

FINAL REGISTRATION REPORT

Part A

Risk Management

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.

Submission date: June 2020

MS Finalisation date: December 2021; April 2022 July 2022

Version history

When	What
12. 2021	RMS finalised the dRR assessment
04.2022	Evaluation after the commenting process
07.2022	Final corrections made on area of Efficacy and Ecotoxicology Sections

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by SHARDA CROPCHEM ESPAÑA S.L. for approval of PENSUI, a capsule suspension formulation containing 455 g/L pendimethalin, for use as herbicide in several crops. zRMS: Poland, cMS: Hungary, Romania, Germany.

1.2 Letters of Access

Not applicable. Letter of access not needed.

1.3 Justification for submission of tests and studies

This dossier relies on tests and studies providing data and information specific to the formulation as required by the EU regulation.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	SHA 2600 E
Product name in MS	PENSUI
Authorization number	-
Function	Herbicide
Applicant	Sharda Cropchem España S.L
Active substance(s) (incl. content)	Pendimethalin; 455 g/l
Formulation type	Capsule Suspension [code: CS]
Packaging	100mL, 250mL, 500mL and 1L bottle HDPE 5, 10 and 20 litre jerrycan HDPE
Coformulants of concern for national authorizations	-
Restrictions related to identity	-

Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

The evaluation of the application for PENSUI resulted in the decision to grant the authorization.

Section Phys-chem:

Authorisation can be granted for one year only.

Analytical methods:

No data gaps.

Mammalian toxicology:

Classification of Penschui is following: **Skin Sens.1/H317 – Repr,2/H361d**

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

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 PENSUI.

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 PENSUI

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

Metabolism and residues:

Noticed data gaps are:

- Residue trials for:

Stone fruits at BBCH 00-09;

Winter oilseed rape at BBCH 10-16;

asparagus, leek, Clover, alfalfa, Artichoke, Fennel, Cucurbits (melon, cucumber, squash, zucchini).

Ecotoxicology Section:

~~The authorisation can be granted for cereals and maize (pre-emergence application BBCH<10).~~

Ecotoxicology:

The unacceptable long-term risk for mammals (vole) was indicated in the following crops:

- Orchards
- Bush and cane fruits
- Vineyards

The risk assessment for aquatic organism indicated an unacceptable risk for the following crops:

- **Winter cereals 1 x 1590 g a.s./ha**
- Sunflower 1 x 1183 g a.s./ha
- Bulb vegetables 1 x 1590 g a.s./ha
- Bulb vegetables 1 x 1137 g/ha
- Beans 1 x 1590 g a.s./ha
- Beans 1 x 1137 g a.s./ha
- Carrots, parsley, parsnip and fennel 1 x 1590 g a.s./ha
- Asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop 1 x 1590 g/ha)
- Potato 1 x 1590 g a.s./ha
- Cucurbits (fruiting vegetables 1 x 1590 g/ha)

2.3 Substances of concern for national monitoring

Not relevant.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Skin Sens. 1; Aquatic Acute 1; Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS07, GHS08, GHS09
Signal word:	Warning
Hazard statement(s):	H317, H361d, H400, H410
Precautionary statement(s):	P261, P280, P302+P352, P333+P311, P308+P313, P362+P364, P391, 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

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
Committee for Risk Assessment RAC opinion proposing harmonised classification and labelling at EU level of pendimethalin Adopted 8 October 2020	

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

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	<p>To protect aquatic organism following risk mitigation measures should be applied to surface water bodies:</p> <p>Winter cereals 1 x 1137 g a.s./ha, pre-emergence application</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Winter cereals 1 x 1137 g a.s./ha, post emergence application</p> <p>- 20m no spray buffer zone + 20m vegetative strip + 75 % nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Maize, 1 x 1590 g a.s./ha, pre emergence application</p> <p>- 20m no spray buffer zone + 20m vegetative strip + 75 90% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Maize 1 x 1590 g a.s./ha, post emergence application</p> <p>- 20m no spray buffer zone + 20m vegetative strip + 75 90% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Maize 1 x 1137 g a.s./ha, pre emergence application</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Maize 1 x 1137 g a.s./ha, post emergence application</p> <p>- 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Orchards 1x 1590 g a.s./ha, early application</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Soybean 1 x 1183 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Carrots, parsley, parsnip and fennel 1 x 1137 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Lupine (legume) 1 x 1183 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone+ 10m vegetative strip + 90% nozzle reduction</p> <p>Winter oilseed rape 1 x 455 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip +50% drift nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction</p>

	<p>Winter oilseed rape 1 x 910 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction</p> <p>Strawberry 1 x 1590 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Strawberry 1 x 1137 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Raspberry 1 x 1365 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction</p> <p>Currants and grapevine (vines early application 1 x 1590 g/ha between rows)</p> <p>-20 m no spray buffer zone + 20 m 45m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Potato 1 x 1137 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Ornamentals (vines, early application 1 x 1590 g a.s./ha)</p> <p>-20m no spray buffer zone + 20m vegetative strip + 90% 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Clover and alfalfa (grass 1 x 1000 g a.s./ha)</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p>
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
P280	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
Worker protection:	
P280	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.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	<p>To protect aquatic organism following risk mitigation measures should be applied to surface water bodies:</p> <p>Winter cereals 1 x 1137 g a.s./ha, pre-emergence application</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Winter cereals 1 x 1137 g a.s./ha, post emergence application</p> <p>- 20m no spray buffer zone + 20m vegetative strip + 75 % nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Maize, 1 x 1590 g a.s./ha, pre emergence application</p> <p>- 20m no spray buffer zone + 20m vegetative strip + 75 90% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Maize 1 x 1590 g a.s./ha, post emergence application</p> <p>- 20m no spray buffer zone + 20m vegetative strip + 75 90% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Maize 1 x 1137 g a.s./ha, pre emergence application</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Maize 1 x 1137 g a.s./ha, post emergence application</p> <p>- 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Orchards 1x 1590 g a.s./ha, early application</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Soybean 1 x 1183 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Carrots, parsley, parsnip and fennel 1 x 1137 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray</p>

	<p>buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Lupine (legume) 1 x 1183 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone+ 10m vegetative strip + 90% nozzle reduction</p> <p>Winter oilseed rape 1 x 455 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip +50% drift nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction</p> <p>Winter oilseed rape 1 x 910 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip +75% or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction</p> <p>Strawberry 1 x 1590 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Strawberry 1 x 1137 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Raspberry 1 x 1365 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction</p> <p>Currants and grapevine (vines early application 1 x 1590 g/ha between rows)</p> <p>-20 m no spray buffer zone + 20 m 45m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Potato 1 x 1137 g a.s./ha</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Ornamentals (vines, early application 1 x 1590 g a.s./ha)</p> <p>-20m no spray buffer zone + 20m vegetative strip + 90% 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p> <p>Clover and alfalfa (grass 1 x 1000 g a.s./ha)</p> <p>-20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction</p>
Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

Not relevant.

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): Pendimethalin 45.5% CS
Active substance 1: pendimethalin
Active substance 2:
Safener: -
Synergist: -
Applicant: SHARDA Cropchem España
Zone(s): Central
Verified by MS: yes/~~no~~

GAP rev. 0, date: 2019-June-5th
Formulation type: CS (capsule suspension)
Conc. of as 1: 455 g/L
Conc. of as 2:
Conc. of safener: -
Conc. of synergist: -
Professional use: ☒
Non professional use: ☐

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Zonal uses (field or outdoor uses, certain types of protected crops)												
1	CEU	Winter cereals (wheat, barley, rye, oats, triticale)	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200-400	<p>Ecotox Section: The risk for aquatic risk assessment for dose 1.59 kg a.s./ha is not acceptable. The risk need further refinement for mammals for application 1.59 kg a.s./ha.</p> <p>Efficacy section: only winter wheat and barley can be accepted</p>
2	CEU	Winter cereals (wheat, barley, rye, oats, triticale)	F	Broadleaved and grass weeds	Spray	Post emergence BBCH 10-13	a) 1 b) 1	NA	a) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200-400	<p>Ecotox Section: The risk need further refinement for mammals for application 1.59 kg a.s./ha. The for aquatic organism for dose 1.59 kg a.s./ha is not acceptable. Efficacy section: winter wheat and barley can be accepted</p>
3	CEU	Maize	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200-400 600	<p>Efficacy section: water volume should be 200-400 L/ha The risk need further refinement for mammals for application 1.59 kg a.s./ha.</p>
4	CEU	Maize	F	Broadleaved and grass weeds	Spray	Post emergence BBCH 10-13	a) 1 b) 1	NA	a) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200-600	<p>Ecotox Section: The risk needs further refinement for mammals. The risk need further refinement for mammals for application 1.59 kg a.s./ha.</p>
5	CEU	Pome fruits (apple, pear)	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09 applications	a) 1 b) 1	NA	a) 3.5 b) 2.5	a) 1.59 b) 1.59	200-600	<p>After harvest and before emergence next season Ecotox Section: The risk needs further</p>

						between rows							refinement for mammals
													Efficacy section: this use can be accepted.

6	CEU	Stone fruits (peach, apricot, plum, nectarine, cherry)	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09 applications between rows After harvest	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200-600	Residues section: After harvest and before emergence next season Accepted Efficacy: can be accepted only according to Article 51 Ecotox Section: The risk needs further refinement for mammals.
7	CEU	Sunflower	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 2.6 b) 2.6	a) 1.183 b) 1.183	200-400	Efficacy: can be accepted only according to Article 51 Ecotox Section: The risk for aquatic organism is not acceptable.
8	CEU	Soybean	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 2.6 b) 2.6	a) 1.183 b) 1.183	200-400	Efficacy: can be accepted only according to Article 51
9	CEU	Bulb vegetables (onion, garlic, shallot, spring onion)	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200-400	Efficacy: can be accepted only according to Article 51 Ecotox Section: The risk for aquatic organism is not acceptable.
10	CEU	Bulb vegetables (onion, garlic, shallot, spring onion)	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Post emergence BBCH 10-13	a) 1 b) 1	NA	a) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200-400	Efficacy: can be accepted only according to Article 51 Ecotox Section: The risk for aquatic organism is not acceptable.
11	CEU	Bean, pea, broad bean, field bean	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200-400	Efficacy: can be accepted only according to Article 51 Ecotox Section: The risk for aquatic organism is not acceptable.

												ble.
12	CEU	Carrot, parsley	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200-400	Efficacy: can be accepted only according to Article 51 Ecotox Section: The risk for aquatic organism is not acceptable for dose 1.59 kg a.s./ha
13	CEU	Lupine	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 2.6 b) 2.6	a) 1.183 b) 1.183	200-400	Efficacy: can be accepted only according to Article 51
14	CEU	Winter oilseed rape	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 1.0 b) 1.0	a) 0.455 b) 0.455	200-400	
15	CEU	Winter oilseed rape	F	Broadleaved and grass weeds	Spray	Post emergence BBCH 10-16	a) 1 b) 1	NA	a) 2.0 b) 2.0	a) 0.91 b) 0.91	200-400	Not accepted (see B7) B7: accepted Efficacy section: not accepted
16	CEU	Asparagus	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200-400	Efficacy: can be accepted only according to Article 51 Not accepted (see B7) Section Ecotoxicology: The risk for aquatic organism is not acceptable for dose 1.59 kg a.s./ha
17	CEU	Brassica vegetables (broccoli, Brussels sprouts, cabbage, cauliflower)	F	Broadleaved and grass weeds	Spray	Pre-transplanting	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200-400	Efficacy: can be accepted only according to Article 51 Section Ecotoxicology: The risk for aquatic organism is not acceptable for dose 1.59 kg a.s./ha
18	CEU	Strawberry	F	Broadleaved and grass weeds	Spray	Pre emergence	a) 1	NA	a) 3.5 3.0	a) 1.137-1.59	200-400	Efficacy: can be accepted only according to

			annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)		BBCH 00-09 applications between rows	b) 1		b) 3.5 3.0	1.365 b) 1.137-1.59 1.365			Article 51 B7: Only at BBCH: 00 Application rate: max. 1.365 kg as/ha
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19	CEU	Raspberry	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Pre emergence BBCH 00-09 applications between rows	a) 1 b) 1	NA	a) 3.0 b) 3.0	a) 1.365 b) 1.365	200- 400		Efficacy: can be accept- ed only according to Article 51 B7: Only BBCH: 00 Section Ecotoxicology The risk needs further refinement for mammals.
20	CEU	Currants	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Pre emergence BBCH 00-09 applications between rows	a) 1 b) 1	NA	a) 3.5 3.0 b) 3.5 3.0	a) 1.59 1.365 b) 1.59 1.356	200- 400		Efficacy: can be accept- ed only according to Article 51 B7: Only at BBCH: 00 Application rate: max. 1.365 kg as/ha Section Ecotoxicology The risk needs further refinement for mammals.
21	CEU	Leek	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200- 400		Not accepted (see B7) Section Ecotoxicology: The risk for aquatic organism is not accepta- ble for dose 1.59 kg a.s./ha
22	CEU	Leek	F	Broadleaved and grass weeds	Spray	Post emergence BBCH 10-13	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200- 400		Not accepted (see B7) Section Ecotoxicology: The risk for aquatic organism is not accepta- ble for dose 1.59 kg a.s./ha
23	CEU	Parsnip	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200- 400		Efficacy: can be accept- ed only according to Article 51 Section Ecotoxicology: The risk for aquatic organism is not accepta- ble for dose 1.59 kg a.s./ha
24	CEU	Lettuce, endive	F	Broadleaved and grass weeds	Spray	Pre-transplanting	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200- 400		Efficacy: can be accept- ed only according to Article 51 Section Ecotoxicology: The risk for aquatic

												organism is not acceptable for dose 1.59 kg a.s./ha
25	CEU	Potato	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200-400	<p>Section Ecotoxicology: The risk for aquatic organism is not acceptable for dose 1.59 kg a.s./ha</p> <p>Efficacy section: not accepted this use</p>
26	CEU	Grapevine	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09 applications between rows	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200-400	<p>Efficacy: can be accepted only according to Article 51</p> <p>Section Ecotoxicology: The risk needs further refinement for mammals.</p>
27	CEU	Ornamentals	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200-400	<p>Efficacy: can be accepted only according to Article 51</p>
28	CEU	Clover, alfalfa	F	Broadleaved and grass weeds	Spray	Post emergence BBCH 13-18	a) 1 b) 1	NA	a) 2.2 b) 2.2	a) 1.0 b) 1.0	200-400	Not accepted (see B7)
29	CEU	Artichoke	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200-400	<p>Not accepted (see B7)</p> <p>Section Ecotoxicology: The risk for aquatic organism is not acceptable for dose 1.59 kg a.s./ha</p>
30	CEU	Fennel	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200-400	<p>Not accepted (see B7)</p> <p>Section Ecotoxicology: The risk for aquatic organism is not acceptable for dose 1.59 kg a.s./ha</p>
31	CEU	Cucurbits (melon, cucumber, squash, zucchini)	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200-400	<p>Not accepted (see B7)</p> <p>Section Ecotoxicology The risk for aquatic organism is not acceptable for dose 1.59 kg</p>

													a.s./ha
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													
Minor uses according to Article 51 (zonal uses)													
5													
6													
Minor uses according to Article 51 (interzonal uses)													
7													
8													

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey. Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	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	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is yellow to brown viscous liquid having non-characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 375 °C. In aqueous solution, it has a pH value around 9.53 ± 0.01 at 20 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. A shelf life of at least 2 years at ambient temperature is on-going and the final report will be provided as soon as available. Its technical characteristics are acceptable for a *capsule suspension* formulation.

3.2 Efficacy (Part B, Section 3)

Pendimethalin 45.5% CS is a Capsule Suspension (CS) formulation containing 455 g/L pendimethalin for use as herbicide in winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peans, carrot, parsley, strawberry, potato, asparagus, brassicas, currants, leek, parsnip, lettuce, endive, gravepine, ornamentals, artichoke, fennel, cucurbits, raspberry, sunflower, soybean, lupine, clover and alfalfa and winter oilseed rape.

In compliance with the GAP the following dose rates are applied for registration:

- One applications in cereals, maize and apple to control grass and broadleaved weeds, target rate: 2.5-3.5 L/ha

To support the registration of Pendimethalin 45.5% CS in the GAP claimed crops, trials have been set up in cereals, maize and apple. In the trials conducted in Czech Republic, Poland, Lithuania, Slovakia, Romania, Spain and Italy, the pendimethalin formulation prepared by Sharda Cropchem España – Pendimethalin 45.5% CS – was compared against a reference pendimethalin standard (Stomp Aqua, Stomp 400SC, Activus SC) and two **Sharda products** (Pendimethalin 33 EC and Pendimethalin 40 SC) registered over 10 years ago now out of protection currently on the market in Europe. The trials were conducted in 2019 season in a range of European countries in the Maritime (i.e. Czech Republic), the North-east (i.e. Poland and Lithuania), the South-east (i.e. Slovakia and Romania) and the Mediterranean (i.e. Spain and Italy) EPPO zones.

According to the GAP, the proposed application rate of Pendimethalin 45.5% CS is 2.5-3.5 L per hectare (L/ha), with one application per season, for the pre-emergence or post emergence control of grasses and broadleaved weeds in winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peans, carrot, parsley, strawberry, potato; 3.5 L per hectare (L/ha) asparagus, brassicas, currants, leek, parsnip, lettuce, endive, gravepine, ornamentals, artichoke, fennel, cucurbits; 3.0 L per hectare in raspberry; 2.6 L per hectare in sunflower, soybean, lupine; 2.2 L per hectare (L/ha) in clover and alfalfa; 1.0-2.0 L per hectare (L/ha) in winter oilseed rape. This will deliver 910-1956 g pendimethalin per hectare. In the treated crops, the test product was tested against registered rates of the reference products employed, currently marketed in the countries where the trials were conducted.

