

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 2600 E

Product name(s): PENSHUI

Chemical active substance:

Pendimethalin, 455 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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January 2021	Assessment by expert
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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on SHA 2600 E / PENSHUI *

Product name and code	PENSHUI / SHA 2600 E
Formulation type	Capsule suspension [Code: CS]
Active substance(s) (incl. content)	Pendimethalin 455 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 SHA 2600 E / PENSHUI can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for SHA 2600 E / PENSHUI 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, P280, P302+P352, P333+P311, P308+P313 P501
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Contains isocyanates. May produce an allergic reaction.” [EUH204]. EUH208: Contains 1,2-benzisothiazolin-3-one, chloro-methyl-isothiazolin-one and methyl-isothiazolin-one. May produce an allergic reaction

Note:

Based on the ECHA “Registry of CLH intentions until outcome” website <https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e181ed6ba6>, Netherlands has submitted a CLH dossier to ECHA proposing the following classification

Skin Sens. 1B, H317; Repr. 2, H361d

But not yet has been finalized by the time of the dRR preparation, it is expected that a RAC opinion will have been adopted by the finalization of the RR

Committee for Risk Assessment RAC opinion proposing harmonised classification and labelling at EU level of pendimethalin Adopted 8 October 2020 is obligatory

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for SHA 2600 E / PENSHUI

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Bare soil (pre-emergence) - Work wear (arms, body and legs covered) + gloves at M/L Cereals (post- emergence) - Work wear (arms, body and legs covered) + gloves at M/L Vegetables (post-emergence) - Work wear (arms, body and legs covered) + gloves at M/L Winter oilseed rape (post-emergence) - Work wear (arms, body and legs covered) + gloves at M/L
Workers	Acceptable	Cereals and Winter oilseed rape (post- emergence) - Work wear (arms, body and legs covered) Bulb vegetables (post-emergence) - Work wear (arms, body and legs covered), gloves and period of 18.5 days for re-entry.
Residents& Bystanders	Acceptable	Bare soil, cereals and bulb vegetables - 10m buffer zone and drift reduction technology. None

No unacceptable risk for operators, workers and resident was identified when the product is used as intended and provided that the PPE stated in Note:

Based on the ECHA “Registry of CLH intentions until outcome” website <https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e181ed6ba6>, Netherlands has submitted a CLH dossier to ECHA proposing the following classification
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Committee for Risk Assessment RAC opinion proposing harmonised classification and labelling at EU level of pendimethalin Adopted 8 October 2020 is obligatory

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 situa- tion (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safen- er/synergist (L/ha)) critical gap for operator, worker, resident or bystand- er exposure based on [Exposure model]	Acceptability of exposure assessment			
			Method / Kind (incl. appli- cation technique ***	Max. number (min. interval between applica- tions) a) per use b) per crop/ season	Max. application rate kg as/ha a) a.s. 1 b) a.s. 2	Water L/ha min / max			Operator	Worker	Residents	Bystander
1	Winter cereals, maize Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					

1	2	3	4	5	6	7	8	9	10			
2	Winter cereals, maize, Winter oilseed rape Post emergence BBCH 10-13	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
5	Pome fruits, stone fruits Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-600	-					
7	Sunflower, Soybean, Winter oilseed rape Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.183	200-400	-					
9	Bulb vegetables, Bean, pea, broad bean, field bean, Lupine, Asparagus, Brassica vegetables, Lettuce, endive, Artichoke, Fennel, Cucurbits (melon, cucumber, squash, zucchini) Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
10	Bulb vegetables, Leek Post emergence BBCH 10-13	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
12	Carrot, parsley, Leek, Parsnip, Potato Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
18	Strawberry, Raspberry, Currants Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
26	Grapevine Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
27	Ornamentals Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
28	Clover, alfalfa Post emergence BBCH 13-18	F	Spraying, LCTM	a) 1 b) 1	1.0	200-400	-					

* 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

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)

