RVNAS	8,04%	1,35%	1,38%	17,29%	20,17%

~~Table A 18: Input parameters considered for the refinement of the estimation of longer term resident exposure~~

Resident exposure for		
Croptype	Bare soil	
Application method	Downward spraying	
Application equipment	Vehicle-mounted-Drift Reduction	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Buffer strip	2-3	m
Application rate of the product	0,24	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	1,2	g a.s./l
Dermal absorption of product	25,00%	
Dermal absorption of in-use dilution	70,00%	
Oral absorption	100,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,72	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0,25	hours
Light clothing adjustment factor	18,0%	
Breathing rate adult	0,23	m^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/day/kg
Drift percentage on surface (75th percentile)	5,60%	
Drift percentage on surface (mean)	4,10%	
Turf transferable residues percentage	5,00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h **x 0%**
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h **x 0%**

~~Table A 19: Estimation of longer term resident exposure towards Flufenacet according to EFSA guidance refinement to reduce the Transfer Coefficient~~

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)	0,1127508	0,0107000	0,0132048	0,0000000	0,0824618
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0112751	0,0010700	0,0013205	0,0000000	0,0082462
% of RVNAS	66,32%	6,29%	7,77%	0,00%	48,51%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1619280	0,0138000	0,0343392	0,0000000	0,1158584
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0026988	0,0002300	0,0005723	0,0000000	0,0019310
% of RVNAS	15,88%	1,35%	3,37%	0,00%	11,36%

A 3.3.2 Calculations for Pendimethalin

Table A 20: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for		
Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted-Drift Reduction	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Buffer strip	5	m
Application rate of the product	1,2	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	6	g a.s./l
Dermal absorption of product	25,00%	
Dermal absorption of in-use dilution	70,00%	
Oral absorption	57,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	3,6	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	0,23798	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0,2175	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00009	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00017	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0,12278	ml spray dilution/person
Resident dermal spray drift exposure mean - child	0,12	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00008	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00014	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0,25	hours
Light clothing adjustment factor	18,0%	
Breathing rate adult	0,23	m^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/day/kg
Drift percentage on surface (75th percentile)	2,30%	
Drift percentage on surface (mean)	1,80%	
Turf transferable residues percentage	5,00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

Resident exposure for		
Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Buffer strip	2-3	m
Application rate of the product	1,2	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	6	g a.s./l
Dermal absorption of product	0,48%	
Dermal absorption of in-use dilution	12,00%	
Oral absorption	57,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	3,6	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0,25	hours
Light clothing adjustment factor	18,0%	
Breathing rate adult	0,23	m^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/day/kg
Drift percentage on surface (75th percentile)	5,60%	
Drift percentage on surface (mean)	4,10%	
Turf transferable residues percentage	5,00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

Table A 21: Estimation of longer term resident exposure towards Pendimethalin according to EFSA guidance

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)	0,3750450	0,0107000	0,0262566	1,4175000	1,3685286
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0375045	0,0010700	0,0026257	0,1417500	0,1368529
% of RVNAS	22,06%	0,63%	1,54%	83,38%	80,50%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,4100716	0,0138000	0,0705180	4,7250000	4,0480552
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0068345	0,0002300	0,0011753	0,0787500	0,0674676
% of RVNAS	4,02%	0,14%	0,69%	46,32%	39,69%

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)	0,1943808	0,0107000	0,0265205	0,2430000	0,3311608
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0194381	0,0010700	0,0026520	0,0243000	0,0331161
% of RVNAS	11,43%	0,63%	1,56%	14,29%	19,48%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,2780880	0,0138000	0,0588672	0,8100000	0,8350447
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0046348	0,0002300	0,0009811	0,0135000	0,0139174
% of RVNAS	2,73%	0,14%	0,58%	7,94%	8,19%

~~Table A 22: Input parameters considered for the refinement of the estimation of longer term resident exposure~~

Resident exposure for		
Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted-Drift Reduction	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Buffer strip	5	m
Application rate of the product	1,2	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	6	g a.s./l
Dermal absorption of product	25,00%	
Dermal absorption of in-use dilution	70,00%	
Oral absorption	57,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	3,6	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	0,23798	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0,2175	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00009	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00017	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0,12278	ml spray dilution/person
Resident dermal spray drift exposure mean - child	0,12	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00008	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00014	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0,25	hours
Light clothing adjustment factor	18,0%	
Breathing rate adult	0,23	m^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/day/kg
Drift percentage on surface (75th percentile)	2,30%	
Drift percentage on surface (mean)	1,80%	
Turf transferable residues percentage	5,00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	1400	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	420	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	1100	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	330	cm^2/h

~~Table A 23: Estimation of longer term resident exposure towards Pendimethalin according to EFSA guidance refinement to reduce the Transfer Coefficient~~

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)	0,3750450	0,0107000	0,0262566	0,2646000	0,4462086
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0375045	0,0010700	0,0026257	0,0264600	0,0446209
% of RVNAS	22,06%	0,63%	1,54%	15,56%	26,25%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,4100716	0,0138000	0,0705180	0,8820000	0,9736552
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0068345	0,0002300	0,0011753	0,0147000	0,0162276
% of RVNAS	4,02%	0,14%	0,69%	8,65%	9,55%

~~Table A 24: Input parameters considered for the estimation of longer term resident exposure~~

Resident exposure for		
Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted-Drift Reduction	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Buffer strip	2-3	m
Application rate of the product	1,2	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	6	g a.s./l
Dermal absorption of product	25,00%	
Dermal absorption of in-use dilution	70,00%	
Oral absorption	57,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	3,6	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0,001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0,25	hours
Light clothing adjustment factor	18,0%	
Breathing rate adult	0,23	m^3/day/kg
Breathing rate child (1-3 year old)	1,07	m^3/day/kg
Drift percentage on surface (75th percentile)	5,60%	
Drift percentage on surface (mean)	4,10%	
Turf transferable residues percentage	5,00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50,00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9,5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20,00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h x0%
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h x0%

~~Table A 25: Estimation of longer term resident exposure towards Pendimethalin according to EFSA guidance refinement to reduce the Transfer Coefficient~~

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)	0,5637540	0,0107000	0,0639290	0,0000000	0,3679752
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0563754	0,0010700	0,0063929	0,0000000	0,0367975
% of RVNAS	33,16%	0,63%	3,76%	0,00%	21,65%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,8096400	0,0138000	0,1716960	0,0000000	0,5240920
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0134940	0,0002300	0,0028616	0,0000000	0,0087349
% of RVNAS	7,94%	0,14%	1,68%	0,00%	5,14%

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)

None.