The data presented in this dossier fully support the label claim for pendimethalin for the control of grasses and broadleaved weeds in the crops claimed in the GAP table.

3.3 Efficacy data

Preliminary tests

The activity of pendimethalin is well known, as it has been marketed since the mid-seventies for the use in e.g. sunflower, carrots, onion, winter cereals, grapevine and strawberry to control grasses and broad-leaved weeds. Based on the knowledge about the active substance and the experiences in the label claimed crops, the necessary application rates to obtain sufficient control of the weeds are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Minimum effective dose tests

The applicant has proposed doses of PENSUI (product code: SHA 2600 E) that reflect those of currently-authorized pendimethalin products across the EU.

In order to provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate researches of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2).

During field tests Applicant used different doses of herbicide PENSUI (product code: SHA 2600 E) containing pendimethalin. So, in the appropriate researches of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2).

SHA 2600 E was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with PENSUI applied at:

- maize (pre- and post-emergence): three different doses were studied during trials: 2,0 l/ha; 2,5 l/ha; and 3,5 l/ha. Trials were carried out in MAR, N-E, S-E and MED EPPO zone;
- cereals: winter wheat and winter barley (pre- and post-emergence use): three different doses were studied during trials: 2,0 l/ha; 2,5 l/ha; and 3,5 l/ha. Trials were carried out in MAR, N-E and MED EPPO zone;
- apple (only post-emergence use): three different doses were studied during trials: 2,0 l/ha; 2,5 l/ha; and 3,5 l/ha. Trials were carried out in MAR, N-E, S-E and MED EPPO zone.

Based on results achieved on studied weeds in the 97 trials (in total): MAR (36), N-E (33), S-E (6) and MED (22), it can be concluded that to consistently control frequently occurring weeds in maize, cereals and apple – PENSUI should be applied at the recommended dose of 2.5-3.5 L/ha. What is important, the efficacy of recommended dose was similar to tested product – PENSUI. However, in our opinion, the higher of the doses should be used under conditions of high weed infestation.

Efficacy tests and conclusions regarding authorization of intended uses

We are dealing with the active substances used commonly for many years in many countries. According to the EPPO Standard PP1/226: Number of efficacy trials, a major target in a major crop must be supported by 10 trials (range 6-15 trials required depending on factors such as range of environmental and climatic conditions, levels of target pressure and consistency of results) and a minor use/target must be supported by 3 trials (range 2-6 trials).

The field experiments of the herbicide – PENSUI (product code: SHA 2600 E) were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized. The reports include a detailed data about conditions, agro-technological procedures, fore-crop as well as technical details etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards (some exceptions will be described later). The Applicant submitted reports showing the results in research into product efficacy carried out between one growing season for maize and apple, which is not in line to EPPO PP 1/181(4). However, the Applicant provided an adequate explanation for conducting the study in only one growing season, which was accepted by Evaluator (ZRMS-PL).

cMS should use scale of efficacy in line with its national guidelines (ex. SANCO). Applicant presented

scale of weed sensitivity according to SANCO scale. However, for Poland we should use different scale: S (susceptible) > 85%; MS (moderately susceptible) 70-85%; MT (moderately tolerant) 60-70%; T (tolerant) < 60%.

We are dealing with the active substances used commonly for many years in many countries. So, in the list of weeds controlled should include only those species that occurred (with appropriate intensity) a minimum of two localizations, and in the case of the species with the highest hazard of the plants at least in four locations. The level (>5%) of weed infestation in all studies was sufficient. Only trials with greater than 5 weeds/m² or over 2% ground cover have been included.

Applicant submitted following number of trials for:

- **maize:** for pre- and post-emergence use in total 32 trials were presented (MAR: 12 – CZ; MED: 4 – IT; S-E: 4 – SK (2), RO (2) and N-E: 12 – PL (10), LT (2)). Only for MAR and N-E EPPO zone Applicant submitted sufficient number of trials. cMS from S-E and MED should decide if only 4 trials can be acceptable.
- **cereals:** For pre-emergence use in total 40 trials were presented: MAR: 14 (CZ), MED: 12 (ES) and N-E: 14 (PL-12, LT-2). For post-emergence use in total 45 trials were presented: MAR: 18 (CZ); MED: 12 (ES) and N-E: 15 (PL-12, LT-2, ES-1). Applicant submitted enough number of trials for pre- and post-emergence use for MAR, MED and N-E. Lack of trials for S-E, which, in our opinion, is related to the lack of possibility of registration in this zone. However, final decision is left to cMS.
- **apple:** for post-emergence use in total 20 trials were presented (MAR: 6 -CZ, MED: 6 – ES (4) and IT (2), S-E: 2 – RO and N-E: 6 – PL). Applicant submitted enough number of trials for MAR, MED and N-E EPPO zone. cMS from S-E should decide if limited number of trials (2) can be acceptable.

Also, Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the reference product in their own Member State. The evaluation was conducted in accordance with Uniform Principles.

cMS should decide which weed species can be accepted on the basis on presented documentation and their national rules.

Following weed species should be considered by each cMS if they can be acceptable on the basis on submitted documentation:

- **maize:**
 - **pre-emergence use:** Maritime – CAPBP (4), CHEAL (2 – in one trial not sufficient level of infestation was observed); ECHCH (5), FUMOF (2), MATIN (5), POLCO (3), STEME (2), THLAR (3), VIOAR (3 – in one trial not sufficient level of infestation was observed); N-E EPPO zone: AMARE (2), CHEAL (5), ECHCG (5), POLCO (3), STEME (3), VIOAR (3); S-E EPPO zone: CHEAL (2), ECHCG (2); MED EPPO zone: AMARE (2).
 - **post-emergence use:** Maritime: - CAPBP (5), CHEAL (3), ECHCG (5), FUMOF (2), GALAP (2), POLCO (3), POLLA (2), STEME (2), THLAR (4), VERPE (2); N-E EPPO zone: CHEAL (6), ECHCG (5), LAMPU (2), POLCO (4), VERPE (2); S-E EPPO zone: CHEAL (2), ECHCG (2), MED EPPO zone: ECHCG (2 – in all trials not sufficient level of infestation was observed)
- **cereals:**
 - **pre-emergence use:** Maritime: – THLAR (3), VERPE (3), VIOAR (3), STEME (7), CAPBP (7), POAAN (2), ALOMY (2), APESV (6), GALAP (5), ECHCG (4), MATIN (2); N-E EPPO zone: APESV (3), VIOAR (4), STEME (3), CAPBP (3), ANTAR (2); MED EPPO zone: AMARE (3), DIPER (2).
 - **post-emergence use:** Maritime: VERPE (8), VIOAR (5), STEME (9), CAPBP (6), POAAN (3), ALOMY (3), MATIN (5), THLAR (4), LAMPU (3), APESV (6), PAPRH (2), FUMOF (2), ARBTH (2), GALAP (3), ECHCG (2); N-E EPPO zone: APESV (4), AGREE (2), VIOAR (7), STEME (7), PAPRH (2), ANTAR (2), LAMPU (2), VERPE (4), CAPBP (3), GALAP (2), MATIN (3); MED EPPO zone: AMARE (6), CHEAL (2), CHEPO (2), CYPPO (2 – one trial with not sufficient level of infestation), DATST (2), DIPER (4), MALSI (2 – one trial with not sufficient level of infestation), SOLNI (2).

- **apple:**

- **post-emergence use:** Maritime: AMARD (3 – one trial with not sufficient level of infestation), ATXPA (3), CAPBP (4 – all trials with not sufficient level of infestation), CIRAR (6 – 3 trials with not sufficient level of infestation), ECHCG (6 – one trial with not sufficient level of infestation), LAMPU (2), POAAN (3 – all trials with not sufficient level of infestation), SETPU (2 – all trials with not sufficient level of infestation), STEME (2); N-E EPPO zone: ECHCG (3), LAMPU (5 – one trial with not sufficient level of infestation), POAAN (4 – one trial with not sufficient level of infestation), STEME (6), TAROF (3), VERPE (2); S-E EPPO zone: CAPBP (2) and SETSS (2); MED EPPO zone: LOLMU (2) and SOLNI (2).

Applicant submitted limited data for most studied weeds. In the opinion of Evaluator weeds studied only in 1 trial should be excluded from GAP table and label project.

Following weed species should be excluded due to not enough number of trials (only 1 trial was present-
ed):

- **maize:**

- **pre-emergence use:** Maritime: APESV, GAETE, GALAP, POLLA, VERPE; N-E EPPO zone: CAPBP, EPHHE, GASPA, LAMPU, SENVU, SINAR, THLAR, VERPE; S-E EPPO zone: AMARE, AMBEL, CHEHY, GIGSA, MERAN, SETSS, STEME, XANSI; MED EPPO zone: CHEAL, ECHCG, SOLNI, DIGSA.
- **post-emergence use:** Maritime: APESV, GAETE; N-E EPPO zone: AMARE, BRNSW, CAPBP, SETVI, SINAR, SOLNI, STEME, VIOAR; S-E EPPO zone: AMARE, AMBEL, CAPBP, DIGSA, GALAP, MATIN, POLCO, SETSS, THLAR, VIOAR, XANSI; MED EPPO zone: ABUTH, AMARE, CHEAL, SETVI, SOLNI.

- **cereals:**

- **pre-emergence use:** Maritime: PAPRH, FUMOF; N-E EPPO zone: POLAV, VERPE, PAPRH, BRNSW, MATIN, GALAP, SINAR; MED EPPO zone: BEAVX, CHEAL, CHEPO, CYPRO, DATST, MALSI, SOLNI.
- **post-emergence use:** N-E EPPO zone: ALOMY, POLAV, BROSE, GAETE, BRNSW, VICCRE, MYOAR, SINAR; MED EPPO zone: BEAVX, MAQVU.

- **apple:**

- **post-emergence use:** Maritime: ERICA, N-E EPPO zone: AREEL, CHEAL, GERPU, MATIN, POLPI, SENVU; S-E EPPO zone: ANGAR, APESV, DAUCA, DIGSA, ECHCG, ERIAN, GALAP, POAAN, RANRE, SONOL, VERSS; MED EPPO zone: AMARE, BEAVX, CHEAL, CIRAR, CONAR, CRUBO, DIGSA, DIPER, ECHCG, MATCH, POAAN, SENVU, SONOL.

Applicant correctly presented results. Due to the limited number of results for particular weeds species, it is difficult to make a clear conclusion for the label, especially for weeds which are considered to be major. Therefore, the sufficiency of results should be considered on the national level based on importance of weed in their country.

Extrapolations results from registered products containing pendimethalin should be considered by individual member states on a national level based on current registration, data protection and experience with similar active compounds products. The spectrum of weeds should be checked with label claims on these reference products.

Presented the effectiveness of PENSUI in apple according to LWA approach is not required, in the opinion of Evaluator. Because applications are made between rows to the intra-rows (inner strips between the trees within a row), application rates per ha are expressed per 'unit of treated surface area'.

Without any efficacy trials minor uses can be registered only on the basis on Article 51: bulb vegetables, leek, strawberry, pome fruits, stone fruits, asparagus, currants, parsnip, grapevine, ornamentals, artichoke, fennel and cucurbits, brassicas, bean, pea, carrot, parsley, sunflower, soybean, lupine, lettuce and endive, clover and alfalfa and raspberry for control of annual grass- and broadleaved weeds.

Potato and winter oilseed rape should be excluded from GAP table and label project. For major crops at

least 6 efficacy trials should be presented by Applicant.

For pear no efficacy studies were presented, however according to extrapolation tables, results from apple can be extrapolated on pear.

Efficacy studies were presented for winter wheat and winter barley. Lack of trials for rye, oat and triticale. However, according to extrapolation results rye, oat and triticale can be accepted in the GAP table and label project on the basis on possibility extrapolation results from other winter cereals (for ex. winter wheat).

ASSESSMENT FOR POLAND (N-E EPPO ZONE):

For Poland (N-E) we can take into consideration results from neighbouring countries (DE, CZ)

- **maize:** 24 valid trials for pre- and post-emergence use in Poland (12-CZ, PL-10 and LT-2) – number of trials is acceptable according to EPPO and national rules.

Pre-emergence use:

Following weed species can be accepted in the Polish label:

- CAPBP – 5 trials (CZ-4, PL-1) – minor weed- at 2,5 l/ha and 3,5 l/ha – S;
- CHEAL – 7 trials (CZ-2, PL-5) – major weed – at 2,5 l/ha – MS and at 3,5 l/ha – S;
- ECHCG – 10 trials (CZ-5, PL-5) – major weed – at 2,5 l/ha – MS and at 3,5 l/ha – S;
- FUMOF – 2 trials (CZ) – minor weed – at 2,5 l/ha and 3,5 l/ha – S;
- MATIN – 5 trials (CZ) – major weed – at 2,5 l/ha and 3,5 l/ha – S
- POLCO – 6 trials (CZ-3, PL-3) – minor weeds – at 2,5 l/ha – MT and at 3,5 l/ha – MS;
- STEME – 5 trials (CZ-2, PL-3) – minor weed – at 2,5 l/ha and 3,5 l/ha – S
- THLAR – 4 trials (CZ-3, PL-1) – minor weed – at 2,5 l/ha – MS and 3,5 l/ha –S;
- VERPE - 2 trials (CZ, PL) – minor weed – at 2,5 l/ha and 3,5 l/ha – S;
- VIOAR – 6 trials (CZ-3, PL-3) – minor weed – at 2,5 l/ha and 3,5 l/ha – MS;
- AMARE – 2 trials (PL) – major weed – due to not enough number of trials (at least 4 are required) this weed species should be excluded from label project.

Post – emergence use:

Following weed species can be accepted in the Polish label:

- CAPBP – 6 trials (CZ-5, PL-1) – minor weed- at 2,5 l/ha – MT and 3,5 l/ha – MS;
- CHEAL – 9 trials (CZ-3, PL-6) – major weed – at 2,5 l/ha and at 3,5 l/ha – S;
- ECHCG – 10 trial (CZ-5, PL-5) – major weed – at 2,5 l/ha and 3,5 l/ha – MS
- FUMOF – 2 trials (CZ) – minor weed – at 2,5 l/ha – MT and 3,5 l/ha – MS;
- GALAP – 2 trials (CZ) – major weed - – due to not enough number of trials (at least 4 are required) this weed species should be excluded from label project.
- POLCO – 7 trials (CZ-3, PL-4) – minor weed – at 2,5 l/ha – T and 3,5 l/ha – MT;
- POLLA – 2 trials (CZ) – major weed - due to not enough number of trials (at least 4 are required) this weed species should be excluded from label project.
- STEME – 3 trials (CZ, PL-2) – minor weed – at 2,5 l/ha – MS and 3,5 l/ha – S'
- THLAR – 4 trials (CZ) – minor weed – at 2,5 l/ha – MT and 3,5 l/ha – MS;
- VERPE – 4 trials (CZ-2, PL-2) – minor weed – at 2,5 l/ha and 3,5 l/ha – MS;
- LAMPU – 2 trials (PL) – minor weed – at 2,5 l/ha – MT and 3,5 l/ha – MS.

Based on the summarized data, it is therefore considered that claims for control of weeds in maize by PENSUI (product code: SHA 2600 E) applied at the proposed label rate range of 2.5-3.5 L product/ha and according to other label recommendations, are fully supported.

- **cereals:** 28 valid trials for Poland for pre-emergence use (CZ-14, PL-12, LT-2) and 33 valid trials for post-emergence use (CZ-18, PL-12, LT-2, ES-1) – number of trials is acceptable according to EPPO and national rules.

Pre-emergence use (trials were carried out on winter wheat):

Following weed species can be accepted in the Polish label:

- THLAR – 3 trials (CZ) – major weed – due to not enough number of trials (at least 4 are required) this weed species should be excluded from label project.;
- VERPE – 4 trials (CZ-3, PL-1) – major weed – at 2,5 l/ha – MS and at 3,5 l/ha – S;
- VIOAR – 7 trials (CZ-3, PL-4) – major weed – at 2,5 l/ha and 3,5 l/ha – MS;
- STEME – 10 trials (CZ-7, PL-3) – major weed – at 2,5 l/ha – MS and at 3,5 l/ha – S;
- CAPBP – 10 trials (CZ-7, PL-3) – major weed – at 2,5 l/ha – MS and 3,5 l/ha – S;
- POAAN – 2 trials (CZ) – minor weed – at 2,5 l/ha and 3,5 l/ha – S;
- ALOMY – 2 trials (CZ) – major weed - due to not enough number of trials (at least 4 are required) this weed species should be excluded from label project.;
- APESV – 9 trials (CZ-6, PL-3) – major weed – at 2,5 l/ha – MS and 3,5 l/ha – S;
- GALAP – 5 trials (CZ) – major weed – at 2,5 l/ha – MS and 3,5 l/ha – S;
- ECHCG – 4 trials (CZ) – minor weed – at 2,5 l/ha – MS and 3,5 l/ha – S;
- MATIN – 2 trials (CZ) – major weeds – at 2,5 l/ha and 3,5 l/ha – MS;
- PAPRH – 2 trials (CZ, PL) – major weed - due to not enough number of trials (at least 4 are required) this weed species should be excluded from label project.;
- ANTAR -2 trials (PL) – minor weed - at 2,5 l/ha – MT and 3,5 l/ha – MS.