	Pendimethalin
Common Name	Pendimethalin
CAS-No.	40487-42-1
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended) Annex VI updated on 09 September 2016	Hazard classes, categories: Skin Sens. 1 Code(s) for hazard pictogram: GHS07 Signal word: Warning Hazard statements: H317 Repr. 2 H361d
Additional C&L proposal	Repr. 2, H361d EFSA Journal 2016; 14 (3): 4420 and Additional C&L proposal submitted by The Netherlands https://echa.europa.eu/it/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e181ed6ba6
Agreed EU endpoints	
AOEL systemic	0.17 mg/kg bw/d
Reference	Committee for Risk Assessment RAC opinion proposing harmonised classification and labelling at EU level of pendimethalin Adopted 8 October 2020 Peer review of the pesticide risk assessment of the active substance pendimethalin EFSA Journal 2016;14(3):4420; 17 March 2016 SANTE/11656/2016, 18 May 2017 rev.2
Conditions to take into account/critical areas of concern with regard to toxicology	
According to EFSA Conclusion	The operators have to use proper PPE

6.3 Toxicological Evaluation of Plant Protection Product

The assessment of all acute toxicological properties of Pendimethalin 45.5% CS are derived from the classification of the active compound and co-formulants. When considering the properties of all co-formulants and toxicity study Pendimethalin 45.5% CS is classified as “H317: May cause an allergic skin reaction”. Details in Appendix 2

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Pendifin 400 SC

Type of test, species, model system (Guideline)	Results	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat	ATEmix >2000mg/kg bw	Yes	None	Based on CLP calculation method., Appendix 2.
LD ₅₀ dermal, rat	ATEmix >2000mg/kg bw	Yes	None [#]	Based on CLP calculation method., Appendix 2.
LC ₅₀ inhalation, rat	ATEmix >5 mg/L	Yes	None	Based on CLP calculation method. Appendix 2.
Skin irritation, rabbit	No skin irritant	Yes	None*	Based on CLP calculation method. Appendix 2.
Eye irritation, rabbit	No eye irritant	Yes	None	Based on CLP calculation method, Appendix 2
Skin sensitisation, guinea pig	Skin sensitizer	No	H317 None	Based on CLP calculation method., Appendix 2.
Supplementary studies for combinations of plant protection products	No data – not required			

Table 6.3-2: Additional toxicological information relevant for classification/labelling of SHA 2600 E / PENSHUI

	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)	Pendimethalin (45.5% (w/w))	H317 H361d	Reg. 1272/2008 Committee for Risk Assessment RAC opinion proposing harmonised classification and labelling at EU level of pendimethalin Adopted 8 October 2020	H317 H361d
Toxicological properties of non-active substance(s) (relevant for	-	-	-	-

	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)
classification of product)				
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

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

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in SHA 2600 E / PENSHUI are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in SHA 2600 E / PENSHUI

	Pendimethalin	
	Value	Reference
Concentrate	25%	Default value (EFSA Journal 2017;15(6):4873)
Dilution	70%	Default value (EFSA Journal 2017;15(6):4873)
	Pendimethalin	
	Value	Reference
Concentrate	2.2%	New study reported in Appendix 2 – XXX, 2021
Dilution	22%	New study reported in Appendix 2 – XXX, 2021

6.5.1 Justification for proposed values - Pendimethalin

No data on dermal absorption for Pendimethalin in SHA 2600 E / PENSHUI 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: Summary of the results of submitted dermal absorption studies for Pendimethalin

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

Proposed dermal absorption rates for Pendimethalin are based on dermal absorption studies on formulation Pendimethalin 455 g/L CS. The study results are summarised in the following table. Full summaries of studies on the dermal absorption of Pendimethalin 455 g/L CS 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)	2.2 %	22%	SHA 2600 E / PENSHUI	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.	XXX, 2021

* indicates that a study was reviewed at EU level

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	SHA 2600 E / PENSHUI
Formulation type	CS
Category	Herbicide
Active substance(s) (incl. content)	Pendimethalin 455 g/L
AOEL systemic	0.17 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	57%
Dermal absorption	Concentrate: 25% Dilution: 70% (Default values)

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
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, G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/synergist (L/ha))	Acceptability of exposure assessment
			Method / Kind (incl. application technique ***	Max. number (min. interval between applications) a) per use b) per crop/ season	Max. application rate kg as/ha a) a.s. 1 b) a.s. 2	Water L/ha min / max		critical gap for operator, worker, resident or bystander exposure based on [Exposure model]	Operator Worker Residents Bystander