Post – emergence use (trials were carried out on winter wheat and winter barley):

Following weed species can be accepted in the Polish label:

- VERPE – 12 trials (CZ-8, PL-4) – major weed- at 2,5 l/ha and 3,5 l/ha –S;
- VIOAR – 12 trials (CZ-5, PL-7) – major weed – at 2,5 l/ha – MT and at 3,5 l/ha –MS;
- STEME – 16 trials (CZ-9, PL-7) – major weed – at 2,5 l/ha and 3,5 l/ha – S;
- CAPBP – 9 trials (CZ-6, PL-3) – major weed – at 2,5 l/ha and 3,5 l/ha -MS;
- POAAN - 3 trials (CZ) – minor weed – at 2,5 l/ha and 3,5 l/ha -S;
- ALOMY – 4 trials (CZ-3, PL-1) – major weed – at 2,5 l/ha – MS and at 3,5 l/ha – S;
- MATIN – 9 trials (CZ_5, PL-3) – major weed – at 2,5 l/ha – MS and at 3,5 l/ha -S);
- THLAR – 4 trials (CZ) – major weed – at 2,5 l/ha and 3,5 l/ha – S;
- LAMPU – 5 trials (CZ-3, PL-2) – minor weed – at 2,5 l/ha – MS and at 3,5 l/ha – S;
- APESV – 6 trials (CZ) – major weed – at 2,5 l/ha and 3,5 l/ha – S;
- PAPRH – 4 trials (CZ-2, PL-2) – major weed – at 2,5 l/ha and 3,5 l/ha – S;
- FUMOF – 2 trials (CZ) – minor weed – at 2,5 l/ha and 3,5 l/ha – S;
- ARBTH – 2 trials (CZ) – minor weed – at 2,5 l/ha and 3,5 l/ha – S;
- GALAP – 5 trials (CZ-3, PL-2) – major weed – at 2,5 l/ha – MT and at 3,5 l/ha – MS;
- ECHCG – 2 trials (CZ) – minor weed – at 2,5 l/ha – MS and at 3,5 l/ha – S;
- APESV – 4 trials (PL) – major weed – at dose 2,5 l/ha and 3,5 l/ha – MS;
- AGREE – 2 trials (PL) – minor weed – at dse 2,5 l/ha – MS and dose 3,5 l/ha – S;
- ANTAR – 2 trials (PL) – minor weed – at dose 2,5 l/ha and 3,5 l/ha – S.

Based on the summarized data, it is therefore considered that claims for control of weeds in cereals by PENSUI (product code: SHA 2600 E) applied at the proposed label rate range of 2.5-3.5 L product/ha and according to other label recommendations, are fully supported. Only winter wheat and winter barley can be accepted in GAP table and Polish label. For rye, oat and triticale is needed at least 3-4 selectivity trials for possibility extrapolation resuly from winter wheat.

- **apple:** 12 valid trials (CZ-6, PL-6) for use post-emergence in Poland – number of trials is acceptable according to EPPO and national rules.

The species composition of weeds in orchards is shaped primarily by human activity. The method of soil care, unified on a national scale, determines that Polish orchards are dominated by several dozen weed species, the same both in coastal and submontane areas. The species composition of weeds is not constant and unchangeable. A few dozen years ago, permanent shadowy weeds dominated in the orchards, under the spread tree crowns. Today, we don't find them in well sunny orchards, but in shady parks and gardens. In young orchards, established after agricultural crops, weeds are mostly one year old. Within the framework of succession, we may have to deal with weeds characteristic for the crops preceding the

orchard establishment, e.g. field poppy. These are gradually replaced by weeds typical of orchards. As the orchard ages and the soil under the tree crowns is not cultivated, the relative share of perennial weeds in the weed infestation increases, especially those poorly controlled by herbicides (weed compensation). Due to the high dynamics of changes in the type of weed infestation and dominant species, in our opinion, the acceptable minimum number of tests for weeds in orchards should be 2.

Post – emergence use:

Following weed species can be accepted in the Polish label:

- AMARD – 3 trials (CZ) – 2 trials were valid (in one trial the level of infestation was not at acceptable level) – at 2,5 l/ha – MS and at 3,5 l/ha – S;
- ATXPA – 3 trials (CZ) – at 2,5 l/ha – MS and at 3,5 l/ha – S;
- CAPBP – 4 trials (CZ) – in all trials level of infestation was not acceptable – this weed should be excluded due to not enough valid trials from GAP table and label project;
- CIRAR – 6 trials (CZ) – in three trials the level of infestation was not acceptable – at dose 2,5 l/ha – T and at dose 3,5 l/ha – MT;
- ECHCG – 9 trials (CZ-6, PL-3) – in one trial the level of infestation was not acceptable – at dose 2,5 l/ha and 3,5 l/ha – S;
- LAMPU – 5 trials (CZ-2, PL-3) – at dose 2,5 l/ha – MS and at dose 3,5 l/ha – S.
- POAAN – 7 trials (CZ-3, PL-4) – in four trials the level of infestation was not acceptable – at dose 2,5 l/ha and 3,5 l/ha – S;
- SETPU – 2 trials (CZ) – in all trials level of infestation was not acceptable – this weed should be excluded due to not enough valid trials from GAP table and label project;
- STEME – 7 trials (CZ-2, PL-5) – at dose 2,5 l/ha and 3,5 l/ha – S;
- LAMAM – 2 trials (PL) – at dose 2,5 l/ha and 3,5 l/ha – MS;
- TAROF – 3 trials (PL) – at dose 2,5 l/ha and 3,5 l/ha – T;
- VERPE – 2 trials (PL) – at dose 2,5 l/ha and 3,5 l/ha – S.

Based on the summarized data, it is therefore considered that claims for control of weeds in apple by PENSUI (product code: SHA 2600 E) applied at the proposed label rate range of 2.5-3.5 L product/ha and according to other label recommendations, are fully supported. However, due to lack of selectivity trials carried out on apple (higher dose than N should be studied), this use should be excluded from Polish GAP table and label project. At least 4-5 selectivity trials performed on apples are required. Due to fact that Applicat presented additional selectivity trials carried out on apple during commenting period, this sentence was excluded, and apple can be accepted.

Lack of trials for pear – at least 2 selectivity trials are required (then – extrapolation efficacy results from apple is possible).

Lack of trials for potato and winter oilseed rape – at least 6 efficacy trials and 4-5 selectivity trials should be presented. Potato and winter oilseed rape should be excluded from Polish GAP table and label project.

Without any efficacy trials minor uses can be registered only on the basis on Article 51: bulb vegetables, leek, strawberry, pome fruits, stone fruits, asparagus, currants, parsnip, grapevine, ornamentals, artichoke, fennel and cucurbits, brassicas, bean, pea, carrot, parsley, sunflower, soybean, lupine, lettuce and endive, clover and alfalfa and raspberry for control of annual grass- and broad-leaved weeds.

In Polish label following weeds species can be included as:

- *Susceptible*: AMARD (in dose 2,5 l/ha – moderately susceptible), APESV (in dose 2,5 l/ha – moderately susceptible), CAPBP (in dose 2,5 l/ha – moderately susceptible), ECHCG (in dose 2,5 l/ha – moderately susceptible), GALAP ((n dose 2,5 l/ha – moderately susceptible), POAAN (in dose 2,5 l/ha – moderately susceptible), VERPE (in dose 2,5 l/ha – moderately susceptible), ATXPA (in dose 2,5 l/ha – moderately susceptible), CHEAL (in dose 2,5 l/ha – moderately susceptible), MATIN (in dose 2,5 l/ha – moderately susceptible), STEME (in dose 2,5 l/ha – moderately susceptible), FUMOF (in dose 2,5 l/ha – moderately susceptible), THLAR (in dose 2,5 l/ha – moderately susceptible), ALOMY (in dose 2,5 l/ha – moderately susceptible), PAPRH, ARBTH, AGREE (in dose 2,5 l/ha – moderately susceptible);
- *Moderately susceptible*: POLCO (in dose 2,5 l/ha – moderately tolerant), VIOAR, ANTAR (in dose 2,5 l/ha – moderately tolerant), LAMPU (in dose 2,5 l/ha – moderately tolerant), LAMAM
- *Moderately tolerant*: CIRAR (in dose 2,5 l/ha –tolerant)
- *Tolerant*: TAROF

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Pendimethalin belongs to the chemical group of the dinitroanilines. Applied pre-emergence, pendimethalin is effective on some important grass weeds as well as on a wide range of broadleaved weeds. In the post-emergence application, Pendimethalin is predominantly effective on broad-leaved weeds.

The evaluation of the agronomic risk concludes, that Pendimethalin 45.5% CS bears a low risk of resistance.

The Registration of Pendimethalin 45.5% CS is endorsed.

PENSUI (product code: SHA 2600 E) contains pendimethalin which belongs to the chemical group of the dinitroanilines. Applied pre-emergence, pendimethalin is effective on some important grass weeds as well as on a wide range of broadleaved weeds. In the post-emergence application, Pendimethalin is predominantly effective on broad-leaved weeds. PENSUI is a pre and post-emergence herbicide for the control of weeds in many different crops.

HRAC has revised their herbicide mode of action classification system. HRAC group K1 is termed HRAC group 3 now. Due to the primary target site and the chemical subgroup, Pendimethalin is classified as a HRAC group ~~K1~~ 3 herbicide (microtubule assembly inhibition). To group 3 we can included also: Propyzamide=pronamide, Chlorthal-dimethyl=DCPA, Benefin=benfluralin, Butralin, Dinitramine, Ethalfluralin, Fluchloralin, Isopropalin, Nitratin, Oryzalin, Prodiamine, Profluralin, Trifluralin, Butamifos, DMPA, Dithiopyr and Thiazopyr. In the WSSA resistance classification system the dinitroanilines are classified as group 3. ~~The other chemical groups in HRAC group K1 are: phosphoramidates, pyridines, benzamides and benzoic acids.~~

Due to a low to medium resistance risk, the restriction of PENSUI (The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.) is required.

The following table shows the current worldwide resistance weeds specifically to the herbicide glyphosate (according to <http://www.weedscience.org>):

#	Year	Species	Country	MOAs	Actives	Situations
1	1996	Alopecurus myosuroides	Belgium	ACCase inhibitors (A/1), ALS inhibitors (B/2), Microtubule Assembly inhibitors (K1/3), Photosystem II- Serine 264 Binders (C1/5), PSII inhibitors - Serine 264 Binders (C2/7)	clodinafop-propargyl, propaquizafop, fenoxaprop-P-ethyl, flupyrasulfuron-methyl-sodium, atrazine, chlorotoluron, pendimethalin	Winter wheat
2	1992	Echinochloa crus-	Bulgaria	Microtubule Assembly inhibi-	pendimethalin	Orchards

#	Year	Species	Country	MOAs	Actives	Situations
		galli var. crus-galli		tors (K1/3)		
3	2001	Alopecurus myosuroides	Denmark	ACCase inhibitors (A/1), ALS inhibitors (B/2), Microtubule Assembly inhibitors (K1/3)	clodinafop-propargyl, fenoxaprop-P-ethyl, cycloxydim, flupyr-sulfuron-methyl-sodium, pendimethalin, florasulam, iodosulfuron-methyl-sodium, mesosulfuron-methyl, pyrox-sulam	Winter wheat
4	1987	Alopecurus myosuroides	United Kingdom	Microtubule Assembly inhibitors (K1/3)	pendimethalin	Wheat
5	2012	Poa annua	United States (Alabama)	Microtubule Assembly inhibitors (K1/3)	prodiamine, pendimethalin, dithiopyr	Turf
6	2016	Amaranthus palmeri	United States (Arkansas)	ALS inhibitors (B/2), EPSP synthase inhibitors (G/9), Microtubule Assembly inhibitors (K1/3), PPO inhibitors (E/14), Very Long-Chain Fatty Acid Synthesis inhibitors (K3/15)	imazethapyr, pyri-thiobac-sodium, flumetsulam, fomesafen, lactofen, acifluorfen-sodium, fluthiacet-methyl, carfentrazone-ethyl, glyphosate, pendimethalin, pyraflufen-ethyl, trifloxysulfuron-sodium, S-metolachlor	Cotton, Soybean
7	1992	Sorghum halepense	United States (Mississippi)	Microtubule Assembly inhibitors (K1/3)	pendimethalin	Cotton
8	1994	Eleusine indica	United States (Mississippi)	Microtubule Assembly inhibitors (K1/3)	pendimethalin, trifluralin	Cotton
9	1997	Poa annua	United States (North Carolina)	Microtubule Assembly inhibitors (K1/3)	prodiamine, pendimethalin	Golf courses, Turf
10	1988	Eleusine indica	United States (Tennessee)	Microtubule Assembly inhibitors (K1/3)	prodiamine, pendimethalin, trifluralin	Cotton, Golf courses, Turf
11	2007	Poa annua	United States (Tennessee)	Microtubule Assembly inhibitors (K1/3)	prodiamine, pendimethalin, dithiopyr	Golf courses, Turf

Applicant submitted detailed information's about possibilities of development the resistance or cross-resistance. Evaluator accepted the strategy management about possible development of resistance or cross-resistance proposed by Applicant.

Always follow HRAG guidelines for the prevention and managing herbicide resistant grass and broadleaved weeds.

The proposed resistance risk management strategy is acceptable. Final assessment of the resistance risk has to be carried out on member state level since the agronomic factors influencing the risk of resistance development tend to vary between the Member States.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

The crop safety of Pendimethalin 45.5% CS was assessed in Maize, Cereals and Apple in 64 97 efficacy trials (18 MAR, 18 NE, 36 MAR, 33 NE, 6 SE and 22 MED) and 15 37 selectivity trials (4 MAR, 4 NE and 7 MED) (12 MAR, 16 NE, 2 SE and 7 MED) where Pendimethalin 45.5% CS was applied at 2.0, 2.5, 3.0, 3.5, 6.0 and 7.0 L/ha. In the efficacy- and selectivity trials conducted in Cereals, Maize and Apple, Pendimethalin 45.5% CS was applied pre- and post-emergence.

~~The trials were conducted in the Maritime EPPO zone (22, i.e. Czech Republic (18 eff. and 4 sel.)), the North-east EPPO zone (21, i.e. Poland (15 eff. and 3 sel.) and Lithuania (2 eff. and 1 sel.)), the South-east EPPO zone (6, i.e. Romania (4 eff.) and Slovakia (2 eff.)) and the Mediterranean EPPO zone (29, i.e. Spain (26, 20 eff. and sel. 6) and Italy (2 eff. and 1 sel.)) in 2019 season, to evaluate the crop safety of Pendimethalin 45.5% CS in Cereals, Maize and Apple.~~

The trials were conducted in the Maritime EPPO zone (48, i.e. Czech Republic (36 eff. and 12 sel.)), the North-east EPPO zone (48, i.e. Poland (27 eff. and 11 sel.), Estonia (1 eff. and 2 sel.), and Lithuania (4 eff. and 3 sel.)), the South-east EPPO zone (8, i.e. Romania (4 eff.), Hungary(2 sel.) and Slovakia (2 eff.)) and the Mediterranean EPPO zone (29, i.e. Spain (26, 20 eff. and sel. 6) and Italy (2 eff. and 1 sel.)) in 2019, 2020 and 2021 season, to evaluate the crop safety of Pendimethalin 45.5% CS in Cereals, Maize and Apple.

The Selectivity tests about herbicide PENSUI (product code: SHA 2600 E) have been carried out in accordance with appropriate EPPO Guidelines. The conduct of the field work is principally compliant with “Good Agricultural Practice “and in accordance with EPPO-Guidelines PP 1/135 (4).

Selectivity studies on herbicide were performed in 2019 and 2020 and 2021 on winter wheat, winter barley and maize and apples by companies authorized to conduct studies on efficacy of plant protection products. The trials were performed with the use of different agricultural practice. The trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. The herbicide has been used in two doses: N and 2N. In all trials studied product was compared to the standard reference containing the same active ingredient. Statistical analysis of the data was performed. Also, quality of yield was evaluated in some trials.

Applicant presented following trials:

- **maize:** 9 valid trials (Maritime-4 trials (CZ) , N-E-4 trials (PL-3, LT-1), MED -1 trial IT)). During selectivity trials dose 3,5 l/ha (N) and 7,0 l/ha (2N) was studied. Based on the absence of phytotoxic symptoms or effects on crop growth and development or only very low and transient levels of symptoms or effects across trials, it is reasonable to conclude that a single application of PENSUI at up to the highest proposed label rate in the proposed range of 2,5-3.5 L product/ha), and applied according to label recommendations, is crop safe on maize.
- **winter wheat:** 11 valid trials (Maritime – 4 trials (CZ), N-E – 4 trials (PL-2, ES-1, LT-1), MED – 3 trials (ES)). During selectivity trials dose 3,5 l/ha (N) and 7,0 l/ha (2N) was studied. Based on the absence of phytotoxic symptoms or effects on crop growth and development or only very low and transient levels of symptoms or effects across trials, it is reasonable to conclude that a single application of PENSUI at up to the highest proposed label rate in the proposed range of 2,5-3.5 L product/ha), and applied according to label recommendations, is crop safe on winter wheat.
- **winter barley:** 11 trials (Maritime – 4 trials (CZ), N-E – 4 trials (PL-2, ES-1, LT-1), MED – 3 trials (ES)). During selectivity trials dose 3,5 l/ha (N) and 7,0 l/ha (2N) was studied. Based on the absence of phytotoxic symptoms or effects on crop growth and development or only very low and transient levels of symptoms or effects across trials, it is reasonable to conclude that a single application of PENSUI at up to the highest proposed label rate in the proposed range of 2,5-3.5 L product/ha), and applied according to label recommendations, is crop safe on winter barley.
- **apple:** 6 additional trials (S-E – 2 trials (RO); N-E- 4 trials (PL)). During selectivity trials dose 3,5 l/ha (N) and 7,0 l/ha (2N) was studied. Based on the absence of phytotoxic symptoms or effects on crop growth and development or only very low and transient levels of symptoms or effects across trials, it is reasonable to conclude that a single application of PENSUI at up to the highest proposed label rate in the proposed range of 2,5-3.5 L product/ha), and applied according to label recommendations, is crop safe on apple.

Also, during efficacy trials, no negative impact on studied crops was observed after treatment by tested PENSUI.

In the opinion of Evaluator Applicant submitted sufficient documentation for Poland for maize and cereal (winter wheat and winter barley) and apples. Lack of trials for pear. cMS should decide if presented documentation is sufficient according to their national rules.

~~Lack of selectivity trials on apples. Pensiui is an herbicide, so selectivity trials, in which dose 2N is studied are required. Due to lack of selectivity trials, apple and pear should be excluded from GAP table and label project, in the opinion of Evaluator. For Poland at least 4-5 selectivity trials carried out on apple and at least 2 carried out on pear are required for registration.~~

Effects on yield and quality

~~Fifteen selectivity trials conducted in 2019 were harvested to evaluate the effect of Pendimethalin 45.5% CS on yield of cereals and maize. The results presented here in this section were therefore derived from 15 selectivity trials conducted in the the Maritime EPPO zone (4, i.e. Czech Republic (4)), the North-east EPPO zone (4, i.e. Poland (3) and Lithuania (1)) and Mediterranean EPPO zone (7; i.e. Spain (6) and Italy (1)).~~

Thirty-seven selectivity trials conducted in 2019, 2020 and 2021 were harvested to evaluate the effect of Pendimethalin 45.5% CS on yield of cereals, maize and apple. The results presented here in this section were therefore derived from 37 selectivity trials conducted in the the Maritime EPPO zone (12, i.e. Czech Republic (12)), the North-east EPPO zone (16, i.e. Poland (11), Estonia (2) and Lithuania (3)) the South-east EPPO zone (2, i.e. Hungary (2)) and Mediterranean EPPO zone (7; i.e. Spain (6) and Italy (1)).

In all selectivity trials conducted in cereals and maize, Pendimethalin 45.5% CS was applied pre-emergence. All trials conducted on cereals and maize presented in this Biological Assessment Dossier were located within the Maritime zone (12), the North-east zone (12), the South-east zone (4) and the Mediterranean zone (7), as defined by EPPO Standard PP1/241(1).

Pendimethalin 45.5% CS applied at the recommended dose rate did not affect the quality of the harvested yield in any of the 45 37 trials taken to harvest. In the vast majority of the trials, Pendimethalin 45.5% CS applied at dose rates higher than the recommended rate – representative for sprayer overlap – did not significantly affect the quality of the harvested crop either.

Furthermore, the data obtained in trials harvested demonstrate that Pendimethalin 45.5% CS is as safe to the crop as the reference products used in the trials.

Applicant submitted selectivity trials carried out in N-E, S-E, MED and Maritime EPPO zone. During those field trials the impact of PENSUI on the yield of maize and cereals (winter wheat and winter barley) and apples was studied. In all trials no detrimental effect on the yield was recorded at the proposed dose rate and even at the double dose rate. Application of PENSUI provided a yield similar to the untreated plots and to those treated with the reference products. No statistical differences were observed between untreated and treated plots and also between the tested product and the standard product.

~~In the opinion of Evaluator, studies for yield from apples should be presented for dose N and 2N. Lack of those trials. Apple should be excluded from GAP table. Results of apple yield should be presented.~~

3.3.3 Observations on other undesirable or unintended side-effects

Impact on treated plants or plant products to be used for propagations

Special tests to investigate this purpose are not required.

The product complies with the Uniform Principles.

Impact on succeeding crops

The half-life (DT_{50}) for pendimethalin is 27-186 days. As regards effects on succeeding crops the Evaluator proposed the following label text, cause necessary precautions to prevent the negative impact on succeeding crops should be included in the label claim: *"The product decomposes in soil during the vegetation period to a level that does not pose a threat to succeeding crops. If a plantation treated with the product needs to be liquidated earlier (as a result of plant damage caused by frost, disease or pests), only maize and winter cereals (wheat, barley) can be cultivated after pre-sowing ploughing."*

Comparable plant protection products in Germany have the restriction "Damage to cultivated dicotyledonous intercrops and winter rape possible". So, we proposed to add following sentence to label project: *However, leaf discoloration is possible in broadleaf crops and winter oilseed rape.*

Impact on other plants including adjacent crops

Studies on the toxicity to non-target terrestrial plants have been carried out with Pendimethalin. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of Pendimethalin.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Effects on beneficial and other non-target organisms

From the experimentation carried out with Pendimethalin 45.5% CS in 2019, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 9.

3.4 Methods of analysis (Part B, Section 5)

Analytical methods for pendimethalin in water, air, soil, liquid media and plants are available.

3.4.1 Analytical method for the formulation

Active substance

The active ingredient concentration of the formulation PENSUI (pendimethalin 455 g/L CS) is determined by high performance liquid chromatography on a reversed phase column using Acetonitrile (90%): MilliQ Water (10%), v/v as mobile phase and UV detection at 240 nm. The validation parameters are presented below.

Methods suitable for the determination of pendimethalin in plant protection product pendimethalin 455 g/L CS

	Pendimethalin 455 g/L CS
Author(s), year	XXX, 2017
Principle of method	HPLC-UV
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	54.32 to 200.33 (mg/L) Correlation Coefficient 0.999
Precision – Repeatability Mean (%RSD)	The repeatability was assessed by analysing five samples on two different days. RSD=0.03% Acceptable RSDr (Horwith) = 1.54% Horrat value=0.019
Accuracy (% Recovery)	The accuracy was assessed by analysing three samples on three fortification levels. Marginal recovery=98.99%
Interference/ Specificity	No interference, the method is specific
Comment	-

	Pendimethalin
Author(s), year	B. XXX-, 2021
Principle of method	HPLC-UV
Linearity (linear between mg/L / % range of the declared content)	347 – 520 mg/L y=0.2825x-4.9096 R=0.9991

	Pendimethalin
(correlation coefficient, expressed as r)	
Precision – Repeatability Mean n = 5 (in duplicate) (%RSD)	RSD = 0.41% RSD _R =2.25% RSD _r =1.51% Hr=0.27<1
Accuracy n = 7 (% Recovery)	Total recovery: 90%: 101.2% 110%: 101.1%
Interference/ Specificity	No interference. The method is specific
Comment	

	Free Pendimethalin
Author(s), year	B. XXX-, 2021
Principle of method	HPLC-UV
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	4.44-6.66 mg/L y=0.2867x-0.033 R=0.9955
Precision – Repeatability Mean n = 5 (in duplicate) (%RSD)	RSD = 5.56% RSD _R =12.34% RSD _r =8.27% Hr=0.67<1
Accuracy n = 7 (% Recovery)	Total recovery: 90%: 127.9% 110%: 127.0%
Interference/ Specificity	No interference. The method is specific

From the results of the analytical methods' validations, it is concluded that the analytical methods is are specific, sensitive, precise and accurate for the analysis of pendimethalin in the formulation PENSUI (pendimethalin 455 g/L CS). The results of validation criteria are within the specified limits of SAN-CO/3030/99 rev. 4 and rev. 5, Dir. 91/414/EEC (2000), U.S. EPA, (OCSP) 830.1800 and ABNT NBR 14029 guidelines.

Relevant impurities

The determination of 1,2-dichloroethane in the formulation PENSUI (pendimethalin 455 g/L CS) is performed by headspace analysis in combination with gas chromatography and flame ionization detection (HS-GC-FID) using external standard method with application of placebo of PENDIMETHALIN 455 g/l CS preparation as a matrix to which known amount of 1,2-dichloroethane was added to determine the individual validation parameters.

The determination of N-nitrosopendimethalin in the formulation PENSUI (pendimethalin 455 g/L CS) is performed using reversed phase high performance liquid chromatography (RP-HPLC) with UV detection at wavelength 206 nm using external standard method.

The validation parameters are presented below.

Methods suitable for the determination of relevant impurities in plant protection product pendimethalin 455 g/L CS

	1,2-dichloroethane	N-nitrosopendimethalin
Author(s), year	A. XXX, 2017	A. XXX, 2017
Principle of method	HS-GC-FID	HPLC with UV-DAD
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	0.0050 - 0.1000 mg/mL R=0.9999	0.039 – 0.088 µg/mL R=0.9933
Precision – Repeatability Mean (%RSD)	RSD = 1.06% Acceptable RSDr (Horwith) = 6.60% Horrat value=0.16	RSD = 3.38% Acceptable RSDr (Horwith) = 7.58% Horrat value=0.45
Accuracy (% Recovery)	The accuracy was assessed by analysing six samples on two fortification levels Marginal recovery=99.2%	The accuracy was assessed by analysing six samples on two fortification levels Marginal recovery=97.6%
Interference/ Specificity	No interference, the method is specific	No interference, the method is specific
LOQ	0.025 g/kg	0.010 g/kg
Comment	-	-

From the results of the analytical methods validations, it is concluded that the analytical methods for the determination of relevant impurities 1,2-dichloroethane and N-nitrosopendimethalin in the formulation PENSUI (pendimethalin 455 g/L CS) are specific, sensitive, precise and accurate. The results of validation criteria are within the specified limits of SANCO/3030/99 rev. 4 and rev. 5, Dir. 91/414/EEC (2000), U.S. EPA, (OCSP) 830.1800 and ABNT NBR 14029 guidelines.

	N- Nitrosopendimethalin	1,2-dichloroethane	N- Nitrosodimethylamine	N- Nitrosomethylethylamine
Author(s), year	S. XXX, 2021			
Principle of method	LC-MS/MS	GC-FID	GC-MS/MS	GC-MS/MS
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	5 points 0.00605 to 0.24205 µg/mL First mass transition $y=346748x-41$ R=0.9998 Second mass transition $y=82890.15201x-51.713$ R=0.9995	5 points 0.504 to 20.158 µg/mL First mass transition $y=1684.36x-216.46$ R=0.9999	5 points 0.0201 to 0.2510 µg/mL First mass transition $y=1505x+334165$ R=0.9996 Second mass transition $y=414988$ $114989x+154.45$ R=0.9996	5 points 0.0201 to 0.2511 µg/mL First mass transition $y=1328x+370502$ R=0.9995 Second mass transition $y=182860.6884x+484.3878$ R=0.9997
Precision – Repeatability Mean n = 5 (%RSD)	First mass transition %RSD=3.458 %RSD _R =12.26 %RSD _I =8.21 Hr=0.42<1	First mass transition %RSD=2.113 %RSD _R =9.78 %RSD _I =6.55 Hr=0.32<1	First mass transition %RSD=2.103 %RSD _R =14.12 %RSD _I =9.46 Hr=0.22<1	First mass transition %RSD=1.670 %RSD _R =14.12 %RSD _I =9.46 Hr=0.18<1

	N- Nitrosopendimethalin	1,2-dichloroethane	N- Nitrosodimethylamine	N- Nitrosomethylethylamine
	Second mass transition %RSD=5.357 %RSD _R =12.30 %RSD _r =8.24 Hr=0.67<1		Second mass transition %RSD=4.141 %RSD _R =14.12 %RSD _r =9.46 Hr=0.44<1	Second mass transition %RSD=2.509 %RSD _R =13.93 %RSD _r =9.33 Hr=0.27<1
Accuracy 3 concentrations n = 3 (% Recovery)	First mass transition Total mean recovery = 88.932 ± 5.95% Second mass transition 86.390 ± 4.655%	Total mean recovery = 107.337 ± 8.684%	First mass transition Total mean recovery = 103.786 ± 8.035% Second mass transition 99.298 ± 5.062%	First mass transition Total mean recovery = 108.136 ± 5.552% Second mass transition 99.412 ± 3.08%
Interference/ Specificity	No interference. The method is specific.	No interference. The method is specific.	No interference. The method is specific.	No interference. The method is specific.
LOQ	0.006 µg/mL	0.504 µg/mL	0.967 mg/kg	0.968 mg/kg
Comment	-	-	-	-

	N- Nitrosodiethylamine	N- Nitrosopyrrolidine	N- Nitrosodipropylamine	N- Nitrosopiperidine	N- Nitrosodibutylamine
Author(s), year	S. XXX, 2021				
Principle of method	GC-MS/MS	GC-MS/MS	GC-MS/MS	GC-MS/MS	GC-MS/MS
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	5 points 0.0201 to 0.2508 µg/mL First mass transition y=1067x+291975 R=0.9995 Second mass transition y=113220.3120x+354.6928 R=0.9995	5 points 0.0201 to 0.2508 µg/mL First mass transition y=184180x+490 R=0.9995 Second mass transition y=175963.8595x+552.1607 R=0.9995	5 points 0.0201 to 0.2509 µg/mL First mass transition y=283845x+98 R=0.9974 Second mass transition y=166593.1973x+444.3638 R=0.9987	5 points 0.0201 to 0.2508 µg/mL First mass transition y=234217x+835 R=0.9995 Second mass transition y=124810.5807x+239.8151 R=0.9996	5 points 0.0201 to 0.2508 µg/mL First mass transition y=203337x+994 R=0.9996 Second mass transition y=131830.7235x-146.0902 R=0.9994
Precision – Repeatability Mean n = 5 (%RSD)	First mass transition %RSD=1.650 %RSD _R =14.12 %RSD _r =9.46 Hr=0.17<1 Second mass transition %RSD=1.330 %RSD _R =14.12 %RSD _r =9.46	First mass transition %RSD=2.223 %RSD _R =14.03 %RSD _r =9.40 Hr=0.24<1 Second mass transition %RSD=4.497 %RSD _R =14.03 %RSD _r =9.40	First mass transition %RSD=6.205 %RSD _R =13.74 %RSD _r =9.21 Hr=0.67<1 Second mass transition %RSD=3.771 %RSD _R =13.93 %RSD _r =9.33	First mass transition %RSD=1.014 %RSD _R =13.93 %RSD _r =9.33 Hr=0.11<1 Second mass transition %RSD=2.632 %RSD _R =13.93 %RSD _r =9.33	First mass transition %RSD=3.494 %RSD _R =14.03 %RSD _r =9.40 Hr=0.37<1 Second mass transition %RSD=7.982 %RSD _R =14.12 %RSD _r =9.46

	Hr=0.14<1	Hr=0.36<1	Hr=0.40<1	Hr=0.28<1	Hr=0.84<1
Accuracy 3 concentrations = 3 (% Recovery)	First mass transition Total mean recovery = 111.631 ± 5.661% Second mass transition 100.268 ± 5.82%	First mass transition Total mean recovery = 108.209 ± 6.712% Second mass transition 107.164 ± 4.565%	First mass transition Total mean recovery = 110.973 ± 3.196% Second mass transition 99.629 ± 12.29%	First mass transition Total mean recovery = 111.379 ± 6.018% Second mass transition 107.499 ± 5.42%	First mass transition Total mean recovery = 103.855 ± 5.261% Second mass transition 110.780 ± 4.191%
Interference/ Specificity	No interference. The method is specific.	No interference. The method is specific.	No interference. The method is specific.	No interference. The method is specific.	No interference. The method is specific.
LOQ	0.966 mg/kg	0.966 mg/kg	0.967 mg/kg	0.966 mg/kg	0.967 mg/kg
Comment	-	-	-	-	-

According to SANCO/3030/99 rev. 5 the methods were successfully validated and are suitable for determination of relevant impurities (1,2-dichloroethane, N-Nitrosopendimethalin, and N-Nitrosoamines) of pendimethalin in the plant protection product PENSUI.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Noticed data gaps are:

- none

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for Pendimethalin 45.5% CS were not evaluated as part of the EU review of Pendimethalin. All relevant data were provided and are considered adequate. The assessment of all acute toxicological properties of Pendimethalin 45.5% CS was derived from the calculation method based on the classification of the active compound and co-formulants.

Classification: ~~H317—May cause an allergic skin reaction~~
H361d- Suspected of damaging the unborn child

3.5.1 Operator exposure

Operator exposure to Pendimethalin 45.5% CS was not evaluated as part of the EU review of pendimethalin for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.

Estimations of potential operator exposure have been undertaken for pendimethalin using the AOEM.

Conclusion

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

According to the EFSA calculator, it can be concluded that the risk for operator is acceptable with the use of

Implication for labelling: P280: Wear protective gloves.

3.5.2 Worker exposure

Operator exposure to Pendimethalin 45.5% CS was not evaluated as part of the EU review of pendimethalin for this sub-mitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.

Estimations of potential operator exposure have been undertaken for pendimethalin using the AOEM.

Conclusion

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

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 PENSUI.

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 PENSUI when a time period of 18.5 days after application is respected.

3.5.3 Bystander and resident exposure

Bystander and resident exposures to Pendimethalin 45.5% CS was not evaluated as part of the EU review of pendimethalin. Therefore, all relevant data and risk assessments have been provided and are considered adequate. Calculations were made using the AOEM.

According to the EFSA calculator, when a 5 m buffer zone is employed and drift reduction technology is incorporated, the risk for residents can be considered as acceptable.