1	2	3	4	5	6	7	8	9	10			
1	Winter cereals, maize Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
2	Winter cereals, maize, Winter oilseed rape Post emergence BBCH 10-13	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
5	Pome fruits, stone fruits Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-600	-					
7	Sunflower, Soybean, Winter oilseed rape Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.183	200-400	-					
9	Bulb vegetables, Bean, pea, broad bean, field bean, Lupine, Asparagus, Brassica vegetables, Lettuce, endive, Artichoke, Fennel, Cucurbits (melon, cucumber, squash, zucchini) Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
10	Bulb vegetables, Leek Post emergence BBCH 10-13	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
12	Carrot, parsley, Leek, Parsnip, Potato Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
18	Strawberry, Raspberry, Currants Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
26	Grapevine Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
27	Ornamentals Pre emergence BBCH 00-09	F	Spraying, LCTM	a) 1 b) 1	1.59	200-400	-					
28	Clover, alfalfa Post emergence BBCH 13-18	F	Spraying, LCTM	a) 1 b) 1	1.0	200-400	-					

. A list of all intended uses within the zone is given in Part B, Section 0.

Justification

Intended uses of the GAP given in Part B, Section 0, were separated here in two critical GAPs between uses with pre-emergence applications and uses with post-emergence applications.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of SHA 2600 E / PENSHUI according to the critical use(s) is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Bare soil (pre-emergence) 3.5 L product/ha Cereals Winter oilseed rape (post-emergence) 3.5 L product/ha Vegetables (post-emergence) 3.5 L product/ha
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

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

		Pendimethalin	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to bare soil (pre-emergence)			
Application rate		1 x 1.59 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	1.1453946	674
	Work wear (arms, body and legs covered) + gloves at M/L	0.1681473	99
Tractor mounted boom spray application outdoors to low crops (post-emergence)			
Application rate		1 x 1.59 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	1.1453946	674
	Work wear (arms, body and legs covered) + gloves at M/L	0.1681473	99

~~According to the EFSA calculator, it can be concluded that the risk for operator is acceptable with the use of gloves during mixing/loading~~

Implication for labelling: P280: Wear protective gloves.

New calculations have been conducted considering endpoints from dermal absorption study conducted with PENSHUI (2.2 % for concentrate and 22% for dilution).
Please refer to point A 2.10 for details about dermal absorption values.

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

		Pendimethalin	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to bare soil (pre-emergence)			
Application rate		1 x 1.59 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.1505013	89
	Work wear (arms, body and legs covered)	0.0990692	58
Tractor mounted boom spray application outdoors to low crops (post-emergence)			
Application rate		1 x 1.59 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.1505013	89
	Work wear (arms, body and legs covered)	0.0990692	58

According to the EFSA calculator, it can be concluded that the risk for operator is acceptable without the use of personal protective equipment.

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), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-5 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Pendimethalin 45.5 % CS according to the critical use(s). Outcome of the estimation is presented in Table 6.6-6 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-5: Exposure models for intended uses

Critical use(s)	Cereals Winter oilseed rape (post-emergence) 3.5 L product/ha Vegetables (post-emergence) 3.5 L product/ha
Models	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

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

		Pendimethalin	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Cereals, Winter oilseed rape (post-emergence) Inspection, irrigation/Outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha			
Number of applications and application rate		1 × 1.59 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	1.39125	818
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.15582	92
	Work wear (arms, body and legs covered) and gloves	no TC available for this assessment	
Bulb vegetables (post-emergence) Reaching, picking/Outdoor Work rate: 8 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha			
Number of applications and application rate		1 × 1.59 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	2.58216	1519
	Work wear (arms, body and legs covered) TC: 2500 cm ² /person/h	1.11300	655
	Work wear (arms, body and legs covered) and gloves TC: 580 cm ² /person/h	0.258216	152
Proposal re-entry 18.5 days Bulb vegetables (post-emergence) Reaching, picking/Outdoor Work rate: 8 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha			
Number of applications and application rate		1 × 1.59 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	1.6870112	992
	Work wear (arms, body and legs covered) TC: 2500 cm ² /person/h	0.7271600	428
	Work wear (arms, body and legs covered) and gloves TC: 580 cm ² /person/h	0.1687011	99

For an application on cereals and winter oilseed rape is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment for maintenance when re-entering treated crops with PENSHUI. For an application on low crops (bulb vegetables) it is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment

~~(gloves) for maintenance activities when for re-entering cotton treated with PENSHUI when a time period of 18.5 days after application is respected.~~

New calculations have been conducted considering endpoints from dermal absorption study conducted with PENSHUI (2.2 % for concentrate and 22% for dilution).