3.6 Residues and consumer exposure (Part B, Section 7)

Reference value	Source	Year	Value	Study relied upon	Safety factor
Pendimethalin					
ADI	SANTE/11656/2016 18 May 2017 rev 2	2017	0.125	2-year toxicity study in dogs	100
ARfD	SANTE/11656/2016 18 May 2017 rev 2	2017	0.3	rabbit, developmental toxicity	100

3.7 Residues and consumer exposure (Part B, Section 7)

Reference value	Source	Year	Value	Study relied upon	Safety factor
Pendimethalin					
ADI	SANTE/11656/2016 18 May 2017 rev 2	2017	0.125	2-year toxicity study in dogs	100
ARfD	SANTE/11656/2016 18 May 2017 rev 2	2017	0.3	rabbit, developmental toxicity	100

3.7.1 Residues

Magnitude of residues in plants

Winter cereals (wheat, barley, rye, oats, triticale)

Proposed uses:

1 x 1.137-1.59 kg as/ha, BBCH: 00-09, PHI: not required

1 x 1.137-1.59 kg as/ha, BBCH: 10-13, PHI: not required

EU GAP (SANTE/11656/2016, 18 May, 2017, rev.2): 1 x 1.600 kg as/ha, BBCH: 00-29 autumn, PHI: not required

Proposed uses are within the EU GAP.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application (harvest and decline).

Trials GAP:

Wheat, 1 x 1.498 – 1.650 kg as/ha, BBCH 25-30, outdoor

Barley, 1 x 1.510 – 1.752 kg/ha. as/ha, BBCH 25-30, outdoor

Application time is more critical compared to the proposed one. However, these trials are acceptable as worst case situation.

Results

Wheat grain: 6 x < 0.01, 0.02, 2 x 0.03 mg/kg

Barley grain: 7 x < 0.01, 0.01

Additionally applicant refers to the unprotected EU studies.

The number of trials is sufficient as to support the use of Pendimethalin in winter cereals according to the proposed GAP in Central Zone.

The residues arising from the proposed use will not exceed the MRLs for cereals set at 0.05 mg/kg (Reg. (EU) 2019/1791).

According to SANCO 7525/VI/95 Rev. 10.3 extrapolation from wheat and barley to rye, oats and triticale is possible.

Uses are accepted.

Note: Some of the studies presented were carried out on spring crops instead of winter. Application timing in spring is considered more critical due to the shorter interval between application and harvest. Therefore, these trials are accepted.

Maize

Proposed uses:

1 x 1.137-1.59 kg as/ha, BBCH: 00-09, PHI: not required

1 x 1.137-1.59 kg as/ha, BBCH: 10-13, PHI: not required

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application (harvest and decline).

Trials GAP:

Maize, 1 x 1.584 – 2.010 kg as/ha, BBCH 00-16, outdoor

Results

Maize grain: 6 x < 0.01 mg/kg

The number of trials is sufficient as to support the use of Pendimethalin in maize according to the proposed GAP in Central Zone (all results from trials are below LOQ and LOD).

The residues arising from the proposed use will not exceed the MRLs for maize grain set at 0.05 mg/kg (Reg. (EU) 2019/1791).

Uses are accepted.

Pome fruits (apple, pear)

Proposed use:

1 x 1.59 kg as/ha, BBCH: 00-09 (applications between rows), PHI: not required

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application (harvest).

Trials GAP (more critical than proposed):

Apple: 1 x 1.886 – 2.283 kg as/ha, BBCH 61-69, outdoor

Results:

Apple: 6 x < 0.01 mg/kg

Additionally, applicant refers to the unprotected EU studies.

Pears

Applicant refers to the unprotected EU studies. Application rates in the EU trials are more critical than application rate in proposed use.

The number of trials is sufficient as to support the use of Pendimethalin in apple and pears according to the proposed GAP in Central Zone.

The residues arising from the proposed use (apple and pears) will not exceed the MRLs for apple and pears set at 0.05 mg/kg (Reg. (EU) 2019/1791).

Uses are accepted.

Stone fruits (peach, apricot, plum, nectarine, cherry)

Proposed use:

1 x 1.59 kg as/ha, BBCH: 00-09 (applications between rows), PHI: not required

No data (residue trials) are provided for stone fruits.

Uses are not accepted. Only post harvest use is acceptable.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application (harvest).

Trials GAP (more critical than proposed):

Plum: 1 x 2 kg as/ha, BBCH 65,69, outdoor

Results:

Apple: 4 x < 0.01 mg/kg

According to SANTE/2019/12752 extrapolation from apples (minimum 4 trials) + plum (representant of stone fruits) to whole stone fruits group is possible.

Uses are accepted

Sunflower, Soybean

Proposed use:

1 x 1.183 kg as/ha, BBCH: 00-09, PHI: not required

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP (more critical than proposed – application rate):

Sunflower: 1 x 1.835 – 2.143 kg as/ha, BBCH 00-09, outdoor

Soybean: 1 x 1.952 – 2.123 kg as/ha, BBCH 00-09, outdoor

Results:

Soybean: 4 x < 0.01 mg/kg

Sunflower seeds: 4 x < 0.01, 0.01 mg/kg

Additionally, applicant refers to the unprotected EU studies.

The number of trials is sufficient as to support the use of Pendimethalin in sunflower and soybean according to the proposed GAP in Central Zone.

The residues arising from the proposed use (sunflower and soybean) will not exceed the MRLs for sunflower and soybean set at 0.05 mg/kg (Reg. (EU) 2019/1791).

Uses are accepted.

Winter oilseed rape

14. 1 x 0.455 kg as/ha, BBCH: 00-09, PHI: not required

15. 1 x 0.91 kg as/ha, BBCH: 10-16, PHI: not required

According to SANCO 7525/VI/95 Rev. 10.3 extrapolation from sunflower to oilseed rape is possible (use No 14).

Use No 15 is **not** accepted because proposed BBCH for oil seed rape is not within accepted for sunflower.

Differences in the application timings are considered as not significant and tolerable within the 25 % rule.

Taking into account the early application time residues above the current MRL are not expected. Use can be accepted.

Bulb vegetables (onion, garlic, shallot, spring onion)

1 x 1.137-1.59 kg as/ha, BBCH: 00-09, PHI: not required

1 x 1.137-1.59 kg as/ha, BBCH: 10-13, PHI: not required

Garlic

Applicant refers to the unprotected EU studies (pre-emergence).

Residues: 6x <0.05 mg/kg (EU studies)

Onion

Applicant refers to the unprotected EU studies (post emergence and pre-emergence) and new studies.

Trials GAP (new studies): 1 x 1.318 – 1.650 kg as/ha, BBCH 00-05, outdoor

Residues: 4x < 0.01 mg/kg

According to SANCO 7525/VI/95 Rev. 10.3 extrapolation from onion to garlic, shallot and spring onion is possible.

The number of trials is sufficient as to support the use of Pendimethalin in onion, garlic, shallot, spring onion according to the proposed GAP in Central Zone.

The residues arising from the proposed use will not exceed the MRLs for onion, garlic, shallot, spring onion set at 0.05 mg/kg (Reg. (EU) 2019/1791).

Uses are accepted.

Bean, pea, broad bean, field bean

Proposed uses: 1 x 1.137-1.59 kg as/ha, BBCH: 00-09, PHI: not required

EU GAPs:

Green bean: 1 x 1.593 kg as/ha, pre-emergence, PHI: not required

Dry bean: 1 x 1.593 kg as/ha, BBCH 00-13, PHI: not required

Green peas: 1 x pre 1.365, post 1.593 kg as/ha, BBCH 00-13, PHI: 56

Dry peas: 1 x 1.593 kg as/ha, BBCH 00-13, PHI: 56

Beans

Applicant refers to the unprotected EU studies

Residues:

Pods: 9x<0.05 mg/kg

Seed: 9x<0.05 mg/kg

Peas

Applicant refers to the new studies and unprotected EU studies.

Trials GAP (new studies): 1 x 1.317 – 1.980 kg as/ha, pre-emergence, BBCH: 01- 15

Residues (new studies):

Seeds: 9x<0.01 mg/kg

Pods: 2x<0.0025(ND)

Seeds with pods: <0.003(ND)

The number of trials is sufficient as to support the use of Pendimethalin in peas and beans according to the proposed GAP in Central Zone.

The residues arising from the proposed use will not exceed the MRLs for legumes set at 0.05 mg/kg (Reg. (EU) 2019/1791).

According to SANCO 7525/VI/95 Rev. 10.3 extrapolation to pulses is possible.

According to SANCO 7525/VI/95 Rev. 10.3 extrapolation to broad bean and field bean is possible.

Lupine

Proposed use: 1 x 1.183 kg as/ha, Pre emergence BBCH 00-09

According to SANCO 7525/VI/95 Rev. 10.3 extrapolation from beans (with pods) or peas (with pods) to lupine is possible (before forming of the edible part).

Carrot, parsley

Proposed uses: 1 x 1.137-1.59 kg as/ha, BBCH: 00-09, PHI: not required

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: carrot, 1 x 1.282 – 2.085 kg as/ha, BBCH 00 - 14

Residues: 2x<0.0025 (ND), 4x<0.01, 0.01 mg/kg

The number of trials is sufficient as to support the use of Pendimethalin in carrot according to the proposed GAP in Central Zone.

According to SANCO 7525/VI/95 Rev. 10.3 extrapolation to parsley is possible.

The residues arising from the proposed use will not exceed the MRLs for carrot and parsley set at 0.7 mg/kg (Reg. (EU) 2019/1791).

Parsnip

Proposed uses: 1 x 1.59 kg as/ha, BBCH: 00-09, PHI: not required

According to SANCO 7525/VI/95 Rev. 10.3 extrapolation from carrot to parsnip is possible.

Stem vegetables (leek, asparagus, globe artichokes, florence fennels)

Leeks

Proposed uses: 1 x 1.59 kg as/ha, BBCH: 00-09, 10-13, PHI: not required

Applicant refers to the unprotected EU studies.

Application rate: 1 x 1.32-2.64 kg as/ha, growth stage is not stated.

Residues:

6x<0.05 mg/kg

In EFSA Journal 2012;10(4):2683 it is stated that only 2 trials are accepted. There are insufficient data on trials to accept this use.

6 additional residue trials on leek are required.

Artichokes

Proposed uses: 1 x 1.59 kg as/ha, BBCH: 00-09, 10-13, PHI: not required

Applicant refers to the unprotected EU studies.

GAP on which MRL/EU a.s. assessment is based: 1 x 1.32 - 2.64 kg as/ha, pre-emergence, outdoor
4x<0.05 mg/kg

In EFSA Journal 2012;10(4):2683 it is stated that only 2 trials are accepted. There are insufficient data on trials to accept this use.

Proposed uses on stem vegetables are not accepted.

Information provided in Table 7.2-9 about celery trials is not the same as information included in the DAR. . MRL for fennel is 0.05* mg/kg

6 additional residue trials on artichokes are required

4 residue trials on asparagus and 4 residue trials on florence fennels are required

Flowering brassica (broccoli, cauliflower)

Head brassica (brussels sprouts, cabbage)

Proposed uses: 1 x 1.137-1.59 kg as/ha, Pre transplanting, PHI: not required

The number of trials is sufficient as to support the use of Pendimethalin in flowering brassica and head brassica according to the proposed GAP in Central Zone.

Uses are accepted.

Broccoli

GAP on which MRL/EU a.s. assessment is based: 1 x 1.65 – 2.00 kg as/ha, Trasplanting seedling, outdoor
Residues: 2 x <0.05

Cauliflower

GAP on which MRL/EU a.s. assessment is based: 1 x 1.65 kg as/ha, outdoor
Residues: <0.05

GAP on which MRL/EU a.s. assessment is based: 1 x 1.32-2.64 kg as/ha, pre-planting, outdoor
Residues:12x<0.05

GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, before trasplanting, outdoor
Residues:4x<0.05

Cabbage

GAP on which MRL/EU a.s. assessment is based: 1 x 1.32-2.64 kg as/ha, pre-planting, outdoor
2x<0.05

GAP on which MRL/EU a.s. assessment is based: 1 x 1.485 kg as/ha, 2-3 leaf stage, outdoor
4x<0.05

GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, before trasplanting, outdoor
4x<0.05

According to SANCO 7525/VI/95 Rev. 10.3 extrapolation from 8 trials on head cabbages (0242020) + 8 trials on cauliflower (0241020) to whole subgroups (a) flowering brassica (0241000) and (b) head brassi-

ca (0242000) before forming of the edible part is possible.

Strawberry

Proposed uses: 1 x 1.365 kg as/ha, BBCH: 00-09 applications between rows, PHI: not required

New studies (overdosed) on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 1 x 1.822 – 2.014 kg as/ha, pre-emergence, outdoor

Results: 2x<0.003 (ND), 2 x 0.01 mg/kg

Additionally applicant refers to the unprotected EU studies (2.0 – 4.0 kg as/ha, residues below 0.05 mg/kg).

In DAR it is stated: *The number of trials and the results presented for strawberry are acceptable in N Europe, considering that the treatment should be made at the pre-flowering stage.*

Proposed uses is accepted only at BBCH: 00

Grapevine

Proposed uses: 1 x 1.59 kg as/ha, BBCH: 00-09 applications between rows, PHI: not required

New studies (overdosed) on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 1 x 2.022 – 2.025 kg as/ha, BBCH:55, outdoor (more critical than proposed use)

Results: 2x<0.003 (ND)

Additionally applicant refers to the unprotected EU studies (time of application: Pre bud burst., Beginning of spring growth, Swollen bud., application rate: 2.64 - 6.40 kg as/ha).

Results; 18x<0.05 mg/kg

Use is accepted.

cane fruits (Raspberries (red and yellow))
other small fruits and berries (currants)

Proposed uses: 1 x 1.59 kg as/ha, BBCH: 00-09 applications between rows, PHI: not required

According to SANCO 7525/VI/95 Rev. 10.3 extrapolation from 4 trials on strawberries (0152000) + 4 trials on any representative of the subgroups: - (a) grapes, - (c) cane berries, - (d) other small fruits and berries to Whole group Berries and small fruits (0150000) before forming of the edible part is possible.

Accepted uses (like strawberries use): 1 x 1.365 kg as/ha, BBCH: 00, applications between rows, PHI: not required

lettuces and salad plants (lettuce, endive)

Proposed uses: 1 x 1.59 kg as/ha, BBCH: 00, PHI: not required

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP (lettuce): 1 x 1.330 – 1.650 kg as/ha, pre-emergence, outdoor

Results: 2x<0.0025 (ND), 2x<0.01 mg/kg

The number of trials is sufficient as to support the use of Pendimethalin in lettuce according to the proposed GAP in Central Zone.

According to SANCO 7525/VI/95 Rev. 10.3 extrapolation to endive is possible.

Potato

Proposed uses: 1 x 1.137-1.59 kg as/ha, BBCH: 00-09, PHI: not required

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 1 x 1320 - 1.665 kg as/ha, BBCH:07, outdoor

Results: 4x<0.0025 (ND), <0.01 mg/kg

The number of trials is sufficient as to support the use of Pendimethalin in potato according to the proposed GAP in Central Zone.

Additionally applicant refers to the unprotected EU studies.

Use is accepted.

Cucurbits with edible peel (cucumber, zucchini, squash)

Cucurbits with inedible peel (melons)

Residue trials are not provided. Uses are not accepted.

Clover, alfalfa

No residue trials available. Uses are not accepted.

Waiting periods for avoiding residues in succeeding crops are not required.

In the case of early liquidation of the plantation, the plants can be sown after 30 days

3.7.2 Consumer exposure

The accepted uses of pendimethalin in the formulation PENSUI do not represent unacceptable acute and chronic risks for the consumer.

Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	4 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Results for children 14.79% Carrots 2.31% Pears 1.80% Apples 1.58% Peaches 1.05% Parsley roots/Hamburg roots parsley 0.91% Beans 0.70% Plums

	0.58% Apricots
	0.41% Quinces
	0.38% Onions
	0.33% Peas
	0.24% Wheat
	0.23% Medlar
	0.20% Cherries (sweet)
	0.19% Beans (with pods)
	Results for adults
	4.60% Carrots
	2.40% Parsley roots/Hamburg roots parsley
	0.51% Pears
	0.47% Apples
	0.33% Beans
	0.31% Peaches
	0.30% Plums
	0.25% Quinces
	0.25% Onions
	0.18% Apricots
	0.17% Cherries (sweet)
	0.17% Peas
	0.14% Wheat
	0.13% Beans (with pods)
	0.11% Medlar
	Processed commodities
	Results for children
	8.4% Carrots / juice
	0.9% Apples / juice
	0.5% Pears / juice
	0.4% Peaches / canned
	0.4% Maize / oil
	0.4% Peas / canned
	0.3% Peaches / juice
	0.2% Beans (with pods) / boiled
	0.2% Wheat / milling (flour)
	0.2% Plums / juice
	0.1% Peas (without pods) / canned
	0.1% Wheat / milling (wholemeal)-baking
	0.1% Soyabeans / soya drink
	0.1% Rye / boiled
	0.1% Oat / boiled
	Results for adults
	1.9% Carrots / canned
	0.56% Apples / juice
	0.36% Beans / canned
	0.21% Maize / oil
	0.16% Onions / boiled
	0.14% Peaches / canned
	0.13% Peas / canned
	0.12% Barley / beer
	0.09% Beans (without pods) / boiled
	0.07% Wheat / bread/pizza
	0.06% Wheat / pasta
	0.06% Wheat / bread (wholemeal)
	0.06% Peas (with pods) / boiled
	0.05% Peas (without pods) / boiled
	0.03% Oat / boiled

NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

3.8 Environmental fate and behaviour (Part B, Section 8)

No new studies are presented. Appropriate endpoints from the EFSA Journal 2016;14(3):4420 were used to calculate PECs for PENSUI, pendimethalin and its metabolites in soil, ground water, surface water and air for the intended use patterns.

3.8.1 Predicted environmental concentrations in soil (PEC_{soil})

The PEC of PENSUI, pendimethalin and its metabolites in soil and the formulated product has been assessed with the FOCUS Guidance equations. The interception considered was 0 and the DT₅₀ values established in the EU review. The PEC_{soil} was calculated based on the whole GAP worst case 1590 g a.s./ha.