Please refer to point A 2.10 for details about dermal absorption values.

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

		Pendimethalin	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Cereals, Winter oilseed rape (post-emergence) Inspection, irrigation/Outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha			
Number of applications and application rate		1 × 1.59 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.4372500	257
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0489720	29
	Work wear (arms, body and legs covered) and gloves	no TC available for this assessment	
Bulb vegetables (post-emergence) Reaching, picking/Outdoor Work rate: 8 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha			
Number of applications and application rate		1 × 1.59 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	0.8115360	477
	Work wear (arms, body and legs covered) TC: 2500 cm ² /person/h	0.3498000	206
	Work wear (arms, body and legs covered) and gloves TC: 580 cm ² /person/h	0.0811536	48

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves), for maintenance activities when for re-entering vegetables

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 18.5 days. Therefore we propose to calculate DFR value at 18.5 days for bulb vegetables.

Body weight 60 kg.

DFR_t is calculated according the following formula:

$$DFR_t = DFR_0 \times e^{-k \cdot t}$$

Where:

DFR_t—Dislodgeable foliar residue at the time of re-entry (µg/cm²)

DFR₀—Dislodgeable foliar residue just after application (µg/cm²)

k—Degradation constant (days⁻¹), calculated from the half life time:

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

DT₅₀—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/cm² 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):3874¹, corresponding to a half life_{foliar} of 30 days.

Bulb vegetables :

For bulb vegetables , a number of 1 application and MAF is 1.0. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.0 = 3.0 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 3 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

Therefore for 12 days of re-entry interval:

$$DFR_t = DFR_0 \times e^{-k \cdot t} = 3.0 \mu\text{g}/\text{cm}^2 \times 0.653 = 1.96 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_t = DFR_{def \cdot ref} \times MAF = 1.96 \mu\text{g}/\text{cm}^2 \text{ — the } DFR_{def \cdot ref} = 1.96 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

6.6.3.3 Measurement of worker exposure

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

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”

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

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

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

Table 6.6-8: Exposure models for intended uses

Critical use(s)	Bare soil (pre-emergence) 3.5 L product/ha Cereals Winter oilseed rape (post-emergence) 3.5 L product/ha Vegetables (post-emergence) 3.5 L product/ha
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

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

		Pendimethalin	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to bare soil and low crops Buffer zone: 10 (m) Drift reduction technology: yes DT₅₀: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days			
Application rate –		1 × 1.59 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0410415	24.14
	Vapour (75 th perc.)	0.0010700	0.63
	Deposits (75 th perc.)	0.0019664	1.16
	Re-entry (75 th perc.)	0.1878188	110.48
	Sum (mean)	0.1751970	103.06
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0077579	4.56
	Vapour (75 th perc.)	0.0002300	0.14
	Deposits (75 th perc.)	0.0008802	0.52
	Re-entry (75 th perc.)	0.1043438	61.38
	Sum (mean)	0.0882812	51.93

According to the EFSA calculator, it can be concluded that the risk for long term exposure for child residents is unacceptable.

Therefore, further refinements for children are necessary.

Refinement for 1-3 years old child:

According to the EFSA guidance (EFSA Journal 2014;12(10):3874), it is noted that the entry into treated crops for resident is based on exposure from activities such as walking in treated fields and that the method used should be the same as for workers. In this context, and since worker exposure is considered as not applicable for treatment of bare soil, cereals and bulb vegetables the entry into treated crops should not be considered for resident either.

For bare soil, cereals and bulb vegetables Sharda propose to refine the risk by entry into the treated crop by using a refined transfer coefficient due to the early growth stage of the crop.

The transfer coefficient used by default for entry into crop is 1794 cm²/h (mean) and 2250 cm²/h (75th perc.) for children.

The approach for refinement is to reduce the Transfer Coefficient in bare soil to about 20% of the child surface area because only the legs are concerned.