The maximum initial predicted environmental concentration in soil (PECs) were:

Pendimethalin = 2.859 mg/kg

M455H001 = 0.183 mg/kg

M455H033 = 0.491 mg/kg

PENSUI = 5.463 mg/kg

The results for PEC soil for the active substance was used for the eco-toxicological risk assessment.

3.8.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The PEC of pendimethalin and its soil metabolites M455H001 and M455H033 in ground water has been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO v5.5.3 and PEARL 4.4.4 models in winter cereals in all seasons to cover all crops. The predicted environmental concentrations (PEC_{GW}) for pendimethalin and its metabolites following use according to the critical GAP with no foliar interception assumed (many uses are pre-application), were less than 0.1 µg/L for all crops in all scenarios using FOCUS-PELMO using the maximum application rate of 1590 g a.s./ha.

However, in PEARL model several scenarios metabolite M455H001 exceed the threshold. Due to in PEARL Hamburg and Okehampton scenarios, the PEC_{gw} values for the metabolite M455H001 exceeded the threshold value of 0.1 µg/L, in relevant **Hamburg** and Okehampton scenarios, additional modelling at a higher tier were also carried out by reducing the application rates as per GAP table specifications, and considering the crop coverage caused by the weeds (an interception of 25% is frequently used for herbicide applications). After taking into account interception of weeds themselves, PEC_{gw} values for CEU relevant scenarios were less than threshold value of 0.1 µg/L. However, in Poland no acceptable is reducing the application rate and following risk mitigation should be used:

SPe 2: To protect the groundwater do not apply this product in soils with loam texture with a content of organic matter greater than 3.8%, at application rates higher than 1365 g a.i./ha during all seasons.

SPe 2: W celu ochrony wód gruntowych nie należy stosować tego produktu na glebach o strukturze gliniastej z zawartością materii organicznej powyżej 3,8%, przy dawkach wyższych niż 1365 g a.i./ha we wszystkich porach roku.

The models predicts that pendimethalin and its metabolites will not be found in ground water at concentrations greater than 0.1 µg/L. Based on the assessment, the use of PENSUI is not expected to lead to leaching into groundwater at levels that would be unacceptable when applied according to the recommended use pattern.

3.8.3 Predicted environmental concentrations in surface water (PEC_{sw})

The PEC of pendimethalin and its metabolites in surface water (PEC_{sw} and PEC_{sed}) has been assessed with the current version of models FOCUS STEPS 1/2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5 and SWAN 5.0.0.

National scenarios relevant for Poland are D3, D4 and R1. Due to fact that drainage all scenarios were modified manually and the drift values for cereals instead of apple were fixed in TOXSWA since the application is to the weeds not to the trees. Scenarios (D3, D4 and R1) are not available for some crops in programs used for modelling, the surrogate crop was used for sunflower and grass – winter cereals, for soybeans – legumes, for root vegetables and fruit vegetables – vegetables leafy, for vines early appln. – apple early. The calculation was done for surrogate crops, for scenarios D3, D4 and R1 considering all input data.

No accepted the calculations for uses between rows treated area performed for applications 5, 6, 7, 18, 19, 20, 26 with 75% application rate.

The results for PEC surface water and sediment for the pendimethalin and its metabolites was used for the eco-toxicological risk assessment.

3.8.4 Predicted environmental concentrations in air (PEC_{air})

During the renewal of pendimethalin it was considered as medium volatile, several monitoring studies determined that pendimethalin has a medium range transport (1-1000 km) and therefore the dry deposition was considered in PEC_{sw} Step 4 calculations.

3.9 Ecotoxicology (Part B, Section 9)

3.9.1 Effects on terrestrial vertebrates

The risk assessment shows that there is no acute risk for birds after exposure to Pendimethalin 45.5% CS. Most of the crops failed at Tier I for long-term exposure. The refinement of the chronic endpoint showed an acceptable long-term risk for birds except for cereals, maize, pulses and leafy vegetables. Further refinement of foliar DT₅₀ and PT values showed an acceptable long-term risk for birds.

No unacceptable risk is expected from exposure to via drinking water and via secondary poisoning from fish-eating birds.

The risk of secondary poisoning to earthworm eating birds was found acceptable after refinement.

The risk assessment shows that there is no acute risk for mammals after exposure to Pendimethalin 45.5% CS.

The refinement of parameters (e.g. foliar DT₅₀, PT, PD and weight of evidence) showed unacceptable long-term risk for mammals for large herbivorous mammal for cereals and for vole in orchards, bush and cane fruits and vineyards.

For wood mouse the TER_{LT} values were slight below 5 (4.57) for most crops proposed in the GAP.

In case of cereals for large herbivorous mammal there was needs for further refinement at MSs level.

In zRMS's opinion taking into account that for wood mouse the default values of PT=1 and DT₅₀ = 10 days in plants (cereals) were used as most conservative approach and considering that trigger value is

only slight below trigger of 5 the risk can be considered acceptable for PL registration.

In case of large herbivorous mammals (rabbit, hare) for lower rate 1.137 kg a.s./ha, the WoE approach for PL registration was taken into account as follow:

- Pendimethalin is selective to gramineae (grasses) which means that after treatment grasses won't be available anymore and then, the weeds are assumed to be less attractive and palatable for large herbivorous mammals. Thus, the crop is less attractive for rabbit.
- It should be noted that DT₅₀ for pendimethalin seems to be less than 10 days for winter cereals/weeds based on the all information available (DT₅₀ for spring cereals-2.73 d and DT₅₀ for dicot plants of 3 days, additional residue decline studies for Germany and Hungary with DT₅₀=1.5 d values and from Hungary DT₅₀= 2.54 d). It means that default parameter of ftwa of 0.53 parameter in the long-term risk taken is overestimated in case on pendimethalin in winter cereals.
- In addition, when PT=0.69 value for hare estimated by Prosser 2010 (90th percentile, consumer only) was considered, the TER_{LT} is closed to trigger of 5, indicating acceptable long-term risk assessment.

Reprod. toxicity (mg/kg bw/d)		30							
TER criterion		5							
Focal species	Food category, % in diet	FIR/bw*	RUD _m × DF (mg/kg food)	MAF _m × TWA	PT**	PD	DDD _m (mg/kg bw/d)		TER _{LT}
Large herbivorous mammal	Cereals and grasses	0.45	54.2 x 1	0.53	0.69	0.5	5.06	6.07	4.94
	Non-grass herbs	0.45	28.7 x 1	0.2	0.69	0.5	1.01		

**consumers only, 90th percentile

In zRMS opinion based on all available information presented above the long-term risk for mammals for winter cereals is considered as acceptable.

For vole in orchards, bush and cane fruits and vineyards the risk is still unresolved.

No unacceptable risk is expected from exposure to via drinking water and via secondary poisoning from fish-eating mammals. The risk of secondary poisoning to earthworm eating mammals was found acceptable after refinement.

3.9.2 Effects on aquatic species

Based on lowest RAC of 0.23 µg a.s./L agreed at EU level an acceptable risk for aquatic organisms is considered when the following risk mitigation measures for worst case scenarios for each crops are applied:

Winter cereals 1 x 1137 g a.s./ha, pre-emergence application

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Winter cereals 1 x 1137 g a.s./ha, post -emergence application

R1 stream, 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Winter cereals 1 x 1590 g a.s./ha, pre-emergence application

No safe use . For scenarios D4 stream PEC/RAC ratios are >1 even considering the mitigation.

Winter cereals, 1 x 1590 g a.s./ha, post -emergence application

No safe use. For scenarios, D4 stream PEC/RAC ratios are >1 even considering the maximum mitigation measures

Maize, 1 x 1590 g a.s./ha, pre- emergence application

~~R1 stream: 20m no spray buffer zone + 20m vegetative strip + 90% 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction~~

Maize 1 x 1590 g a.s./ha, post emergence application

~~R1 stream: 20m no spray buffer zone + 20m vegetative strip + 90% 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction~~

Maize 1 x 1137 g a.s./ha, pre emergence application

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Maize 1 x 1137 g a.s./ha, post emergence application

R1 stream, 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Orchards 1590 g a.s./ha, early application

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Sunflower 1 x 1183 g a.s /ha

No safe use .For scenario R1 stream the PEC/RAC ratios are > 1 even with risk mitigation measures have to be considered.

Soybean 1 x 1183 g a.s./ha

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Bulb vegetables 1 x 1590 g a.s./ha, pre emergence application

No safe use . For scenario R1 stream the PEC/RAC ratios are below the trigger with mitigation measures have been considered.

Bulb vegetables 1 x 1590 g a.s./ha, post emergence application

No safe use. For scenarios D4 stream the PEC/RAC ratios are below the trigger with mitigation measures. For scenario R1 stream the PEC/RAC ratios are below the trigger with mitigation measures and restriction sentences will have to be considered

Bulb vegetables 1 x 1137 g/ha, pre-emergence application

No safe use. For scenario R1 stream the PEC/RAC ratios are below the trigger with mitigation measures and a restriction will be considered.

Bulb vegetable 1 x 1137 g/h, post –emergence application

No safe use. For scenario R1 stream the PEC/RAC ratios are below the trigger with mitigation measures has to be considered.

Beans 1 x 1590 g a.s./ha

No safe use. For scenario R1 stream, the PEC/RAC ratios are below the trigger even considering risk mitigation measures.

Beans 1 x 1137 g a.s./ha

No safe use. For scenario R1 stream the PEC/RAC ratios are below the trigger even considering risk mitigation measures have to be considered

Carrots, parsley, parsnip and fennel 1 x 1590 g a.s./ha

No safe use. For scenarios D4 stream the PEC/RAC ratios are below the trigger even considering risk mitigation measures.

Carrots, parsley, parsnip and fennel 1 x 1137 g a.s./ha

R1 stream,: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Lupine (legume) 1 x 1183 g a.s./ha

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone+ 10m vegetative strip + 90% nozzle reduction

Winter oilseed rape 1 x 455 g a.s./ha

20m no spray buffer zone + 20m vegetative strip + 50% drift reduction nozzels or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

Winter oilseed rape 1 x 910 g a.s./ha

20m no spray buffer zone + 20m vegetative strip +75% drift reduction nozzels or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

Asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop in pre emergence (leafy vegetables 1st and 2nd crop 1 x 1590 g/ha)

No safe use. For scenarios D4 stream the PEC/RAC ratios are below the trigger even considering risk mitigation measures. **Asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop in post emergence (leafy vegetables 1st and 2nd crop 1 x 1590 g/ha)**

No safe use . For scenarios D4 stream the PEC/RAC ratios are below the trigger even considering mitigation measures..

Strawberry 1 x 1590 g a.s./ha

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Strawberry 1 x 1137 g a.s./ha

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Raspberry 1 x 1365 g a.s./ha

20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction ~~or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction~~

Currants and grapevine (vines early application 1 x 1590 g/ha between rows)

20 m no spray buffer zone + ~~15~~—20 m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Potato 1 x 1590 g a.s./ha

PEC/RAC ratios in potato (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

No safe use . For scenarios D4 stream the PEC/RAC ratios are below the trigger even considering risk mitigation measures.

Potato 1 x 1137 g a.s./ha

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Ornamentals (vines, early application 1 x 1590 g a.s./ha)

20m no spray buffer zone + 20m vegetative strip + ~~75~~—90% nozzle reduction ~~or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction~~

Clover and alfalfa (grass 1 x 1000 g/ha)

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Cucurbits (fruiting vegetables 1 x 1590 g/ha)

No safe use. For scenarios D4 stream, the PEC/RAC ratios are below the trigger even considering risk mitigation measures.

In the label instructions for use of Penshui, risk management for aquatic organisms has been introduced only for uses accepted in all sections, taking into account also the restrictions resulting from the Ecotoxicology section.

Risk management for aquatic organism accepted in the Ecotoxicology Section is given in point 2.5.1

No safe use for aquatic organism is presented above.

3.9.3 Effects on bees

No risk for bees is expected following the application of PENSUI at the proposed rates.

3.9.4 Effects on other arthropod species other than bees

In-field HQ values were higher than the trigger after the first step of the assessment for *T. pyri* and *Aphidius*. Data from higher tier studies showed that the effects on the two indicator species were < 50% on mortality and reproduction even at higher doses than the maximum rate proposed in GAP. Data on additional non-target arthropod species showed no risk at a rates higher than the maximum rate proposed in the GAP.

No off-field risk is expected for non-target arthropods after the application of Pendimethalin 45.5% CS according to the proposed GAP.

Therefore, the application of PENSUI in accordance to the GAP poses no unacceptable risk to non-target arthropods.

3.9.5 Effects on soil organisms

The long-term TER values are above the respective trigger indicating no long-term risk to earthworms and soil macrofauna after the application of PENSUI according to the proposed GAP.

No risk to soil microorganisms is expected following the application of PENSUI at the proposed rates in the GAP.

3.9.6 Effects on non-target terrestrial plants

No risk to non-target plants located outside the treated area after application of PENSUI is expected from proposed uses for Penschui.

3.9.7 Effects on other terrestrial organisms (Flora and Fauna)

No data on other targeted species is required.

3.10 Relevance of metabolites (Part B, Section 10)

No metabolites are predicted to occur in groundwater at concentrations above 0.1 µg/L. Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

PENSUI contains pendimethalin which is approved as a candidate for substitution because two of PBT criteria.

According to comparative assessment, the plant protection product PENSUI cannot be considered as suitable for substitution.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Authorisation can be granted for 1 year only.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Skuteczność:

Z uwagi na brak badań selektywności wykreślono z etykiety ~~jabłoń~~ i gruszę, żyto, pszenżyto i owies. Owoce pestkowe (brzoskwinia, morela, śliwka, nektarynka, wiśnia), słonecznik, soję, warzywa cebulowe (cebula, czosnek, szalotka, cebula dymka), groch, fasolę, bób, marchew, pietruszkę, łubin, szparagi, warzywa kapustne (brokuł, brukselka, kapusta głowiasta, kalafior), truskawkę, porzeczkę, maliny, por, pasternak, sałatę cykorię, winogrona, rośliny ozdobne, czosnek, lucernę, karchoch, fenkuł i melon, ogórek, dynia, cukinia wykreślono z części głównej etykiety. Zastosowania małoobszarowe (bez badań skuteczności) mogą być zaakceptowane tylko w trybie Artykułu 51

Pozostałości:

Brak zgody na:

~~Rzepak ozimy (późna aplikacja)~~

Szparagi

Por

Koniczyna, lucerna

Karczoch

Koper włoski

Melon, ogórek, kabaczek, cukinia

~~Zgoda na ochronę owoców pestkowych tylko po zbiorach.~~

Truskawka, Malina i Porzeczka: stosować tylko przy BBCH: 00 i dawki: max. 1.365

Nie wymagane są okresy karencji dla zaakceptowanych upraw.

Nie wymagane są okresy karencji dla upraw następnych.

W przypadku wcześniejszej likwidacji plantacji można siać rośliny następne po 30 dniach (uwaga dopisana w etykiecie).

Ekotoksykologia: W etykiecie instrukcji stosowania środka Penshui zarządzanie ryzykiem dla organizmów wodnych zostało wprowadzone jedynie dla zastosowań zaakceptowanych we wszystkich sekcjach wraz z uwzględnieniem ograniczeń wynikających z sekcji Ekotoksykologia. Nie weryfikowano zarządzania ryzykiem dla organizmów wodnych dla zastosowań niezaakceptowanych przez inne Sekcje.

W etykiecie instrukcji stosowania brak zgody z zakresu Ekotoksykologii na zastosowanie w Sadach (ziarnkowe i pestkowe), Porzeczce, Malinie oraz Winorośli z uwagi na nieakceptowalne ryzyko dla ssaków. Jednocześnie ze względu na ryzyko dla organizmów wodnych brak zgody na stosowanie w następujących uprawach:

Zboża ozime: 1 x 1590 g a.s./ha

Słonecznik: 1 x 1183 g a.s./ha

Rośliny cebulowe: 1 x 1590 g a.s./ha

Rośliny cebulowe: 1 x 1137 g a.s./ha

Fasola: 1 x 1590 g a.s./ha

Fasola : 1 x 1137 g a.s./ha

- Marchewka, pietruszka, Pasternak i koper włoski 1 x 1590 g a.s./ha

- Szparagi, kapustne, por, sałata, endivia, karczoch (1 x 1590 g/ha)

- Ziemniak 1 x 1590 g a.s./ha

- Ogórek (warzywa owocujące, 1 x 1590 g/ha). Zarządzanie ryzykiem w etykiecie instrukcji stosowania pozostawiono jedynie dla zastosowań zaakceptowanych przez wszystkie Sekcje.

Załącznik do zezwolenia MRiRW nr R -/..... z dnia2020

Posiadacz zezwolenia:

Sharda Cropchem España S.L., Edificio Atalayas Business Center
Carril Condomina nº3, 12th Floor, 30006 Murcia, Hiszpania tel. +34868127589, e-mail:
eu.sales@shardaintl.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

Sharda Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa, tel.: +48 17 240 13 07, e-mail:
eu.sales@shardaintl.com.

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

.....


PENSUI

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

Pendimetalina (substancja z grupy dinitroanilin) - 455 g/l (38,9 %)

Zezwolenie MRiRW nr R- /2020 z dnia . .2020 r.