Dermal exposure = $2250 \text{ cm}^2/\text{h} \times 20\% \times 0.25 \text{ h} \times 4.77 \text{ } \mu\text{g a.s.}/\text{cm}^2 \times 0.001 \times 70\% = 0.375638 \text{ mg a.s.}/\text{day}$

————— = 0.0375638 mg a.s./kg bw/day (given a 10 kg child)

Table 6.6-10: Refined estimated resident exposure (longer term exposure)

		Pendimethalin	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to bare soil and low crops Buffer zone: 10 (m) Drift reduction technology: yes DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 365 days			
Application rate—		1 × 1.956 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0410415	24.14
	Vapour (75 th perc.)	0.0010700	0.63
	Deposits (75 th perc.)	0.0019664	1.16
	Re-entry (75 th perc.)	0.0375638	22
	Sum (mean)	0.0553937	33

According to the EFSA calculator, when a 10m buffer zone and drift reduction technology are employed the risk for residents can be considered as acceptable.

New calculations have been conducted considering endpoints from dermal absorption study conducted with PENSHUI (2.2 % for concentrate and 22% for dilution).

Please refer to point A 2.10 for details about dermal absorption values.

Table 6.6-11: Estimated resident exposure (longer term exposure)

		Pendimethalin	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to bare soil and low crops			

Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 365 days			
Application rate		1 × 1.59 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0470426	27.69
	Vapour (75 th perc.)	0.0010700	0.63
	Deposits (75 th perc.)	0.0058290	3.43
	Re-entry (75 th perc.)	0.0590288	34.72
	Sum (mean)	0.0783536	46.09
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0112477	6.62
	Vapour (75 th perc.)	0.0002300	0.14
	Deposits (75 th perc.)	0.0023833	1.40
	Re-entry (75 th perc.)	0.0327938	19.29
	Sum (mean)	0.0334691	19.69

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

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.6.2	XXX	2021	In vitro percutaneous dermal absorption study of Pendimethalin 455 g/L CS, through human skin. Eurofins Advinus Limited, Study No. G18511 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

No additional study submitted

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
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A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	The acute oral toxicity of Pendimethalin 45.5% CS was estimated to be > 2000 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Pendimethalin 45.5% CS is not classified
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Acute toxicity studies for Pendimethalin 45.5 % CS 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 45.5 % CS can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The acute oral toxicity of Pendimethalin 45.5 % CS was calculated as follow:

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

$$ATE_{mix} = \frac{100}{\frac{xxx}{1221} + \frac{xxx}{670} + \frac{xxx}{100}} = 800\,000\,mg/kg\,bw$$

Conclusion

The acute oral toxicity of Pendimethalin 45.5% CS was estimated to be > 2000 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Pendimethalin 45.5% CS 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:	The acute dermal toxicity of Pendimethalin 45.5% CS was estimated to be > 2000 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Pendimethalin 45.5% CS is not classified
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Acute toxicity studies for Pendimethalin 45.5 % CS 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 45.5 % CS can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The acute dermal toxicity of Pendimethalin 45.5 % CS was calculated as follow:

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

$$ATE_{mix} = \frac{100}{\frac{xxx}{50}} = 100\,0000\,mg/kg\,bw$$

Conclusion

The acute dermal toxicity of Pendimethalin 45.5% CS was estimated to be > 2000 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Pendimethalin 45.5% CS 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:	The acute inhalation toxicity of Pendimethalin 45.5% CS was estimated to be > 5 mg/l. Therefore, according to the Regulation EC No. 1272/2008, Pendimethalin 45.5% CS is not classified
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Acute toxicity studies for Pendimethalin 45.5 % CS 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 45.5 % CS can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The acute inhalation toxicity of Pendimethalin 45.5 % CS was calculated as follow:

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

$$ATE_{mix} = \frac{100}{\frac{xxx}{0.05}} = 10000\,mg/l$$

Conclusion

The acute inhalation toxicity of Pendimethalin 45.5% CS was estimated to be > 5 mg/l. Therefore, according to the Regulation EC No. 1272/2008, Pendimethalin 45.5% CS 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 45.5% CS is not classified. No signal word or hazard statement is required for this hazard.
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Acute toxicity studies for Pendimethalin 45.5 % CS 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 45.5 % CS can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

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 45.5% CS 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:	According to the Regulation EC No. 1272/2008, Pendimethalin 45.5% CS is not classified. No signal word or hazard statement is required for this hazard.
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Acute toxicity studies for Pendimethalin 45.5 % CS 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 45.5 % CS can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The product contains < 1% of co-formulants considered as eye damage (classified as: Eye Dam. 1; H318) and < 10% of co-formulants considered as eye irritant (classified as: Eye Irrit. 2; H319). 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 45.5% CS is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	According to the Regulation EC No. 1272/2008, Pendimethalin 45.5% CS is classified as skin sensitizer, therefore H317 with pictogram GHS07 and signal word "Warning"
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Acute toxicity studies for Pendimethalin 45.5 % CS 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 45.5 % CS can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The product contains > 1% of co-formulants considered as skin sensitizer (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 45.5% CS is classified as skin sensitizer, 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)

~~According to the new EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 adopted: 24 May 2017) a default dermal absorption value 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 – Pendimethalin in Pendimethalin 455 g/L CS

A 2.10.2 Comparative dermal absorption, in vitro human skin

Reference	KCP 7.6.2
Report	In vitro percutaneous dermal absorption study of Pendimethalin 455 g/L CS, through human skin, XXX., 2021. Study No.: G18511
Guideline(s)	OECD Guideline 428 "Skin Absorption: 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-Pendimethalin (TJBIOS-NB67-170-30)
	Test preparation	radioformulation
	Specific activity	28.6 mCi/mmol
	Radiochemical purity	98.9 %
Product	Name (Lot/Batch No.)	Pendimethalin 455 g/L CS (SCL-80067)
	Company code	Pendimethalin
	Concentration a.s.	455 g/L
	Formulation type	Pendimethalin 455 g/L
Blank product	Name (Lot/Batch No.)	Pendimethalin 455 g/L blank formulation (SCL-45623)
	Concentration a.s.	0 g/L

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	51, 53, 47, 45 years
	Skin donors sex	female
	Location	abdomen
	Source	post-mortem
	Integrity test	yes
Receptor	Receptor medium	Ethanol:Water (50:50% v/v) supplemented with 6% PEG
	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	456.67 g·L ⁻¹	1.516 g·L ⁻¹
Area dose	4566.72 µg/cm ²	15.16 µg/cm ²
Specific activity	3.7122 MBq.mL ⁻¹	5.7554 MBq.mL ⁻¹
No. of donors	4	4
No of cells used/valid cells*	8/8	8/8

Results and discussions - Pemdimehalin

Dose group	High dose (Formulation concentrate)	Low dose (Spray dilution 1:300)
Target concentration	455 g·L ⁻¹	1.52 g·L ⁻¹
Mean actual applied dose	4566.72 µg/cm ²	15.16 µg/cm ²

Number of replicates (n)	8		8	
	Mean	S.D.	Mean	S.D.
Dislodgeable dose				
Skin wash	94.64	1.25	68.69	2.81
Donor chamber wash	0.02	0.01	0.22	0.06
Dose associated to skin				
Tape strips: 1 st sample, strips 1 + 2	1.26	0.18	5.40	0.86
Tape strips: 2 nd sample; strips 3 - n	1.08	0.12	13.94	0.73
Skin preparation	0.19	0.05	6.22	0.54
Absorbed dose				
Receptor fluid	0.77	0.11	1.48	0.24
Receptor chamber wash	0.02	0.01	0.22	0.06
Total recovery¹	99.12	1.32	100.74	1.55
Absorption essentially complete at end of study (>75% absorption within half the study duration) [%Absorption at t _{0.5}]	No [60.12± 2.54]		No [63.63± 2.42]	
If no: Absorption estimates = absorbed dose + skin preparation + tape strips sample 2) ²	2.05	0.12	21.85	0.63
If yes: Absorption estimates = absorbed dose + skin preparation	N/A	N/A	N/A	N/A
Absorption estimate considering variability ³ (Absorption (mean value) + ks)	2.05 ± 0.84 × 0.12		21.85 ± 0.84 × 0.63	
Relevant absorption estimate	2.1508		22.3792	
Absorption estimates⁴	2.2		22	

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

Conclusion/endpoint:

2.2 % of dose for undiluted Pendimethalin formulation (concentrate: 455 g/al) Pendimethalin)

22 % of dose for actual spray strength used in the field dilution (1.52 g/L Pendimethalin)

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 Pendimethalin

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

Substance	Pendimethalin 45.5 % CS	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-1,59 kg a.s. /ha	Spray dilution = 7,95 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Bare soil / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absorption	Dermal for product = 25	Dermal for in use dilution = 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		1,1454	% of RVNAS	673,76%
	Acute systemic exposure mg/kg bw/day		4,4699	% of RVAAS	2629,37%
Mixing and Loading	Gloves = Yes		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Substance	Pendimethalin 45.5 % CS	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-1,59 kg a.s. /ha	Spray dilution = 7,95 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10 ⁻³ Pa
Scenario	Bulb vegetables / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absorption	Dermal for product = 2,2	Dermal for in use dilution = 22	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		0,1505	% of RVNAS	88,53%
	Acute systemic exposure mg/kg bw/day		0,6357	% of RVAAS	373,97%
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 2: Estimation of longer term operator exposure towards Pendimethalin according to EFSA guidance

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	68,7236752	10,0888397	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	1,1453946	0,1681473	
% of RVNAS	673,76%	98,91%	

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	9,0300774	5,9441538	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,1505013	0,0990692	
% of RVNAS	88,53%	58,28%	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Pendimethalin

Table A 3: Input parameters considered for the estimation of worker exposure

Worker exposure from residues on foliage for PENSHUI			
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	1,59 kg a.s./ha	i_AppRate	
Number of applications	1	i_AppNo	
Interval between multiple applications	365 days	i_AppInt	
Half-life of active substance	30 days	d_HalfLifeAS	
Multiple application factor	1,0	d_MAF	
Dermal absorption of the product	25,00%	i_AbsorpProduct	
Dermal absorption of the in-use dilution	70,00%	i_AbsorpInuse	
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,77 µg a.s./cm ²	d_DFR	
Working hours	2 hr	d_WorkHr	
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr	d_DermTcUCV	
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr	d_DermTcCV1	
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	d_DermTcCV2	
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ^{^(-3)}	d_InhalTcAut	
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ^{^(-3)}	d_InhalTcCut	
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ^{^(-3)}	d_InhalTcSort	

Worker exposure from residues on foliage for Pendimethalin 45.5 % CS			
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	1,59 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	2,20%		
Dermal absorption of the in-use dilution	22,00%		
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,77 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		
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 4: 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	Comments
Total systemic exposure (mg a.s./day)	83,4750000	9,3492000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	1,3912500	0,1558200		
% of RVNAS	818,38%	91,66%		

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	26,2350000	2,9383200	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,4372500	0,0489720	
% of RVNAS	257,21%	28,81%	

Table A 5: Input parameters considered for the estimation of worker exposure – bulb vegetables

Worker exposure from residues on foliage for PENSHUI			
Crop type	Bulb vegetables		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	1,59 kg a.s./ha		<i>i_AppRate</i>
Number of applications	1		<i>i_AppNo</i>
Interval between multiple applications	365 days		<i>i_AppInt</i>
Half-life of active substance	30 days		<i>d_HalfLifeAS</i>
Multiple application factor	1,0		<i>d_MAF</i>
Dermal absorption of the product	25,00%		<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	70,00%		<i>i_AbsorpInuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	4,77 µg a.s./cm ²		<i>d_DFR</i>
Working hours	8 hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	5800 cm ² /hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	2500 cm ² /hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	580 cm ² /hr		<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA ha/hr*10 [^] (-3)		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 [^] (-3)		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 [^] (-3)		<i>d_InhalTcSort</i>

Worker exposure from residues on foliage for Pendimethalin 45.5 % CS			
Crop type	Bulb vegetables		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	1,59 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	2,20%		
Dermal absorption of the in-use dilution	22,00%		
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	4,77 µg a.s./cm ²		
Working hours	8 hr		
Dermal transfer coefficient - Total potential exposure	5800 cm ² /hr		
Dermal transfer coefficient - arms, body and legs covered	2500 cm ² /hr		
Dermal transfer coefficient - hands, arms, body and legs covered	580 cm ² /hr		
Inhalation transfer coefficient for automated applications	NA ha/hr*10 [^] (-3)		
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 [^] (-3)		
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 [^] (-3)		

Table A 6: Estimation of longer term worker exposure towards Pendimethalin according to EFSA guidance - bulb vegetables

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	154,9296000	66,7800000	15,4929600	
Total systemic exposure per kg body weight (mg/kg bw/day)	2,5821600	1,1130000	0,2582160	
% of RVNAS	1518,92%	654,71%	151,89%	