	
UWAGA	
H317 H361d H410	Może powodować reakcję alergiczną skóry. Podejrzuje się, że działa szkodliwie na dziecko w łonie matki. Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska należy postępować zgodnie z instrukcją użycia.
P261 P280 P302+P352 P333+P313	Unikać wdychania pyłu/dymu/gazu/mgły/par/rozpylonej cieczy. Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy. W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody. W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
308+P313 P362+P364	W przypadku narażenia lub styczości: Zasięgnąć porady/ zgłosić się pod opiekę lekarza. Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

P391	Zebrać wyciek.
P501	Zawartość / pojemnik usuwać zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi

OPIS DZIAŁANIA

PENSUI jest środkiem chwastobójczym w formie zawiesiny kapsuł w cieczy przeznaczonej do rozcieńczania wodą. PENSUI stosuje się doglebowo lub nalistnie w celu zwalczania rocznych chwastów dwuliściennych i jednoliściennych w uprawach zbóż ozimych, kukurydzy, ~~owoców~~ ~~ziarnkowych~~, brzoskwini, moreli, śliwki, nektarynki, wiśni, słonecznika, soi, warzyw cebulowych, fasoli, grochu, marchewki, pietruszki, łubinu, rzepaku ozimego, szparagów, roślin kapustnych, truskawki, maliny, porzeczki, pora, pasternaku, ziemniaka, winogronu, czosnku, roślin ozdobnych, lucerny, karczocha, fenkuł (koper włoski), melona, ogórka, dyni i cukinii. Zgodnie z klasyfikacją według HRAC pendimetalina została zaklasyfikowana do grupy K1.

Środek do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych lub sadowniczych wyposażonych w belkę herbicydową oraz opryskiwaczy ręcznych.

DZIAŁANIE NA CHWASTY

PENSUI jest pobierany przez korzenie i części nadziemne chwastów. Najskuteczniej zwalcza chwasty w okresie ich kiełkowania i wschodów.

Chwasty wrażliwe: szarłat szorstki (w dawce 2,5 l/ha – średnio wrażliwy), ~~kurzyślad polny~~, miotła zbożowa (w dawce 2,5 l/ha – średnio wrażliwa), tasznik pospolity (w dawce 2,5 l/ha – średnio wrażliwy), ~~palusznik krwawy~~, chwastnica jednostronna (w dawce 2,5 l/ha – średnio wrażliwa), ~~przymiotno białe~~, przytulia czepna (w dawce 2,5 l/ha – średnio wrażliwa), wiechlina roczna (w dawce 2,5 l/ha – średnio wrażliwa), ~~rdest plamisty~~, ~~jaskier rozłogowy~~, ~~włośnica~~, ~~mlecz zwyczajny~~, przetacznik perski (w dawce 2,5 l/ha – średnio wrażliwy), ~~szarłat szorstki~~, łoboda rozłożysta (w dawce 2,5 l/ha – średnio wrażliwa), ~~burak pospolity~~, komosa biała (w dawce 2,5 l/ha – średnio wrażliwa), ~~powój polny~~, ~~popioł pospolity~~, ~~marchew zwyczajna~~, ~~konyza kanadyjska~~, ~~jasnota purpurowa~~, maruna nadmorska bezwonna (w dawce 2,5 l/ha – średnio wrażliwa), ~~starzec zwyczajny~~, ~~włośnica sina~~, gwiazdnica pospolita (w dawce 2,5 l/ha – średnio wrażliwa), ~~psianka czarna~~, dymnica pospolita (w dawce 2,5 l/ha – średnio wrażliwa), tobołek polny (w dawce 2,5 l/ha – średnio wrażliwy), wyczyniec polny (w dawce 2,5 l/ha – średnio wrażliwy), mak polny, rzodkiewnik pospolity, perz właściwy (w dawce 2,5 l/ha – średnio wrażliwy),

Chwasty średnio wrażliwe: ~~ostrożeń polny~~, ~~dwurząd~~, ~~bodziszek drobny~~, ~~mniszek pospolity~~, rdestówka powojowata (w dawce 2,5 l/ha – średnio odporna), fiołek polny, rumian polny (w dawce 2,5 l/ha – średnio odporny), jasnota purpurowa (w dawce 2,5 l/ha – średnio odporna), jasnota różowa

Chwasty średnio odporne: ostrożeń polny (w dawce 2,5 l/ha – odporny)

Chwasty odporne: ~~owsik wyniosły~~, ~~mniszek pospolity~~

STOSOWANIE ŚRODKA

Zboża ozime (pszenice, jęczmień, ~~żyto~~, ~~owies~~, ~~pszenżyto~~) (aplikacja wczesna)

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 2,5 l/ha 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,5 l/ha – 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kielkowania. (BBCH 00-09)

Zalecana ilość wody: **200-400 l/ha**.

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zboża ozime (pszenice, jęczmień, żyto, owies, pszenżyto) (aplikacja późna)

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 2,5 l/ha 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,5 – 3,5 l/ha

Liczba zabiegów: **1**

Termin stosowania środka: stosować na glebę wolną od chwastów, od fazy wydobywania się pierwszego liścia z pochewki liściowej do fazy trzeciego liścia (BBCH 10-13)

Zalecana ilość wody: **200-400 l/ha**.

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Kukurydza (wczesna aplikacja)

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,5 – 3,5 l/ha

Liczba zabiegów: **1**

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kielkowania. (BBCH 00-09)

Zalecana ilość wody: **200-400 600 l/ha**.

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Kukurydza (późna aplikacja)

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,5 – 3,5 l/ha

Liczba zabiegów: **1**

Termin stosowania środka: stosować na glebę wolną od chwastów, od fazy wydobywania się pierwszego liścia z pochewki liściowej do fazy trzeciego liścia (BBCH 10-13)

Zalecana ilość wody: **200-600 l/ha**.

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Owoce ziarnkowe (Grusza, jabłoń)

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować po zbiorze lub przed rozwojem pąków następnego sezonu, do końca fazy rozwoju pąków (BBCH 00-09).

Zalecana ilość wody: 200-600 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Owoce pestkowe (brzoskwinia, morela, śliwka, nektarynka, wiśnia)

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować po zbiorze lub przed rozwojem pąków następnego sezonu, do końca fazy rozwoju pąków (BBCH 00-09)

Zalecana ilość wody: 200-600 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Słonecznik

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 2,6 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,6 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kielkowania. (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Soja

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 2,6 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,6 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kielkowania. (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Warzywa cebulowe (cebula, czosnek, szalotka, cebula dymka) (wczesna aplikacja)

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,5 — 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysadu do widocznego zielonego liścia. (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Warzywa cebulowe (cebula, czosnek, szalotka, cebula dymka) (późna aplikacja)

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,5 — 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować na glebę wolną od chwastów, od fazy zaawansowanej wyprostowanego liścia do fazy widocznego trzeciego liścia. (BBCH 10-13)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Groch, fasola, bób

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,5 — 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kielkowania. (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Marchew, pietruszka

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,5 — 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kielkowania. (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Lubin

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 2,6 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,6 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kielkowania. (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Rzepak ozimy (wczesna aplikacja)

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 1,0 l/ha

Zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kielkowania. (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Rzepak ozimy (późna aplikacja)

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 2,0 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,0 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować od fazy liścieni całkowicie rozwiniętych do fazy szóstego liścia. (BBCH 10-16)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Szparagi

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysadu do widocznego zielonego liścia. (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Warzywa kapustne (brokuł, brukselka, kapusta głowiasta, kalafior)

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo przed wysadom

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Truskawka

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,5 – 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysadu do końca fazy rozwoju pąków. (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Malina

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,0 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,0 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysadu do końca fazy rozwoju pąków. (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Porzeczka

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysadu do końca fazy rozwoju pąków. (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Por

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysadu do widocznego zielonego liścia (BBCH 00-09) LUB od fazy zaawansowanej wyprostowanego liścia do fazy widocznego trzeciego liścia. (BBCH 10-13)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pasternak

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kielkowania. (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Salata, cykoria

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo przed wysadzeniem

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Ziemniaki

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,5—3,5 l/ha

Liczba zabiegów: 1

~~Termin stosowania środka: stosować zapobiegawczo od wysadu do końca fazy formowania pędów (BBCH 00-09)~~

~~Zalecana ilość wody: 200-400 l/ha.~~

~~Zalecane opryskiwanie: średniokropliste~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1~~

Winogrono

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 l/ha

Liczba zabiegów: 1

~~Termin stosowania środka: stosować zapobiegawczo od wysadu do końca fazy formowania pąków (BBCH 00-09)~~

~~Zalecana ilość wody: 200-400 l/ha.~~

~~Zalecane opryskiwanie: średniokropliste~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1~~

Rośliny ozdobne

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 l/ha

Liczba zabiegów: 1

~~Termin stosowania środka: stosować zapobiegawczo od wysadu do końca fazy formowania pąków (BBCH 00-09)~~

~~Zalecana ilość wody: 200-400 l/ha.~~

~~Zalecane opryskiwanie: średniokropliste~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1~~

Czosnek, lucerna

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 2,2 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,2 l/ha

Liczba zabiegów: 1

~~Termin stosowania środka: stosować od fazy widocznego trzeciego liścia do fazy widocznego ósmego liścia (BBCH 13-18)~~

~~Zalecana ilość wody: 200-400 l/ha.~~

~~Zalecane opryskiwanie: średniokropliste~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1~~

Karczoch

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysadu do widocznego zielonego liścia (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Fenkuł (koper włoski)

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysadu do widocznego zielonego liścia (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Melon, ogórek, dynia, cukinia

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: 3,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 l/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kielkowania (BBCH 00-09)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zabieg wykonać opryskiwaczem wyposażonym w rozpylacze antyznoszeniowe.

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

Środka nie stosować:

- na rośliny osłabione i uszkodzone przez przymrozki, suszę, szkodniki lub choroby
- na plantacjach nasiennych.

Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

NASTĘPSTWO ROŚLIN

Środek rozkłada się w ciągu okresu wegetacji nie stwarzając zagrożenia dla roślin uprawianych następnie. Po zbiorze roślin uprawnych, w których zastosowano środek w ramach tradycyjnego płodozmianu można uprawiać wszystkie rośliny. Niemniej, w przypadku uprawy roślin szeroko-listnych i rzepaku ozimego możliwe są wystąpienia przebarwień na liściach.

W przypadku konieczności wcześniejszej likwidacji plantacji traktowanej środkiem (w wyniku uszkodzenia roślin przez mróz, choroby lub szkodniki), po wykonaniu orki przewidzianej można uprawiać wyłącznie kukurydzę i zboża ozime (pszenicę, jęczmień).

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.

Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego do połowy wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wleciu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy roboczej i które zwróciły się o taką informację.

Środki ostrożności dla osób stosujących środek: (pracowników oraz osób postronnych)

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.

Środki ostrożności związane z ochroną środowiska naturalnego:

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Rzepak ozimy (dawka 1l/ha)

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20m od zbiorników i cieków wodnych.

LUB

zadarnionej strefy ochronnej o szerokości 5m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%

Słonecznik, soja, łubin, truskawka

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 15m od zbiorników i cieków wodnych.

LUB

wyznaczenie zadarnionej strefy ochronnej o szerokości 5m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%

Zboża ozime, fasole

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 15m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%

LUB

wyznaczenie zadarnionej strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%

Owoce ziarnkowe, owoce pestkowe, malina, porzeczka, winogrono, rzepak ozimy (dawka 2l/ha)

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 15m od zbiorników i cieków wodnych.

LUB

wyznaczenie zadarnionej strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%

LUB

wyznaczenie zadarnionej strefy ochronnej o szerokości 5m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%

Szparagi, warzywa kapustne, por, sałata, cykoria, karczoch

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 15m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%

LUB

wyznaczenie zadarnionej strefy ochronnej o szerokości 5m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%

Kukurydza, marchew, pietruszka, pasternak, fenkuł (koper włoski), rośliny ozdobne, ogórek, melon, dynia, cukinia, ziemniaki

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20m od zbiorników i cieków wodnych

LUB

wyznaczenie zadarnionej strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%

LUB

wyznaczenie zadarnionej strefy ochronnej o szerokości 5m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%

Warzywa cebulowe

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20m od zbiorników i cieków wodnych

LUB

wyznaczenie zadarnionej strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%

LUB

wyznaczenie zadarnionej strefy ochronnej o szerokości 5m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%

SPe3

W celu ochrony roślin niebędących obiektem zwalczania konieczne jest wyznaczenie strefy ochronnej w odległości 5m od terenów nieużytkowanych rolniezo.

LUB

W celu ochrony roślin niebędących obiektem zwalczania konieczne jest zastosowanie rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%.

SPe3: Zboża ozime:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości

-20m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% lub

wyznaczenie zadarnionej strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90% dla dawki 2.5L/ha

SPe3: Kukurydza:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% lub

wyznaczenie zadarnionej strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90% dla dawki 2.5L/ha

SPe3: Owoce ziarnkowe i pestkowe

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% lub wyznaczenie zadarnionej strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%;

SPe3: Marchewka, pietruszka, pasternak, koper włoski, lubin soja

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% lub wyznaczenie zadarnionej strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%;

SPe3 : Rzepak ozimy 1 x 455 g a.s./ha

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20m z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie o 50% od zbiorników i cieków wodnych

SPe3 : Rzepak ozimy 1 x 910 g a.s./ha

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20m z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie o 75 % od zbiorników i cieków wodnych

SPe3: Truskawka 1 x 1590 g a.s./ha

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% lub

wyznaczenie zadarnionej strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%;

SPe3: Truskawka: 1 x 1137 g a.s./ha

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50 % lub

wyznaczenie zadarnionej strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%;

Spe3: Malina 1 x 1365 g a.s./ha

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75 % lub

wyznaczenie zadarnionej strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90

SPe3: Porzeczka i winorośl 1 x 1590 g/ha

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości

20m od zbiorników i cieków wodnych, z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% lub

wyznaczenie zadarnionej strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%

SPe3: Ziemiak 1 x 1137 g a.s./ha

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75 - % lub

wyznaczenie zadarnionej strefy ochronnej o szerokości 10m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%

SPe3: Rośliny ozdobne 1 x 1590 g a.s./ha

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90 - %

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie dotyczy

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie dotyczy

Okres od ostatniego zastosowania środka do sadzenia/siania upraw następnych: 30 dni

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0°C - 30°C, z dala od źródeł ciepła.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności - 1 rok

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

No letters of access to protected data is required.