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	48,6921600	20,9880000	4,8692160
Total systemic exposure per kg body weight (mg/kg bw/day)	0,8115360	0,3498000	0,0811536
% of RVNAS	477,37%	205,76%	47,74%

Table A 7: ~~Input parameters considered for the estimation of worker exposure refinement for bulb vegetables~~

Worker exposure from residues on foliage for Pendimethalin 45.5 % CS	
Crop type	Bulb vegetables
Indoor or outdoor	Outdoor
Application method	Downward spraying
Application equipment	Vehicle-mounted
Worker's task	Reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	1,59 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)	3,1164 µg a.s./cm ²
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	5800 cm ² /hr
Dermal transfer coefficient - arms, body and legs covered	2500 cm ² /hr
Dermal transfer coefficient - hands, arms, body and legs covered	580 cm ² /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ^{^(-3)}
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ^{^(-3)}
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ^{^(-3)}

Table A 8: ~~Estimation of longer term worker exposure towards Pendimethalin according to EFSA guidance refinement for bulb vegetables~~

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	101,2206720	43,6296000	10,1220672
Total systemic exposure per kg body weight (mg/kg bw/day)	1,6870112	0,7271600	0,1687011
% of RVNAS	992,36%	427,74%	99,24%

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Pendimethalin

Table A 9: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for Pendimethalin 45.5 % CS	
Croptype	bare soil, cereals and bulb vegetables
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Buffer strip	2-3 m
Application rate of the product	1,59 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	7,95 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)	3,1164 µg a.s./cm ²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ 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	0,00000 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

Resident exposure for Pendimethalin 45.5 % CS	
Croptype	Bulb vegetables
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Buffer strip	2-3 m
Application rate of the product	1,59 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	7,95 g a.s./l
Dermal absorption of product	2,20%
Dermal absorption of in-use dilution	22,00%
Oral absorption	57,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	4,77 µg a.s./cm ²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ 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 10: Estimation of longer term resident exposure towards Pendimethalin according to EFSA guidance- bare soil, cereals and bulb vegetables

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)	0,4104152	0,0107000	0,0196639	1,8781875	1,7519698
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0410415	0,0010700	0,0019664	0,1878188	0,1751970
% of RVNAS	24,14%	0,63%	1,16%	110,48%	103,06%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,4654721	0,0138000	0,0528119	6,2606250	5,2968732
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0077579	0,0002300	0,0008802	0,1043438	0,0882812
% of RVNAS	4,56%	0,14%	0,52%	61,38%	51,93%

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)	0,4707259	0,0107000	0,0582900	0,5902875	0,7835364
Total systemic exposure per kg body weight (mg/kg a.s./day)	0,0470726	0,0010700	0,0058290	0,0590288	0,0783536
% of RVNAS	27,69%	0,63%	3,43%	34,72%	46,09%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,6748596	0,0138000	0,1429982	1,9676250	2,0081439
Total systemic exposure per kg body weight (mg/kg a.s./day)	0,0112477	0,0002300	0,0023833	0,0327938	0,0334691
% of RVNAS	6,62%	0,14%	1,40%	19,29%	19,69%

Table A 11: Input parameters considered for the estimation of longer term resident exposure – refinement for bare soil, cereals and bulb vegetables

Resident exposure for Pendimethalin 45.5 % CS	
Croptype	bare soil, cereals and bulb vegetables
Application method	Downward spraying
Application equipment	Vehicle-mounted-Drift Reduction
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Buffer strip	10 m
Application rate of the product	1,59 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	7,95 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)	4,77 µg a.s./cm ²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa
Concentration in air	0,001 mg/m ³
Resident dermal spray drift exposure 75th percentile - adult	0,20385 ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0,17965 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	0,00013 ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0,10973 ml spray dilution/person
Resident dermal spray drift exposure mean - child	0,1 ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00007 ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00011 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)	1,30%
Drift percentage on surface (mean)	1,00%
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 x20%
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 x20%

Table A 12: ~~Estimation of longer term resident exposure towards Pendimethalin according to EFSA guidance – refinement for bare soil, cereals and bulb vegetables~~

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)	0,4104152	0,0107000	0,0196639	0,3756375	0,5539366
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0410415	0,0010700	0,0019664	0,0375638	0,0553937
% of RVNAS	24,14%	0,63%	1,16%	22,10%	32,58%

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.