Appendix 4 Lists of data considered for national authorization

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1	XXX	2017	APPEARENCE (COLOUR, PHYSICAL STATE AND ODOUR) OF PENDIMETHALIN 455 g/L CS Report No: 201-2-11-16336 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.2.1	XXX	2017	DETERMINATION OF EXPLOSIVE PROPERTIES OF PENDIMETHALIN 45.5% 455 g/L CS Report No: G14435 Advinus Therapeutics Limited GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.2.2	XXX	2017	OXIDIZING PROPERTIES OF PENDIMETHALIN 455 g/l CS Report No: 230-2-11-18398 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.3.1	XXX	2017	FLASH POINT OF PENDIMETHALIN 455 g/L CS Report No: 221-2-11-16339 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.3.3	XXX	2017	Pendimethalin 455 g/L CS: Determination of auto-ignition temperature Study No: BC-67/17 Institute of Industrial Organic Chemistry GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.4.2	XXX	2017	pH OF PENDIMETHALIN 455 g/L CS Report No: 210-2-11-16337 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.5.1	XXX	2017	VISCOSITY OF PENDIMETHALIN 455 g/L CS Report No: 214-2-11-16338 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.5.2	XXX	2017	SURFACE TENSION OF PENDIMETHALIN 455 g/L CS Report No: 222-2-11-16340 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.6.1	XXX	2017	RELATIVE DENSITY TENSION OF PENDIMETHALIN 455 g/L CS Report No: 260-2-11-16335 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7.1 KCP 2.7.3	XXX	2017	ACCELERATED STORAGE STABILITY AND CORROSION CHARACTERISTICS OF PENDIMETHALIN 455 g/L CS Report No: 234-2-11-16485 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.7.4	XXX	2018	FREEZE-THAW STABILITY TEST OF PENDIMETHALIN 455 g/L CS Report No: 277-2-11-16342 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.8.2	XXX	2017	PERSISTENT FOAMING OF PENDIMETHALIN 455 g/L CS Report No: 248-2-11-16341 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.8.3.1	XXX	2017	SUSPENSIBILITY OF PENDIMETHALIN 455 g/L CS Report No: 251-2-11-16343 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.8.3.2	XXX	2017	SPONTANEITY OF DISPERSION OF PENDIMETHALIN 455 g/L CS Report No: 242-2-11-18394 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.8.5.1.2	XXX	2017	WET-SIEVE TEST OF PENDIMETHALIN 455 g/L CS Report No: 245-2-11-18393 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.8.7.2	XXX	2017	POURABILITY OF PENDIMETHALIN 455 g/L CS Report No: 261-2-11-16344 JAI Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 6.0-001	Anonymous	2020	Biological Assessment Dossier: Pendimethalin 45.5% CS (455 g/L pendimethalin CS) – EU Central zone Sharda Cropchem España -, - Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 5.1.1/01	XXX	2017	Validation of analytical method for determination of active ingredient content of pendimethalin 455 g/L CS. Document no.: 228-2-12-16345 Institute of Industrial Organic Chemistry GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 5.1.1-2 KCP 5.1.2/02	S. XXX	2021	Accelerated storage stability test by heating at elevated temperature of Pendimethalin 455 g/L CS. Report No. G21360 Eurofins Advinus GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1-3	B. XXX-	2021	Pendimethalin 45.5% CS Analysis of active substance content and physicochemical properties of preparation and preparation after accelerated and freeze/thaw storage procedures. Report No. 47/2021 Institute of Heavy Organic Synthesis "Blachownia" GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 5.1.2/01	A. XXX	2017	Pendimethalin 455 g/L CS. Methods validation for determination of the relevant impurities of pendimethalin. Document no.: BA-45/17 IAI Research Foundation Institute of Industrial Organic Chemistry GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 5.3.1	XXX	2017	Validation of the analytical procedure for the determination of pendimethalin (CAS: 40487-42-1), in blood by liquid chromatography. Study No. 16.566423.0007 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 5.3.2	XXX	2017	Validation of the analytical procedure for the determination of pendimethalin (CAS: 40487-42-1), in liver by liquid chromatography. Study No. 16.566423.0004 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.1.1	J. XXX	2019	Stability study of pendimethalin residues in apple samples during 2 years of storage Report No. ZBBZ-2017/24/DPL/1 Food Safety Laboratory GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1.1	T. XXX	2018	Magnitude of the residue of Pendimethalin in wheat (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – one decline curve trial in Poland - 2017. Report No. 17SGS011 SGS Polska Sp. z o.o. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.1.2	M.XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-289-LABCHI-REV.0. Report No. 18.618093.0002 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.1.3	S. XXX	2018	Magnitude of residue of Pendimethalin in wheat Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial and 1 refinement decline trial. Report No. BPL17-010 BIOTEK Agriculture España SL GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.1.4	S. XXX	2019	Residue study (Harvest and Decline) in wheat following one post emergence application with Pendimethalin 33% EC in Germany 2018. Report No. CT17-1-46 CropTrials GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1.5	M.XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-289-LACHI-REV.0. Report No 18.641074.0001 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.1.6	T. XXX	2018	Residue study (Decline) in wheat following one post emergence application with Pendimethalin 33% EC in Germany 2017. Report No. CT17-1-47 CropTrials GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.1.7	M.XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-2289-LABCHI-REV.0 Report No 18.618095.0005 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.1.8	M. XXX	2018	Determination of residues at harvest and decline of Pendimethalin in Wheat, following one broadcast application of PENDIMETHALIN 330 g/L EC, under open field conditions Central Europe – Season 2017, Report No FRS 001/17 Field Research Support GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1.9	J. XXX	2017	Determination of the residues of Pendimethalin applied as "Pendimethalin 330 g/L" in wheat at one site in Germany, 2016 Report No. ZBBZ-2016/12/DPL/10 DE Food Safety Laboratory GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.2.1	S. XXX	2018	Magnitude of residue of Pendimethalin in barley Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial Report No. BPL17-009 BIOTEK Agriculture España SL GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.2.2	T. XXX	2018	Residue study (Harvest and decline) in barley following one post emergence application with Pendimethalin 33% EC in Germany 2017 – field part Report No. CT17-1-45 CropTrials GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.2.3	M. XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in barley by LC-MS according to SOPa-288-LABCHI-Rev. 0 and SOPa-289-LABCHI-Rev. 0 Report No. 18.618095.0004 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.2.4	Ch. XXX	2020	Field residue trials to determine levels of Pendimethalin 33% EC on Barley in Northern Europe Report No. 18-00246 SGS United Kingdom Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.2.5	M.XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in Barley by LC-MS according to SOPa-288-LABCHI-Rev.0 and SOPa-289-LABCHI-Rev.0 Report No. 19.503381.0001 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.3.1	S. XXX	2018	Magnitude of residue of Pendimethalin in maize whole plants and Raw Agricultural Commodity (grains) after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial – Poland – 2017 Report No. BPL17-017 BIOTEK Agriculture España SL GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.3.2	S. XXX	2018	Residue study (Harvest and Decline) in maize following one pre emergence application with Pendimethalin 33% EC in Germany 2017 – field part Report No. CT17-1-48 CropTrials GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.3.3	M.XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in maize by LC-MS according to SOPa-288-LABCHI-Rev.0 and SOPa-289-LABCHI-Rev.0 Report No. 18.618096.0008 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.3.4	K. XXX	2016	Determination of residues at harvest and decline of Pendimethalin in Maize, following one broadcast application of PENDIMETHALIN 330g/L EC, under open field conditions, Central Europe – Season 2016 Report No. FRS 056/16 Field Research Support GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.3.5	J. XXX	2018	Determination of the residues of pendimethalin applied as “Pendimethalin 330 g/L” in maize at one site in Germany 2016 Report No. ZBBZ-2016/12/DPL/9DE Food Safety Laboratory GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.4.1	T. XXX	2018	Residue study (Harvest) in apple following one application with Pendimethalin 33% EC in Germany 2017 Report No. CT17-1-49 CropTrials GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.4.2	M.XXX	2018	Determination of pendimethalin (CAS:40487-42-1) in pome fruits by LC-MS according to SOPa-285-LABCHI-Rev.0 Report No. 18.618095.0009 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.4.3	T. XXX	2018	Magnitude of the residue of Pendimethalin in apple (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – one harvest trial in Poland Report No. 17SGS015 SGS Polska Sp. z o.o. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.4.4	M.XXX	2018	Determination of pendimethalin (CAS:40487-42-1) in pome fruits by LC-MS according to SOPa-285-LABCHI-Rev.0 Report No. 18.618093.0006 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.4.5	Ch. XXX	2020	Field residue trials to determine levels of Pendimethalin 33% EC on Pome Fruits (apples) in Northern Europe Report No. 18-00305 SGS United Kingdom Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.4.6	M.XXX	2019	Determination of Pendimethalin (CAS: 40487-42-1) in Pome Fruits by LC-MS according to SOPa-285-LABCHI-Rev.0 Report No. 19.503381.0002 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.5.1	S. XXX	2018	Residue study (harvest) in soybean following one pre emergence application with Pendimethalin 33% EC in Germany 2017 – field part CropTrials GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.5.2	M. XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in soy bean by LC-MS according to SOPa-284-LABCHI-Rev.0 Report No. 18.618095.0011 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.5.3	K. XXX	2019	Magnitude of the residue of Pendimethalin in soybean (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – two harvest trials in Poland – 2017 Report No. 17SGS016 SGS Polska Sp. z o.o. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.5.4	M. XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in soy bean by LC-MS according to SOPa-284-LABCHI-Rev.0 Report No. 18.618093.0007 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.5.5	Z. XXX	2016	Residue study of pendimethalin/Pendimethalin 33% (harvest) in soybean, Poland (Central Europe) – Season 2016 Report PL-PH/04/2016-1/7-H InHort GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.5.6	J. XXX	2018	Determination of residues of pendimethalin applied as "Pendimethalin 330 g/L EC" in soybean at one site in Poland, 2016 Report No. ZBBZ-2016/12/DPL/8PL Food Safety Laboratory GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.6.1	T. XXX	2018	Residue study (Harvest) in carrot following one post emergence application with Pendimethalin 33% EC in Germany 2017. Report No. CT17-1-32 CropTrials GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.6.2	M. XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in carrot by LC-MS according to SOPa-285-LABCHI-REV.0. Report No. 18.618095.0006 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.6.3	T. XXX	2018	Magnitude of the residue of Pendimethalin in carrot (Taw Agricultural Commodity) after one application of Pendimethalin 33% EC – one decline curve trial and one harvest trial in Poland – 2017. Report No. 17SGS012 SGS Polska Sp. z o.o. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.6.4	M. XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in carrot by LC-MS according to SOPa-285-LABCH-REV.0. Report No. 18.618093.0003 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.6.5	K. XXX	2016	Determination of residues at harvest and decline of Pendimethalin in carrot, following one pre-emergence application of PENDIMETHALIN 330g/L EC, under open field conditions, Central Europe – Season 2016. Report No. FRS 051/16 Field Research Support GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.6.6	J. XXX	2017	Determination of residues of pendimethalin applied as 'PENDIMETHALIN 330 g/L' in carrot at one site in Germany. Report No. ZBBZ-2016/12/DPL/5DE Food Safety Laboratory GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.6.7	S. XXX	2017	Field phase residue trial Pendimethalin 330 g/L EC – carrots – decline – Belgium – 2016 Report No. OL16 WORES1 PCG GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.6.8	S. XXX	2017	Field phase residue trial Pendimethalin 330 g/L EC – carrots – harvest – Belgium – 2016 Report No. OL16 WORES2 PCG GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.6.9	J. XXX	2017	Determination of residues of Pendimethalin applied as “PENDIMETHALIN 330 g/L” in carrot at one site in Belgium, 2017 Report No. ZBBZ/12/DPL/5BE Food Safety Laboratory GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.7.1	K. XXX	2016	Determination of residues at harvest and decline of Pendimethalin in Peas, following one pre-emergence application of Pendimethalin 330 g/L EC under open field conditions, Central Europe – Season 2016 Report No. FRS 055/16 Field Research Support GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.7.2	P. XXX	2018	Magnitude of the residues of Pendimethalin in pea (plant and seeds), following one application of Pendimethalin 330 g/L EC in two trials (1DCS and 1 HS), Central Europe (Germany) – 2016 Report No. ZBBZ – 2016/121/DPL/1DE Food Safety Laboratory GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.7.3	S. XXX	2017	Field phase residue trial Pendimethalin 330 g/L EC Peas (Pisum sativum/Pissa) – Decline – Belgium – 2016 Report No. OL16 ERRES2 PCG GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.7.4	S. XXX	2017	Field phase residue trial Pendimethalin 330 g/L EC Peas (Pisum Sativum/Pissa) – Harvest – Belgium – 2016 Report No. OL16 ERRES3b PCG GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.7.5	P. XXX	2018	Magnitude of the residues of Pendimethalin in Pea (Plant, pods and seeds), following one application of Pendimethalin 330 g/L EC in three trials (1DCS and 2 HS), Central Europe (Belgium) – 2016 Report No. ZBBZ-2016/12/DPL/1BE Food Safety Laboratory GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.7.6	Z. XXX	2016	Residue study of pendimethalin / Pendimethalin 33% EC (decline and harvest) in pea, Poland (Central Europe) – Season 2016 InHort GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.7.7	P. XXX	2018	Magnitude of the residues of pendimethalin in pea (plant, pods and seeds), following one application of pendimethalin 330 g/l ec in two trials (1 dcs and 1 hs), Central Europe (Poland) - 2016 Report No. ZBBZ-2016/12/DPL/1PL Food Safety Laboratory GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.7.8	S. XXX	2018	Residue study (Harvest) in pea following one post emergence application with Pendimethalin 33% EC in Germany 2017 – field part Report No. CT17-1-33 CropTrials GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.7.9	M. XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in peas by LC-MS according to SOPa-285-LABCHI-Rev.0 Report No. 18.618095.0007 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.7.10	T. XXX	2018	Magnitude of the residue of Pendimethalin in peas (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – decline curve trial and harvest trial in Poland – 2017 Report No. 17SGS014 SGS Polska Sp. z o.o. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.7.11	M. XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in peas by LC-MS according to SOPa-285-LABCHI-Rev.0 Report No. 18.618093.0005 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.8.1	K. XXX	2016	Determination of residues at harvest and decline of Pendimethalin in Onion, following one pre-emergence application of Pendimethalin 330 g/L EC, under open field conditions, Central Europe – Season 2016 Report No. FRS 052/16 Field Research Support GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.8.2	J. XXX	2018	Determination of the residues of Pendimethalin applied as “Pendimethalin 330 g/L” in onion at one site in Germany Report No. ZBBZ-2016/12/DPL/3DE Food Safety Laboratory GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.8.3	S. XXX	2018	Field phase residue trial Pendimethalin 330 g/L EC Onions – Decline – Central Zone – Belgium – 2016 Report No. OL16 UIRES1 PCG GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.8.4	S. XXX	2018	Field phase residue trial Pendimethalin 330 g/L EC Onions – Harvest – central zone – Belgium – 2016 Report No. OL16 UIRES2 PCG GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.8.5	J. XXX	2018	Determination of the residues of Pendimethalin applied as “Pendimethalin 330 g/L” in onion at one site in Belgium, 2016 Report No. ZBBZ-2016/12/DPL/3BE Food Safety Laboratory GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.9.1	S. XXX	2018	Residue study (Harvest) in sunflower following one pre emergence application with Pendimethalin 33% EC in Germany 2017 – field part Report No. CT17-1-53 CropTrials GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.9.2	M. XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in sunflower by LC-MS according to SOPa-286-LABCHI-Rev.0 Report No 18.618095.0012 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.9.3	S. XXX	2018	Magnitude of residue of Pendimethalin in sunflower Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial – Poland – 2017 Report No. BPL17-018 BIOTEK Agriculture España SL GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.9.4	Ch. XXX	2020	Field Residue Trials to Determine Levels of Pendimethalin 33% EC on Sunflowers in Northern Europe Report No. 18-00307 SGS United Kingdom Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.9.5	M. XXX	2019	Determination of Pendimethalin (CAS: 40487-42-1) in sunflower by LC-MS according to SOPa-284-LABCHI-Rev. 0 Report No. 19.503381.0003 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.9.6	Z. XXX	2016	Residue study of pendimethalin/Pendimethalin 33% EC (harvest) in sunflower, Poland (Central Europe) – Season 2016 Report No. PL-PH/04/2016-1/8-H InHort GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 8.3.9.7	J. XXX	2018	Determination of residues of pendimethalin applied as “Pendimethalin 330 g/L EC” in sunflower at one site in Poland, 2016 Report No. ZBBZ-2016/12/DPL/7PL Food Safety Laboratory GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.1.1.2-01	XXX, S.	2018	Magnitude of residue of Pendimethalin in wheat Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial and 1 refinement decline trial – Poland 2017 Report No.: BPL17-010 BIOTEK Agriculture España GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.1.1.2-02	XXX, T.	2017	Residue study (decline) in wheat following one post emergence application with Pendimethalin 33% EC in Germany 2017. Report no. CT17-1-47 CropTrials GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.1.1.2-03	XXX, M.	2018	Determination of Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-2289-LABCHI-REV.0 Report No 18.618095.0005 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.1.1.2-04	Wagner, G.	2020	Determination of the residues of pendimethalin in/on wheat after one application of pendimethalin 33% EC in northern Europe- Hungary in 2019 Report No.: 034SRHU19R35 CPR Europe Kft. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.1.1.2-05	XXX, M	2020	Determination of residual trials Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-289-LABCHI-REV.0 Report No.: 19.528632.0002 Chelab S.R.L. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.2.1-01	XXX, E.	2018	Freshwater algae, growth inhibition test with Pendimethalin 40% SC Report No.: 17-99-131-ES Phytosafe s.a.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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KCP 10.2.1-02	XXX, E.	2019	Lemna sp., Growth inhibition test with Pendimethalin 40% SC Report No.: 17-99-134-ES Phytosafe s.a.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.1.1.1	XXX, K.	2019	Acute oral toxicity study of Pendimethalin 455 g/L CS in honey bee (<i>Apis mellifera</i>) Report No. 18-212-G Vanta Bioscience Limited GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.1.1.2	XXX, K.	2019	Acute contact toxicity study of Pendimethalin 455 g/L CS in honeybees (<i>Apis mellifera</i>) Report No. 18-211-G Vanta Bioscience Limited GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.1.2	XXX, A.	2017	Pendimethalin Technical Honeybees (<i>Apis mellifera</i>), chronic oral toxicity test Report No.: B/107/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.1.3	XXX, K.	2017	Pendimethalin Technical – Repeated exposure of honey bee (<i>Apis mellifera</i> L.) larvae under laboratory conditions (<i>in vitro</i>) Report No.: 17 48 BLC 0083 BioChem agrar GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.1-01	XXX, L.	2009	Toxicity of Pendimethalin 40% SC to the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) under worst-case laboratory conditions Report No.: C33732 Harlan Laboratories Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.2.1-02	XXX, L.	2009	Toxicity of Pendimethalin 40% SC to adults of the parasitoid wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) under worst-case conditions in the laboratory Report No: C33721 Harlan Laboratories Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.2.2-01	XXX, S.	2018	Pendimethalin 40% SC: toxicity to the aphid parasitoid <i>Aphidius rhopalosiphi</i> De Stefani Perez (Hymenoptera, Braconidae) under extended laboratory conditions Report No.: S18-05327 Trialcamp S.L.U. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.2.2-02	XXX, S.	2018	Pendimethalin 40% SC: Toxicity to the predatory mite, <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) after exposure to freshly applied and aged spray deposits under extended laboratory conditions Report No.: S18-05605 Trialcamp S.L.U. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.4.1.1	XXX, E.	2019	Earthworm reproduction test with Pendimethalin 40% SC Report No.: 17-99-135-ES Phytosafe s.a.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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KCP 10.4.2.1-01	XXX, E.	2019	Collembolan reproduction test in soil with Pendimethalin 40% SC Report No.: 17-99-128-ES Phytosafe s.a.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.4.2.1-02	XXX, E.	2019	Predatory mite (<i>Hypoaspis aculeifer</i>) reproduction test in soil with Pendimethalin 40% SC Report No.: 17-99-129-ES Phytosafe s.a.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.5.1-02	XXX, A	2009	Effect of Pendimethalin SC on soil microorganisms: Nitrogen transformation test Report No.: 8483 Jai Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.5.2-02	XXX, A	2009	Effect of Pendimethalin SC on soil microorganisms: Carbon transformation test Report No.: 8484 Jai Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.6.2-01	XXX, L.	2013	A study to determine the effects of Pendimethalin 40% SC (Pendimethalin 400 g/L) on the seedling emergence and growth of terrestrial plants Report No 34SRFR12C6 SynTech Research France S.A.S. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited

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KCP 10.6.2-02	XXX, L.	2013	A study to determine the effects of Pendimethalin 40% SC (Pendimethalin 400 g/L) on the vegetative vigour of higher terrestrial plants Report No 34SRFR12C7 SynTech Research France S.A.S. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

List of data relied on and 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner