

**FINAL** REGISTRATION REPORT

**Part B**

**Section 3**

**Efficacy Data and Information**

Concise summary

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

Submission date: June 2020

MS Finalisation date: 15/04/2021 04.2022 07.2022

## Version history

When	What
March 2021	Applicant update
April 2021	ZRMs evaluated dRR updated by Applicant.
February 2022	Applicant update
April 2022	ZRMs corrected dRR updated by Applicant during commenting period.
July 2022	ZRMs corrected dRR according to comment from MRiRW

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### 3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

#### Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Comments of zRMS are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are marked by grey colour). In yellow were marked changes made by ZRMs during commenting period in green corrections according to MRiRW comments were marked.
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#### 3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

##### Abstract

Comments of zRMS:	Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.
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**Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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Use- No. *	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gnp or I**	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val 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			
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>														
1	CEU	Winter cereals (wheat, barley, rye, oats, tritica- le)	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			To be con- firmed by CMS
2	CEU	Winter cereals (wheat, barley, rye, oats, tritica- le)	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Post emergen- ce 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			To be con- firmed by CMS
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 <del>600</del>			To be con- firmed by CMS
4	CEU	Maize	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Post emergen- ce 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 <del>600</del>			To be con- firmed by CMS
5	CEU	Pome fruits (apple, pear)	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 b) 2.5	a) 1.59 b) 1.59	200- 400 <del>600</del>		After harvest and before emergence next season	Not acceptable To be con- firmed by CMS
6	CEU	Stone fruits (peach, apricot, plum, nectarine, cherry)	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 b) 3.5	a) 1.59 b) 1.59	200- 400 <del>600</del>		After harvest and before emergence next season	To be con- firmed by CMS
7	CEU	Sunflower	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			To be con- firmed by CMS

1	2	3	4	5	6				7			13	14	15
					Application				Application rate					
Use- No. *	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fn G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val 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	PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	zRMS Conclusion (efficacy)
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			To be con- firmed by cMS
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			To be con- firmed by cMS
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 emergen- ce 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			To be con- firmed by cMS
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			To be con- firmed by cMS
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			To be con- firmed by cMS
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			To be con- firmed by cMS
14	CEU	Winter oilseed rape	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) 1.0 b) 1.0	a) 0.455 b) 0.455	200- 400			Not accepted

1	2	3	4	5	6				10			13	14	15
					Application				Application rate					
Use- No. *	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gnp or I**	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val 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	PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	zRMS Conclusion (efficacy)
15	CEU	Winter oilseed rape	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Post emergen- ce BBCH 10- 16	a) 1 b) 1	NA	a) 2.0 b) 2.0	a) 0.91 b) 0.91	200- 400			Not accepted
16	CEU	Asparagus	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			To be con- firmed by cMS
17	CEU	Brassica vegeta- bles (broccoli, Brussels sprouts, cabbage, cauli- flower)	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Pre transplan- ting	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200- 400			To be con- firmed by cMS
18	CEU	Strawberry	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) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200- 400			To be con- firmed by cMS
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			To be con- firmed by cMS
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 b) 3.5	a) 1.59 b) 1.59	200- 400			To be con- firmed by cMS
21	CEU	Leek	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			To be con- firmed by cMS

1	2	3	4	5	6				10			13	14	15
					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			
22	CEU	<b>Leek</b>	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) 3.5 b) 3.5	a) 1.59 b) 1.59	200-400			To be confirmed by cMS
23	CEU	<b>Parsnip</b>	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			To be confirmed by cMS
24	CEU	<b>Lettuce, endive</b>	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	Spray	Pre transplanting	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200-400			To be confirmed by cMS
25	CEU	<b>Potato</b>	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			Not acceptable
26	CEU	<b>Grapevine</b>	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 b) 3.5	a) 1.59 b) 1.59	200-400			To be confirmed by cMS
27	CEU	<b>Ornamentals</b>	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			To be confirmed by cMS
28	CEU	<b>Clover, alfalfa</b>	F	Broadleaved and grass weeds annual monocotyledonous weeds (TTMS) and annual dicotyledonous weeds (TTDS)	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			To be confirmed by cMS



Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

## 3.2 Efficacy data (KCP 6)

### Introduction

This document summarises the information related to the efficacy data of the plant protection product **Pendimethalin 45.5% CS (PENSUI; Product code: SHA 2600 E)** containing the active substance pendimethalin, which was included into Annex I of Council Directive 91/414/EEC.

The SANCO report for pendimethalin (7477/VI/98-final) is considered to provide the relevant review information or a reference to where such information can be found.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the active substance pendimethalin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26/September/2008 shall be taken into account. Consideration of active substances for Annex 1 inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of pendimethalin relating to efficacy.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

**The detailed assessment of the individual trial and study data is located in the following report:**

<b>Report:</b> KCP 6.0/001 Biological Assessment Dossier Pendimethalin 45.5% CS, Central
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### Description of the plant protection product

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, peas, carrot, parsley, strawberry, potato, asparagus, brassicas, currants, leek, parsnip, lettuce, endive, grapevine, ornamentals, artichoke, fennel, cucurbits, raspberry, sunflower, soybean, lupine, clover and alfalfa and winter oilseed rape. Please refer to Table 3.1-1 to see the GAP covered by this Review Report.

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, **Estonia**, 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, **2020** and **2021** season in a range of European countries in the Maritime (i.e. Czech Republic), the North-east (i.e. Poland, **Estonia** and Lithuania), the South-east (i.e. Slovakia, **Hungary** 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, peas, carrot, parsley, strawberry, potato; 3.5 L per hectare (L/ha) asparagus, brassicas, currants, leek, parsnip, lettuce, endive, grapevine, 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.

**Table 3.2-1: Simplified table of currently registered uses and requested uses for the product code.**

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Winter cereals (wheat, barley, rye, oats, triticale)	Grasses and broadleaved weeds	CEU	2.5-3.5 L/ha	Pre emergence BBCH 00-09
Winter cereals (wheat, barley, rye, oats, triticale)	Grasses and broadleaved weeds	CEU	2.5-3.5 L/ha	Post emergence BBCH 10-13
Maize	Grasses and broadleaved weeds	CEU	2.5-3.5 L/ha	Pre emergence BBCH 00-09
Maize	Grasses and broadleaved weeds	CEU	2.5-3.5 L/ha	Post emergence BBCH 10-13
Pome fruits (apple, pear)	Grasses and broadleaved weeds	CEU	3.5 L/ha	Pre emergence BBCH 00-09 applications between rows
Stone fruits (peach, apricot, plum, nectarine, cherry)	Grasses and broadleaved weeds	CEU	3.5 L/ha	Pre emergence BBCH 00-09 applications between rows
Sunflower	Grasses and broadleaved weeds	CEU	2.6 L/ha	Pre emergence BBCH 00-09
Soybean	Grasses and broadleaved weeds	CEU	2.6 L/ha	Pre emergence BBCH 00-09
Bulb vegetables (onion, garlic, shallot, spring onion)	Grasses and broadleaved weeds	CEU	2.5-3.5 L/ha	Pre emergence BBCH 00-09
Bulb vegetables (onion, garlic, shallot, spring onion)	Grasses and broadleaved weeds	CEU	2.5-3.5 L/ha	Post emergence BBCH 10-13
Bean, pea, broad bean, field bean	Grasses and broadleaved weeds	CEU	2.5-3.5 L/ha	Pre emergence BBCH 00-09
Carrot, parsley	Grasses and broadleaved weeds	CEU	2.5-3.5 L/ha	Pre emergence BBCH 00-09
Lupine	Grasses and broadleaved weeds	CEU	2.6 L/ha	Pre emergence BBCH 00-09
Winter oilseed rape	Grasses and broadleaved weeds	CEU	1.0 L/ha	Pre emergence BBCH 00-09
Winter oilseed rape	Grasses and broadleaved weeds	CEU	2.0 L/ha	Post emergence BBCH 10-16
Asparagus	Grasses and broadleaved weeds	CEU	3.5 L/ha	Pre emergence BBCH 00-09

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPS
Crop(s)	Target(s)			
Brassica vegetables (broccoli, Brussels sprouts, cabbage, cauliflower)	Grasses and broadleaved weeds	CEU	3.5 L/ha	Pre transplanting
Strawberry	Grasses and broadleaved weeds	CEU	2.5-3.5 L/ha	Pre emergence BBCH 00-09 applications between rows
Raspberry	Grasses and broadleaved weeds	CEU	3.0 L/ha	Pre emergence BBCH 00-09 applications between rows
Currants	Grasses and broadleaved weeds	CEU	3.5 L/ha	Pre emergence BBCH 00-09 applications between rows
Leek	Grasses and broadleaved weeds	CEU	3.5 L/ha	Pre emergence BBCH 00-09
Leek	Grasses and broadleaved weeds	CEU	3.5 L/ha	Post emergence BBCH 10-13
Parsnip	Grasses and broadleaved weeds	CEU	3.5 L/ha	Pre emergence BBCH 00-09
Lettuce, endive	Grasses and broadleaved weeds	CEU	3.5 L/ha	Pre transplanting
Potato	Grasses and broadleaved weeds	CEU	2.5-3.5 L/ha	Pre emergence BBCH 00-09
Grapevine	Grasses and broadleaved weeds	CEU	3.5 L/ha	Pre emergence BBCH 00-09 applications between rows
Ornamentals	Grasses and broadleaved weeds	CEU	3.5 L/ha	Pre emergence BBCH 00-09
Clover, alfalfa	Grasses and broadleaved weeds	CEU	2.2 L/ha	Post emergence BBCH 13-18
Artichoke	Grasses and broadleaved weeds	CEU	3.5 L/ha	Pre emergence BBCH 00-09
Fennel	Grasses and broadleaved weeds	CEU	3.5 L/ha	Pre emergence BBCH 00-09
Cucurbits (melon, cucumber, squash, zucchini)	Grasses and broadleaved weeds	CEU	3.5 L/ha	Pre emergence BBCH 00-09

Further details are in the table “All intended uses” in Part B - Section 0.

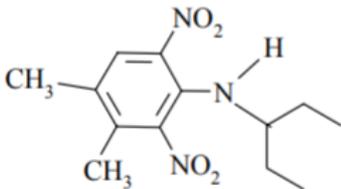
### Description of active substance pendimethalin

Pendimethalin is a selective contact and residual soil herbicide used in a range of crops including winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peas, carrot, parsley, strawberry, potato, asparagus, brassicas, currants, leek, parsnip, lettuce, endive, grapevine, ornamentals, artichoke, fennel, cucurbits, raspberry, sunflower, soybean, lupine, clover and alfalfa and winter oilseed rape for broad-spectrum control of important grasses and broadleaved weeds across all climatic zones of Europe.

Pendimethalin was first developed in 1974. It belongs to the chemical group of Dinitroaniline.

Today, pendimethalin is registered and commercialised in several formulations around the world.

**Table 3.2-2: Identity of pendimethalin**

<b>Common name (ISO)</b>	PENDIMETHALIN
<b>Chemical name (IUPAC)</b>	N-(1-ethylpropyl)-2,6-dinitro-3,4-xylidene
<b>Chemical name (CA)</b>	N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine
<b>CIPAC No</b>	357
<b>CAS No</b>	40487-42-1
<b>EEC No</b>	609-042-00-X
<b>FAO SPECIFICATION</b>	None
<b>Minimum purity</b>	900 g/kg
<b>Molecular formula</b>	C <sub>13</sub> H <sub>19</sub> N <sub>3</sub> O <sub>4</sub>
<b>Molecular mass</b>	281.3
<b>Structural formula</b>	

### Mode of action

The herbicidal properties of Pendimethalin were first described in 1974. It belongs to the chemical group of dinitroanilines. It is absorbed by plant roots and shoots (seedlings). When applied post-emergence, it is taken up by shoots predominantly. Monocotyledonous weeds are predominantly sensitive to root and cotyledon uptake, while dicotyledonous weeds are also sensitive to leaf uptake. Susceptible weed seedlings die either shortly after germination or their growth is strongly inhibited for several days. The leaves may become red or purple in colour, may become necrotic and will finally die.

Pendimethalin inhibits cell division by binding to  $\beta$ -tubuline and preventing assembly of tubuline heterodimers into microtubules (primary mode of action). In addition Pendimethalin inhibits RNA, DNA and protein synthesis and at higher concentrations an uncoupling of the oxidative phosphorylation was observed.

Today, pendimethalin is registered and commercialised in several formulations around the world.

### Information on similar formulations and current approvals

Pendimethalin 45.5% CS is a Capsule Suspension (CS) formulation containing 455 g/L pendimethalin. Data presented in this dossier is generated using this formulation in comparison with the pendimethalin (Stomp Aqua, Stomp 400SC, Activus SC) reference products and two **Sharda products** (Pendimethalin 33 EC and Pendimethalin 40 SC) registered over 10 years ago now out of protection containing pendimethalin with the same loading as Pendimethalin 45.5% CS. Pendimethalin is currently registered under a variety of trade names and formulations throughout Europe and a selection of these are described in table below.

**Table 3.2-3: Current approvals of pendimethalin in the EU Central zone as well as connected EPPO zones where trials were conducted. National reference products used in trials are also included**

Country	Product	Active ingredient	Approval number
Spain	Stomp Aqua	Pendimethalin 45% CS	25580
	Sharpen 33 EC	Pendimethalin 33% EC	ES-00063
	Penshar 40 SC	Pendimethalin 40% SC	ES-00064
Italy	Stomp Aqua	Pendimethalin 45.5% CS	013093
	Sharpen 33 EC	Pendimethalin 33% EC	015754
	Sharpen 40 SC	Pendimethalin 40% SC	015745
Croatia	Sharpen 33 EC	Pendimethalin 33% EC	UP/I-320-20/12-01/331
Czech Republic	Stomp 400SC	Pendimethalin 40% SC	159341323699-6
	Stomp Aqua	Pendimethalin 45.5% CS	5003-0
	Sharpen 33 EC	Pendimethalin 33% EC	5025-0
	Sharpen 40 SC	Pendimethalin 40% EC	5025-1
Denmark	Sharpen 33 EC	Pendimethalin 33% EC	653-11
Estonia	Sharpen 33 EC	Pendimethalin 33% EC	0654/27.01.17
	Sharpen 40 SC	Pendimethalin 40% EC	0655/27.01.17
France	Sharpen 33 EC	Pendimethalin 33% EC	2150786
Hungary	Sharpen 330 EC	Pendimethalin 33% EC	6300/19769-2/2019
	Sharpen 40 SC	Pendimethalin 40% EC	04.2/9678-1/2015
	Stomp Aqua	Pendimethalin 45% CS	2025.08.31
Netherlands	Sharpen 33 EC	Pendimethalin 33% EC	14754
Poland	Stomp Aqua	Pendimethalin 45.5% CS	R-90/2014
	Sharpen 33 EC	Pendimethalin 33% EC	R-198/2015
	Sharpen 400 SC	Pendimethalin 40% EC	R-199/2015
Romania	Activus SC	Pendimethalin 40% SC	R-1/2016 wu
	Sharpen 33 EC	Pendimethalin 33% EC	104PC/21.01.2015
	Sharpen 40 SC	Pendimethalin 40% SC	104PC/21.01.2015
Slovakia	Sharpen 33 EC	Pendimethalin 33% EC	14-11-1487
	Sharpen 40 SC	Pendimethalin 40% SC	17-000016-AU
	Stomp Aqua	Pendimethalin 45% CS	18-00215-POOS
Lithuania	Stomp CS	Pendimethalin 45% CS	AS2-15H(2019)
	Sharpen 33 EC	Pendimethalin 33% EC	-
	Sharpen 40 SC	Pendimethalin 40% SC	-
Portugal	Sharpen 33 EC	Pendimethalin 33% EC	0672

### Description of the target pests

The damaging economic effects of grass- and broadleaved weeds in GAP-claimed crops are well established, and justification for their control well documented. Pendimethalin control a number of very important annual grass weeds and annual broadleaved weeds found in autumn- and spring-sown field crops. Among the species that are controlled by Pendimethalin 45.5% CS are Annual bluegrass (*Poa annua*), Common bristlegrass (*Setaria sphacelata*), Redroot pigweed (*Amaranthus retroflexus*), Common Lambsquarters (*Chenopodium album*), Common fumitory (*Fumaria officinalis*), Red shank (*Persicaria maculosa*), Black Nightshade (*Solanum nigrum*) and others.

All the listed weeds are present throughout or in parts of the Central zone and in relevant EPPO zones. These weed species compete with the crops for light, moisture and nutrients, reducing crop yields and may obstruct harvestability.

**Table 3.2-4: Glossary of pests mentioned in the dossier.**

EPPO code	Scientific name	Common name
ALOMY	<i>Alopecurus myosuroides</i>	blackgrass
ECHCG	<i>Echinochloa crus-galli</i>	Common barnyard grass
MALSI	<i>Malva sylvestris</i>	High mallow
POAAN	<i>Poa annua</i>	Annual bluegrass

EPPO code	Scientific name	Common name
SETSP	<i>Setaria sphacelata</i>	Common bristlegrass
SETVE	<i>Setaria verticillata</i>	Bristly foxtail
AMARE	<i>Amaranthus retroflexus</i>	Redroot pigweed
CHEAL	<i>Chenopodium album</i>	Common lambsquarters
CIRAR	<i>Cirsium arvense</i>	Canada thistle
CONAR	<i>Convolvulus arvensis</i>	Field bindweed
DATST	<i>Datura stramonium</i>	False castor oil-plant
DIGSA	<i>Digitaria sanguinalis</i>	large crabgrass
FUMOF	<i>Fumaria officinalis</i>	Common fumitory
POLAV	<i>Polygonum aviculare</i>	prostrate knotweed
POLPE	<i>Persicaria maculosa</i>	Red shank
RANSA	<i>Ranunculus sardous</i>	Hairy buttercup
SOLNI	<i>Solanum nigrum</i>	Black nightshade
SONOL	<i>Sonchus oleraceus</i>	Annual sowthistle
TAROF	<i>Taraxacum officinale</i>	Blowball
THLAR	<i>Thlaspi arvense</i>	Field pennycress
VERPE	<i>Veronica persica</i>	Common field speedwell
VIOAR	<i>Viola arvensis</i>	Field pansy
APESV	<i>Apera spica-venti</i>	Loose silky-bent
ARREL	<i>Arrhenatherum elatius</i>	False oat
ATXPA	<i>Atriplex patula</i>	Common orache
BEAVX	<i>Beta vulgaris</i>	Beet
BRSNW	<i>Brassica napus</i>	Winter rape
CAPBP	<i>Capsella bursa-pastoris</i>	Shepherd's purse
CHEPO	<i>Lipandra polysperma</i>	Many-seeded poosefoot
CRUBO	<i>Carduus bourgeanus</i>	Cardo borriquero
CYPRO	<i>Cyperus rotundus</i>	Purple nutsedge
DAUCA	<i>Daucus carota</i>	Bee's nest
DIPER	<i>Diplotaxis erucooides</i>	Garden wall-rocket
EPHHE	<i>Euphorbia helioscopia</i>	Sun spurge
ERICA	<i>Erigeron canadensis</i>	Canada horseweed
GAETE	<i>Galeopsis tetrahit</i>	Common hemp nettle
GALAP	<i>Gallium aparine</i>	Cleavers
LAMPU	<i>Lamium purpureum</i>	Red deadnettle
MAQVU	<i>Marrubium vulgare</i>	Common horehound
MATIN	<i>Tripleurospermum inodorum</i>	Scentless mayweed
MYOAR	<i>Myosotis arvensis</i>	common scorpiongrass
MERAN	<i>Mercurialis annua</i>	Annual mercury
POLLA	<i>Persicaria lapathifolia</i>	Green smartweed
SENVU	<i>Senecio vulgaris</i>	Common groundsel
SINAR	<i>Sinapis arvensis</i>	Kelk
STEME	<i>Stellaria media</i>	Common chickweed
XANSI	<i>Xanthium orientale</i>	Californian burr
FUMOF	<i>Fumaria officinalis</i>	common fumitory

**Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS).**

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Winter cereals	CEU	CEU	Mono- and dicotyledon weeds	CEU	-
Maize	CEU		Mono- and dicotyledon weeds	CEU	-
Pome fruits	CEU		Mono- and dicotyledon weeds	CEU	-

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Stone fruits		CEU	Mono- and dicotyledon weeds	CEU	-
Sunflower	CEU	CEU	Mono- and dicotyledon weeds	CEU	-
Soybean	CEU		Mono- and dicotyledon weeds	CEU	-
Bulb vegetables		CEU	Mono- and dicotyledon weeds	CEU	-
Bean, pea, broad bean, field bean		CEU	Mono- and dicotyledon weeds	CEU	-
Carrot, parsley		CEU	Mono- and dicotyledon weeds	CEU	-
Lupine		CEU	Mono- and dicotyledon weeds	CEU	-
Winter oilseed rape	CEU	CEU	Mono- and dicotyledon weeds	CEU	-
Asparagus		CEU	Mono- and dicotyledon weeds	CEU	-
Brassica vegetables		CEU	Mono- and dicotyledon weeds	CEU	-
Strawberry	CEU	CEU	Mono- and dicotyledon weeds	CEU	-
Raspberry		CEU	Mono- and dicotyledon weeds	CEU	-
Currants		CEU	Mono- and dicotyledon weeds	CEU	-
Leek		CEU	Mono- and dicotyledon weeds	CEU	-
Parsnip		CEU	Mono- and dicotyledon weeds	CEU	-
Lettuce, endive		CEU	Mono- and dicotyledon weeds	CEU	-
Potato	CEU		Mono- and dicotyledon weeds	CEU	-
Grapevine	CEU	CEU	Mono- and dicotyledon weeds	CEU	-
Ornamentals		CEU	Mono- and dicotyledon weeds	CEU	-
Clover, alfalfa	CEU	CEU	Mono- and dicotyledon weeds	CEU	-
Artichoke		CEU	Mono- and dicotyledon weeds	CEU	-
Fennel		CEU	Mono- and dicotyledon weeds	CEU	-
Cucurbits		CEU	Mono- and dicotyledon weeds	CEU	-

### Compliance with the Uniform Principles

Comprehensive field trials were conducted in Czech Republic, Poland, Estonia, Lithuania, Slovakia, Romania, Hungary, Spain and Italy in 2019, 2020 and 2021 seasons. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

### Information on trials submitted (3.1 Efficacy data)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. In general, the trials were conducted according to the respective EPPO guidelines.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application for registration of Pendimethalin 45.5% CS, 97 efficacy trials were conducted in the Maritime (36), the North-east (33), the South-east (6) and the Mediterranean (22) EPPO zones.

**Table 3.2-6: Presentation of efficacy trials (efficacy trials, preliminary trials...)**

Use(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
Maize	Grasses and broadleaved weeds	Italy	2019	MED + E + S	-	4	-	-	GEP	Pre-/post-em.
		Czech Republic	2019	MED + E + S	12	-	-	-	GEP	Pre-/post-em.
		Poland	2019	MED + E + S	-	-	-	10	GEP	Pre-/post-em.
		Lithuania	2019	MED + E + S	-	-	-	2	GEP	Pre-/post-em.
		Slovakia	2019	MED + E + S	-	-	2	-	GEP	Pre-/post-em.
		Romania	2019	MED + E + S	-	-	2	-	GEP	Pre-/post-em.
		<b>Total, Maize</b>					<b>12</b>	<b>4</b>	<b>4</b>	<b>12</b>
Cereals	Grasses and broadleaved weeds	Spain	2019	MED + E + S	-	12	-	-	GEP	Pre-/post-em.
		Czech Republic	2020	MED + E + S	14	1	1	1	GEP	Pre-/post-em.
			2019	MED + E + S	4	1	1	1	GEP	Post-em.
		Poland	2020	MED + E + S	1	1	1	12	GEP	Pre-/post-em.
		Estonia	2019	MED + E + S	1	1	1	1	GEP	Post-em.
		Lithuania	2020	MED + E + S	1	1	1	2	GEP	Pre-/post-em.
		<b>Total, Cereals</b>					<b>18</b>	<b>12</b>	<b>-</b>	<b>15</b>
Apple	Grasses and broadleaved weeds	Spain	2019	MED + E + S	-	4	-	-	GEP	Post-em.
		Italy	2019	MED + E + S	-	2	-	-	GEP	Post-em.
		Czech Republic	2019	MED + E + S	6	-	-	-	GEP	Post-em.
		Poland	2019	MED + E + S	-	-	-	6	GEP	Post-em.
		Romania	2019	MED + E + S	-	-	2	-	GEP	Post-em.
		<b>Total, Apple</b>					<b>6</b>	<b>6</b>	<b>2</b>	<b>6</b>
<b>Total, all crops</b>					<b>36</b>	<b>22</b>	<b>6</b>	<b>33</b>		

### Climatic zones

Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country<sup>1</sup>.

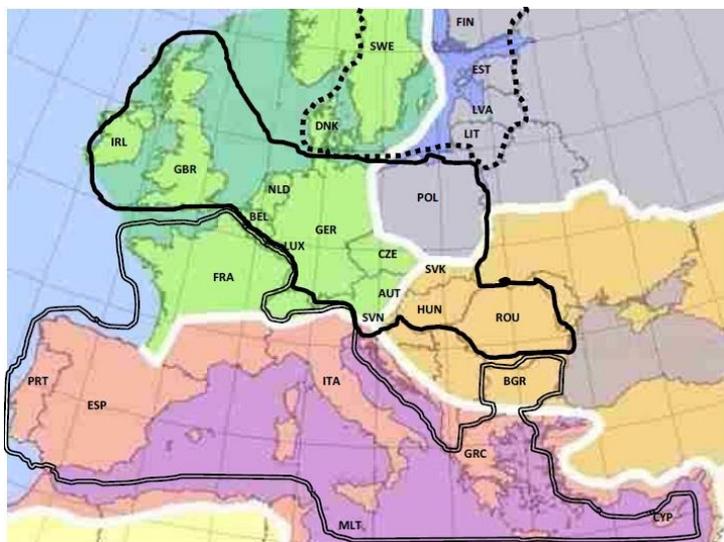
Czech Republic is located in the Maritime EPPO zone; Poland, Estonia and Lithuania is located in the North-east EPPO zone; Romania, Hungary and Slovakia is located in the South-east EPPO zone; Spain and Italy are located in the Mediterranean EPPO zone (Figure 3.2-1).

This Registration Report is prepared to support the submission of Pendimethalin 45.5% CS throughout the Central Registration zone, therefore data from the Maritime zone, North-east and

<sup>1</sup> Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, E. Bouma, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

South-east EPPO zone are included. Data obtained in the Mediterranean has also been added as supporting information, however, the data from each climatic zone is summarised separately.

**Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)**



### Agronomic conditions

Cultural conditions of cereals, maize and apple and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between Czech Republic, Poland, Estonia, Lithuania, Romania, Hungary, Slovakia, Spain and Italy. The same pendimethalin containing herbicides are already registered and used in the countries where tested for the same uses, i.e. to control grasses and broadleaved weed species in the GAP-claimed crops with pre- or post-emergence application.

#### (i) Weed physiology

Annual bluegrass (*Poa annua*), Bristly foxtail (*Setaria verticillata*), Italian Ryegrass (*Lolium multiflorum*), Common Fumitory (*Fumaria officinalis*), Common lambsquarters (*Chenopodium album*), Black nightshade (*Solanum nigrum*) and others are all controlled by Pendimethalin 45.5% CS and are all key weeds throughout Central Europe. In each country these weeds are very common and can cause large reductions in yield.

#### (ii) Site selection

Although trials were performed throughout the EU, in each country the sites were carefully selected to ensure that for each weed species, the level of control was assessed on a range of populations and application timings. To exert maximum control pressure and to exacerbate treatment differences in each country this included some trials which contained high weed densities. No differences in the level of control were apparent between the different countries or regions in which the trials were conducted. For each weed species equivalent levels of control were recorded in the countries where present in trials.

#### (iii) Agronomic practices

Agronomic practices in cereals, maize and apple are similar throughout the Central zone as well as in the countries in the connected EPPO zones where trials were conducted. The levels of inorganic fertilizers and other crop inputs are similar between the countries.

(iv) *Varieties*

Although crop varieties tend to differ between countries, the crop safety of Pendimethalin 45.5% CS has been tested on a wide range of varieties in selectivity- as well as efficacy trials. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance and yield data generated in one country is therefore relevant in another Member state.

(v) *Trial methodology*

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(vi) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for cereals, maize and apple production due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

The active ingredient of Pendimethalin 45.5% CS – Pendimethalin – has soil as well as foliar activity. Therefore, in each country, trials have been conducted on a range of soil types with no difference seen in the level of control.

On the basis that the above factors do not influence the overall performance of Pendimethalin 45.5% CS, it is the applicant’s contention that data from Czech Republic, Estonia, Poland, Lithuania, Slovakia and Romania is equally valid in demonstrating the products performance throughout the Central EU zone and the data from Italy, Spain is valid as supporting data.

The reference products used in the efficacy trials are listed in Table 3.2-7.

**Table 3.2-7: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)**

Trade name	Formulation	Composition	Rates [l/ha]	Indication	Country	Nº of Trials
<b>Pendimethalin reference products</b>						
STOMP AQUA	CS	Pendimethalin 455 g/L	2.5 l/ha 3.0 l/ha	Pre- and post-emergence control of weeds	SK, PL, LU, CZ, ES, IT	79
STOMP 400SC	SC	Pendimethalin 400 g/L	3.5 l/ha	Pre- and post-emergence control of weeds	CZ, PL, LT, EE	16
ACTIVUS SC	SC	Pendimethalin 330 g/L	4.0 l/ha	Pre- and post-emergence control of weeds	RO	2
PENDIMETHALIN 33 EC	EC	Pendimethalin 400 g/L	4.0 l/ha 5.0 l/ha	Pre- and post-emergence control of weeds	SK, PL, CZ, ES, IT, LU, RO	87
PENDIMETHALIN 40 SC	SC	Pendimethalin 400 g/L	3.5 l/ha 4.0 l/ha	Pre- and post-emergence control of weeds	SK, PL, CZ, ES, IT, LU, RO	87

Comments of zRMS:	<p>This document summarizes the information related to the efficacy of the plant protection product – PENSHUI (product code: SHA 2600 E).</p> <p>SHA 2600 E is a capsule suspension (CS) formulation containing 455 g/L pendimethalin, that is intended for use in a range of crops including winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peas, carrot, parsley, strawberry, potato, asparagus, brassicas, currants, leek, parsnip, lettuce, endive, grapevine, ornamentals, artichoke, fennel, cucurbits, raspberry, sunflower, soybean, lupine, clover and alfalfa and winter oilseed rape for broad-spectrum control</p>
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	<p>of important grasses and broadleaved weeds across all climatic zones of Europe. For now, this mentioned active substance is on the list of approved active substances.</p> <p>All necessary information's about tested plant protection products, active substance, studied weeds, reference products, etc. are correctly presented in this drp by Applicant.</p> <p>Pendimethalin inhibits cell division by binding to <math>\beta</math>-tubuline and preventing assembly of tubuline heterodimers into microtubules (primary mode of action). In addition, Pendimethalin inhibits RNA, DNA and protein synthesis and at higher concentrations an uncoupling of the oxidative phosphorylation was observed.</p> <p>In Poland 24 plant protection products containing pendimethalin are already registered. The product – Penshui (product code: SHA 2600 E) containing pendimethalin by Sharda Cropchem España has not been previously evaluated in any country according to Uniform Principles.</p> <p>Poland is a ZRMs.</p>
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### 3.2.1 Preliminary tests (KCP 6.1)

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, tomato, grapevine and strawberry to control grasses and broadleaved 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.

Comments of zRMS:	Pendimethalin is an active substance that is authorised in a number of products for weed control across the EU. No preliminary range finding tests are required, in the opinion of Evaluator for PENSHUI (product code: SHA 2600 E).
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### 3.2.2 Minimum effective dose tests (KCP 6.2)

To determine the minimum effective dose rate, data from 97 trials conducted in cereals, maize and apple are included in this section. In the cereals, maize and apple trials, Pendimethalin 45.5% CS was applied at 2.0, 2.5 and 3.5 L/ha in the Maritime, North-east and South-east EPPO zone and 2.0, 2.5 and 3.0 L/ha in the Mediterranean EPPO zone for the control of annual grasses and broadleaved weeds. The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy is tested under a range of environmental conditions to fully challenge the product. Data is presented from trials conducted in the Maritime EPPO zone (36, i.e. Czech Republic (36)) EPPO zone, the North-east EPPO zone (33, i.e. Poland (28), Estonia (1) and Lithuania (4)) EPPO zone, the South-east EPPO zone (6, i.e. Romania (4) and Slovakia (2)) EPPO zone and the Mediterranean EPPO zone (22, i.e. Spain (16) and Italy (6)). Data from each zone has been summarized separately.

In the 97 trials, the level of control obtained by Pendimethalin 45.5% CS was assessed on annual grasses and broadleaved weeds present in the trials.

### 3.2.2.1 Summary and evaluation of Minimum Effective Dose trial results for 2.5-3.5 L/ha Pendimethalin 45.5% CS target rate against broadleaved and grass weeds in Maize

In order to prove and to support the requested dose rate of 2.5-3.5 L/ha Pendimethalin 45.5% CS [1.137-1.59 kg pendimethalin per hectare] applied pre- and post-emergence for the control of broadleaved and grass weeds, the assessment results of 32 efficacy trials with broadleaved and grass weeds, performed in the Maritime, North-east, South-east and Mediterranean EPPO zone in 2019 season, are reported. A Pendimethalin 45.5% CS was included in these trials at 2.5-3.0-3.5 L/ha to demonstrate the recommended dose rate as well as at a lower than recommended dose rate (2.0 L/ha [0.91 kg pendimethalin per hectare]). The rates reflect the proposed label rate as well as 66% of the full recommended rate of Pendimethalin 45.5% CS in maize, in accordance with the EPPO standard PP 1/225(2) ‘*Minimum effective dose*’ and the Central zone efficacy requirements.

The control of frequently occurring monocotyledonous and dicotyledonous weeds in maize was assessed at different timings throughout the trial period. In the Maritime, North-east, South-east and Mediterranean zone, the data obtained from the assessment carried out after regrowth of the weeds was considered as the most accurate representation of whole plot product performance and this data is therefore presented in the summary tables. Table 3.2-8, Table 3.2-9, Table 3.2-10 and Table 3.2-11 therefore contains a summary of the assessment data obtained by visually estimating control obtained by the applied products at 10-61 days after pre- or post-emergence application in the Maritime, North-east, South-east and Mediterranean EPPO zone.

**Table 3.2-8: Maritime zone: Minimum effective dose of Pendimethalin 45.5% CS applied pre- or post-emergence against frequently occurring broadleaved and grass weeds in maize.**

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment Mean (min-max)	Efficacy obtained with Pendimethalin 45.5% CS at:		
				2.0 L/ha	2.5 L/ha	3.5 L/ha
<b>Pre-emergence application</b>						
APESV	Pre-em.	1	10.0	100	100	100
CAPBP	Pre-em.	4	23.4 (6.0-63.8)	89.4 (73.8-98.0)	93.0 (81.3-100)	95.3 (88.8-100)
CHEAL	Pre-em.	2	8.6 (1.3-15.8)	100 (100-100)	100 (100-100)	100 (100-100)
ECHCG	Pre-em.	5	25.7 (5.5-100)	100 (100-100)	100 (100-100)	100 (100-100)
FUMOF	Pre-em.	2	15.7 (13.5-17.8)	94.8 (91.5-98.0)	96.9 (93.8-100)	98.3 (96.5-100)
GAETE	Pre-em.	1	8.0	97.8	97.8	98.8
GALAP	Pre-em.	1	5.3	92.5	99.8	100
MATIN	Pre-em.	5	18.1 (7.8-31.0)	86.7 (77.5-96.0)	85.4 (80.0-97.0)	90.8 (85.0-98.8)
POLCO	Pre-em.	3	8.2 (4.5-12.3)	85.1 (70.0-92.8)	90.5 (80.0-96.5)	94.6 (85.0-100)
POLLA	Pre-em.	1	5.3	100	100	100
STEME	Pre-em.	2	13.9 (8.3-19.5)	99.9 (99.8-100)	100 (100-100)	100 (100-100)
THLAR	Pre-em.	3	15.2 (5.5-26.0)	100 (100-100)	100 (100-100)	100 (100-100)
VERPE	Pre-em.	1	2.5	100	100	100
VIOAR	Pre-em.	3	11.2 (1.5-17.0)	92.1 (76.3-100)	92.9 (78.8-100)	95.0 (85.0-100)
Mean of all assessments		34	12.2	95.6	96.9	98.1
<b>Post-emergence application</b>						
APESV	Post-em.	1	9.0	90.0	95.0	98.0
CAPBP	Post-em.	5	21.4 (8.5-59.8)	48.8 (20.0-90.0)	55.0 (32.5-90.0)	68.5 (37.5-95.0)
CHEAL	Post-em.	3	14.7 (8.0-21.0)	62.5 (22.5-90.0)	87.1 (81.3-95.0)	90.0 (82.5-95.0)
ECHCG	Post-em.	5	18.3 (10.8-26.0)	52.5 (10.0-93.8)	61.0 (25.0-96.0)	77.8 (60.0-99.0)
FUMOF	Post-em.	2	15.3 (10.0-20.5)	45.0 (0.0-90.0)	60.0 (30.0-90.0)	75.0 (55.0-95.0)
GAETE	Post-em.	1	6.3	100	100	100
GALAP	Post-em.	2	5.2 (5.0-5.3)	72.5 (70.0-75.0)	72.5 (70.0-75.0)	90.7 (87.5-93.8)
POLCO	Post-em.	3	11.7 (7.8-19.0)	8.3 (0.0-17.5)	17.5 (0.0-27.5)	41.7 (37.5-50.0)
POLLA	Post-em.	2	7.3 (5.0-9.5)	48.8 (0.0-97.5)	47.5 (0.0-95.0)	87.5 (77.5-97.5)
STEME	Post-em.	2	12.8 (9.0-16.5)	92.5 (90.0-95.0)	96.0 (95.0-97.0)	98.8 (98.0-99.5)
THLAR	Post-em.	4	16.9 (8.3-37.5)	60.3 (42.5-80.0)	67.5 (50.0-88.8)	76.0 (57.5-96.3)
VERPE	Post-em.	2	15.2 (14.3-16.0)	98.5 (97.0-100)	96.7 (92.5-100)	98.2 (96.3-100)
Mean of all assessments		18	12.8	65.0	71.3	83.5

**Table 3.2-9: North-east zone: Minimum effective dose of Pendimethalin 45.5% CS applied pre- or post-emergence against frequently occurring broadleaved and grass weeds in maize.**

EPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment Mean (min-max)	Efficacy obtained with Pendimethalin 45.5% CS at:		
				Mean (min-max)		
				2.0 L/ha	2.5 L/ha	3.5 L/ha
<b>Pre-emergence application</b>						
AMARE	Pre-em.	2	11.8 (8.3-15.3)	55.7 (40.0-71.3)	68.8 (52.5-85.0)	77.5 (62.5-92.5)
CAPBP	Pre-em.	1	9.3	75.0	92.5	95.0
CHEAL	Pre-em.	5	10.7 (6.5-16.3)	66.3 (62.5-75.0)	81.3 (72.5-92.5)	90.3 (82.5-100)
ECHCG	Pre-em.	5	16.3 (7.3-34.5)	66.8 (53.8-75.0)	78.6 (63.8-86.5)	88.3 (73.8-100)
EPHHE	Pre-em.	1	5.0	78.8	50.0	87.5
GASPA	Pre-em.	1	9.0	0.0	7.8	21.0
LAMPU	Pre-em.	1	6.0	57.0	78.5	88.7
POLCO	Pre-em.	3	7.5 (5.0-10.0)	61.1 (44.5-70.0)	68.0 (60.3-73.8)	79.8 (67.0-90.0)
SENVU	Pre-em.	1	5.8	23.8	30.0	38.7
SINAR	Pre-em.	1	14.8	38.8	50.5	57.5
STEME	Pre-em.	3	7.6 (6.5-8.8)	72.4 (66.3-75.8)	86.0 (80.0-91.3)	92.4 (87.5-96.3)
THLAR	Pre-em.	1	8.0	43.8	64.3	81.8
VERPE	Pre-em.	1	7.5	63.0	85.5	97.0
VIOAR	Pre-em.	3	6.4 (5.8-7.5)	62.5 (60.0-65.0)	72.5 (70.0-75.0)	82.5 (81.3-85.0)
Mean of all assessments		29	9.0	54.6	65.3	77.0
<b>Post-emergence application</b>						
AMARE	Post-em.	1	11.5	48.8	65.0	75.0
BRSNW	Post-em.	1	10.0	61.3	71.3	73.8
CAPBP	Post-em.	1	6.3	63.8	71.3	82.6
CHEAL	Post-em.	6	13.8 (7.0-31.3)	62.9 (52.0-88.5)	74.1 (65.0-88.8)	83.6 (72.5-91.8)
ECHCG	Post-em.	5	12.0 (8.5-16.0)	56.6 (43.8-70.0)	71.3 (55.0-78.8)	82.2 (68.8-87.5)
LAMPU	Post-em.	2	6.5 (6.5-6.5)	45.0 (45.0-45.0)	64.8 (64.8-64.8)	74.8 (74.8-74.8)
POLCO	Post-em.	4	9.8 (9.5-10.3)	44.5 (35.3-62.5)	58.4 (50.5-72.5)	65.7 (56.3-77.5)
SETVI	Post-em.	1	9.0	62.5	71.3	80.0
SINAR	Post-em.	1	33.8	70.0	70.0	72.5
SOLNI	Post-em.	1	5.5	58.8	70.0	81.3
STEME	Post-em.	1	8.3	65.0	77.5	87.5
VERPE	Post-em.	2	7.5 (7.5-7.5)	50.8 (50.8-50.8)	74.3 (74.3-74.3)	82.8 (82.8-82.8)
VIOAR	Post-em.	1	7.0	62.5	71.3	73.8
Mean of all assessments		27	10.8	57.9	70.0	78.1

**Table 3.2-10: South-east zone: Minimum effective dose of Pendimethalin 45.5% CS applied pre- or post-emergence against frequently occurring broadleaved and grass weeds in maize.**

EPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment Mean (min-max)	Efficacy obtained with Pendimethalin 45.5% CS at:		
				Mean (min-max)		
				2.0 L/ha	2.5 L/ha	3.5 L/ha
<b>Pre-emergence application</b>						
AMARE	Pre-em.	1	5.5	98.0	100	100
AMBEL	Pre-em.	1	4.0	95.0	100	100
CHEAL	Pre-em.	2	35.5 (7.0-64.0)	94.9 (89.7-100)	98.7 (97.4-100)	99.1 (98.1-100)
CHEHY	Pre-em.	1	47.0	100	100	100
DIGSA	Pre-em.	1	10.5	86.5	92.3	95.0
ECHCG	Pre-em.	2	20.4 (15.8-25.0)	80.9 (75.3-86.5)	88.6 (80.8-96.3)	92.7 (85.3-100)
MERAN	Pre-em.	1	38.0	94.0	98.0	100
SETSS	Pre-em.	1	10.0	94.5	98.0	100
STEME	Pre-em.	1	18.0	100	100	100
XANSI	Pre-em.	1	4.5	93.1	97.3	98.9
Mean of all assessments		12	19.3	93.7	97.3	98.6
<b>Post-emergence application</b>						
AMARE	Post-em.	1	9.8	91.6	94.6	96.0
AMBEL	Post-em.	1	9.8	85.9	94.1	97.8
CAPBP	Post-em.	1	10.0	15.0	20.0	30.0
CHEAL	Post-em.	2	21.7 (13.3-30.0)	51.5 (21.5-81.5)	80.8 (72.8-88.8)	90.9 (88.0-93.8)
DIGSA	Post-em.	1	9.3	88.2	88.9	94.7
ECHCG	Post-em.	2	11.8 (7.0-16.5)	52.9 (22.083.8)	60.7 (32.8-88.6)	78.2 (62.0-94.4)
GALAP	Post-em.	1	6.0	29.3	39.5	80.8
MATIN	Post-em.	1	8.0	11.5	17.3	27.3
POLCO	Post-em.	1	5.0	36.3	46.0	57.5
SETSS	Post-em.	1	10.0	84.5	89.0	96.4
THLAR	Post-em.	1	20.0	85.0	86.0	95.3

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment Mean (min-max)	Efficacy obtained with Pendimethalin 45.5% CS at:		
				Mean (min-max)		
				2.0 L/ha	2.5 L/ha	3.5 L/ha
VIOAR	Post-em.	1	3.0	94.0	95.8	96.5
XANSI	Post-em.	1	5.5	91.5	93.8	93.8
Mean of all assessments		15	10.0	62.9	69.7	79.6

**Table 3.2-11: Mediterranean zone: Minimum effective dose of Pendimethalin 45.5% CS applied pre- or post-emergence against frequently occurring broadleaved and grass weeds in maize.**

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment Mean (min-max)	Efficacy obtained with Pendimethalin 45.5% CS at:		
				Mean (min-max)		
				2.0 L/ha	2.5 L/ha	3.0 L/ha
<b>Pre-emergence application</b>						
AMARE	Pre-em.	2	10.6 (7.3-13.8)	89.2 (88.8-89.5)	94.5 (93.0-96.0)	98.3 (97.5-99.0)
CHEAL	Pre-em.	1	5.5	98.5	99.5	100
ECHCG	Pre-em.	1	2.8	82.5	91.3	90.0
SOLNI	Pre-em.	1	6.3	95.8	99.0	99.5
DIGSA	Pre-em.	1	37.5	87.5	91.8	96.3
Mean of all assessments		6	12.5	90.7	95.2	96.8
<b>Post-emergence application</b>						
ABUTH	Post-em.	1	10.0	75.0	80.0	85.0
AMARE	Post-em.	1	12.5	92.5	92.5	97.3
CHEAL	Post-em.	1	5.0	98.0	98.0	98.0
ECHCG	Post-em.	2	4.3 (4.3-4.3)	90.1 (88.8-91.3)	93.5 (93.3-94.0)	94.5 (94.0-95.0)
SETVI	Post-em.	1	12.5	87.5	92.5	94.0
SOLNI	Post-em.	1	25.0	97.8	96.5	97.8
Mean of all assessments		7	11.6	90.2	92.2	94.4

At the timing of the assessments, the recommended dose of 2.5-3.5 L/ha of Pendimethalin 45.5% CS provided a superior control, to the doses of 2.0 L/ha of Pendimethalin 45.5% CS in the trials conducted in the Mediterranean, Maritime, North-east and South-east EPPO zone.

Based on results achieved on monocotyledonous and dicotyledonous weeds which were present in 32 maize trials included in the minimum effective dose section, it can be concluded that the recommended doses are optimal to consistently control frequently occurring grass and broadleaved weeds. Pendimethalin 45.5% CS should be applied pre- or post-emergence under optimal weather- and soil conditions at recommended dose rate.

### Summary and evaluation of Minimum Effective Dose trial results for 2.5-3.5 L/ha Pendimethalin 45.5% CS target rate against broadleaved and grass weeds in Cereals

In order to prove and to support the requested dose rate of 2.5-3.5 L/ha Pendimethalin 45.5% CS [1.137-1.59 kg pendimethalin per hectare] applied pre- and post-emergence for the control of broadleaved and grass weeds, the assessment results of 44 efficacy trials with broadleaved and grass weeds, performed in the Maritime (18), the North-east (15) and the Mediterranean (12) EPPO zones in 2019 and 2020 season, are reported. A Pendimethalin 45.5% CS was included in these trials at 2.5-3.5 L/ha as at a lower than recommended dose rate (2.0 L/ha [0.91 kg pendimethalin per hectare]). The rates reflect the proposed label rate as well as 55-80% of the full recommended rate of Pendimethalin 45.5% CS in cereals, in accordance with the EPPO standard PP 1/225(2) 'Minimum effective dose' and the Central zone efficacy requirements.

The control of frequently occurring monocotyledonous and dicotyledonous weeds in cereals was assessed at different timings throughout the trial period. In the Maritime, North-east and the Mediterranean zone, the data obtained from the assessment carried out after regrowth of the weeds was considered as the most accurate representation of whole plot product performance and this data is therefore presented in the summary tables. Table 3.2-14, Table 3.2-15 and Table 3.2-16 therefore contains a summary of the as-

assessment data obtained by visually estimating control obtained by the applied products at 12-237 days after pre- or post-emergence application in the Maritime, the North-east and the Mediterranean EPPO zones.

**Table 3.2-12: Maritime zone: Minimum effective dose of Pendimethalin 45.5% CS applied pre- or post-emergence against frequently occurring broadleaved and grass weeds in cereals.**

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment Mean (min-max)	Efficacy obtained with Pendimethalin 45.5% CS at:		
				2.0 L/ha	2.5 L/ha	3.5 L/ha
<b>Pre-emergence application</b>						
THLAR	Pre-em.	3	12.4 (7.3-22.5)	40.0 (20.0-50.0)	49.2 (27.5-60.0)	59.2 (50.0-65.0)
VERPE	Pre-em.	3	24.8 (6.0-54.5)	81.8 (78.0-87.5)	87.6 (85.0-90.0)	93.3 (90.0-100)
VIOAR	Pre-em.	3	18.0 (7.0-39.5)	81.3 (80.0-82.5)	87.9 (86.3-90.0)	91.5 (91.3-92.0)
STEME	Pre-em.	7	10.6 (5.5-17.0)	90.2 (60.0-100)	94.4 (65.0-100)	96.3 (70.0-100)
CAPBP	Pre-em.	7	22.0 (7.0-61.3)	62.5 (20.0-98.0)	68.8 (30.0-100)	73.9 (50.0-100)
POAAN	Pre-em.	2	6.65 (6.5-6.8)	85.0 (85.0-85.0)	90.0 (90.0-90.0)	90.0 (90.0-90.0)
ALOMY	Pre-em.	2	8.9 (7.3-10.5)	87.5 (87.5-87.5)	90.0 (90.0-90.0)	90.0 (90.0-90.0)
APESV	Pre-em.	6	10.3 (7.0-17.0)	82.1 (60.0-100)	86.8 (65.0-100)	89.2 (70.0-100)
GALAP	Pre-em.	5	17.8 (9.0-22.5)	80.6 (60.0-100)	83.8 (65.0-100)	88.0 (70.0-100)
ECHCG	Pre-em.	4	13.6 (8.8-17.0)	79.5 (60.0-100)	83.3 (65.0-100)	85.0 (70.0-100)
MATIN	Pre-em.	2	15.4 (12.0-18.8)	75.0 (60.0-90.0)	83.0 (68.0-98.0)	84.0 (70.0-98.0)
PARPH	Pre-em.	1	55.8	70.0	80.0	90.0
FUMOF	Pre-em.	1	40.8	0.0	50.0	70.0
Mean of all assessments		46	16.5 (5.5-61.3)	75.1 (0.0-100)	84.7 (27.5-100)	88.9 (50.0-100)
<b>Post-emergence application</b>						
VERPE	Post-em.	8	13.8 (7.8-29.0)	89.5 (78.0-100)	91.4 (80.0-100)	96.9 (90.0-100)
VIOAR	Post-em.	5	8.96 (7.0-12.5)	68.0 (20.0-100)	72.0 (30.0-100)	80.0 (50.0-100)
STEME	Post-em.	9	9.4 (7.0-12.5)	87.5 (75.0-100)	94.4 (80.0-100)	97.0 (90.0-100)
CAPBP	Post-em.	6	22.2 (7.8-66.3)	58.8 (20.0-100)	67.9 (30.0-100)	77.1 (50.0-100)
POAAN	Post-em.	3	16.4 (7.8-33.5)	82.5 (75.0-86.3)	96.7 (90.0-100)	100 (100-100)
ALOMY	Post-em.	3	13.1 (7.8-23.5)	83.3 (80.0-85.0)	96.7 (90.0-100)	100 (100-100)
MATIN	Post-em.	5	10.4 (7.0-15.0)	70.6 (40.0-93.0)	78.6 (45.0-95.0)	86.0 (50.0-100)
THLAR	Post-em.	4	11.9 (7.5-20.3)	87.6 (80.0-99.0)	93.6 (90.0-99.5)	96.0 (90.0-100)
LAMPU	Post-em.	3	8.2 (7.8-9.0)	91.6 (75.0-100)	96.7 (90.0-100)	100 (100-100)
APESV	Post-em.	6	18.9 (7.0-27.8)	76.7 (52.5-95.0)	89.1 (78.8-98.0)	96.7 (90.0-100)
PARPH	Post-em.	2	39.8 (10.5-69.0)	86.9 (86.3-87.5)	90.0 (90.0-90.0)	91.9 (91.3-92.5)
FUMOF	Post-em.	2	40.9 (38.3-43.5)	93.8 (92.5-95.0)	98.9 (98.5-99.3)	99.6 (99.3-99.8)
ARBTH	Post-em.	2	27.9 (25.0-30.8)	81.9 (80.0-83.8)	88.8 (87.5-90.0)	93.2 (91.3-95.0)
GALAP	Post-em.	3	9.6 (8.0-12.0)	77.6 (75.0-80.0)	81.0 (80.0-83.0)	95.0 (90.0-100)
ECHCG	Post-em.	2	9.5 (8.0-11.0)	75.0 (75.0-75.0)	80.0 (80.0-80.0)	95.0 (95.0-95.0)
Mean of all assessments		63	15.3 (7.0-22.5)	80.0 (20.0-100)	86.9 (30.0-100)	92.8 (50.0-100)

**Table 3.2-13: North-east zone: Minimum effective dose of Pendimethalin 45.5% CS applied pre- or post-emergence against frequently occurring broadleaved and grass weeds in cereals.**

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment Mean (min-max)	Efficacy obtained with Pendimethalin 45.5% CS at:		
				2.0 L/ha	2.5 L/ha	3.5 L/ha
<b>Pre-emergence application</b>						
APESV	Pre-em.	3	26.4 (5.0-62.3)	73.8 (66.3-77.5)	78.3 (75.0-82.5)	85.9 (82.5-88.8)
VIOAR	Pre-em.	4	13.6 (9.75-19.8)	72.4 (41.3-89.5)	77.7 (52.5-91.8)	81.7 (65.0-92.8)
STEME	Pre-em.	3	11.1 (9.0-14.3)	72.9 (66.3-86.3)	78.3 (72.5-83.8)	85.4 (82.5-88.8)
CAPBP	Pre-em.	3	10.2 (5.5-19.3)	75.3 (56.3-90.8)	81.9 (66.3-95.5)	88.7 (78.8-98.5)
ANTAR	Pre-em.	2	10.2 (9.8-10.5)	57.5 (40.0-75.0)	63.8 (41.3-86.3)	73.8 (61.3-86.3)
POLAV	Pre-em.	1	8.50	71.3	78.8	81.3
VERPE	Pre-em.	1	10.0	82.5	83.8	77.5
PAPRH	Pre-em.	1	5.8	57.5	68.8	81.3
BRSNW	Pre-em.	1	19.5	40.0	51.3	67.5
MATIN	Pre-em.	1	8.3	91.3	92.8	95.5
GALAP	Pre-em.	1	6.0	86.5	91.5	94.5
SINAR	Pre-em.	1	5.8	58.8	72.5	82.5
Mean of all assessments		22	14.3 (5.0-62.3)	66.7 (40.0-91.3)	74.5 (41.3-92.8)	81.7 (61.3-94.5)
<b>Post-emergence application</b>						
APESV	Post-em.	4	40.1 (12.3-70.3)	71.5 (62.5-81.3)	76.6 (71.3-81.3)	83.2 (80.0-85.0)
AGRRE	Post-em.	2	29.1 (19.8-38.3)	75.6 (71.3-80.0)	80.1 (78.8-81.3)	91.3 (90.0-92.5)

EPP0 Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment Mean (min-max)	Efficacy obtained with Pendimethalin 45.5% CS at:		
				Mean (min-max)		
				2.0 L/ha	2.5 L/ha	3.5 L/ha
VIOAR	Post-em.	7	13.4 (7.5-30.5)	61.7 (41.3-90.8)	66.4 (40.0-92.5)	78.9 (63.8-95.0)
STEME	Post-em.	7	9.6 (5.3-25.5)	78.6 (63.8-100)	85.5 (72.5-100)	92.5 (82.5-100)
PARPH	Post-em.	2	26.6 (25.3-27.8)	82.5 (82.5-82.5)	93.2 (92.5-93.8)	98.8 (98.8-98.8)
ANTAR	Post-em.	2	28.5 (21.0-36.0)	81.9 (81.3-82.5)	87.6 (86.3-88.8)	93.8 (93.8-93.8)
LAMPU	Post-em.	2	7.7 (6.0-9.3)	79.8 (70.0-89.5)	83.0 (72.5-93.5)	90.8 (85.0-96.5)
VERPE	Post-em.	4	11.4 (6.3-23.5)	68.5 (35.0-89.0)	84.6 (72.5-97.5)	90.5 (83.8-100)
CAPBP	Post-em.	3	13.0 (6.5-23.0)	61.7 (41.3-90.8)	66.4 (40.0-92.5)	78.9 (63.8-95.0)
GALAP	Post-em.	2	9.4 (8.0-10.8)	38.2 (37.5-38.8)	56.9 (46.3-67.5)	70.7 (66.3-75.0)
MATIN	Post-em.	3	6.6 (5.8-7.5)	55.5 (37.5-91.7)	64.2 (43.8-96.3)	73.9 (60.0-97.7)
ALOMY	Post-em.	1	31.3	77.5	81.3	90.0
POLAV	Post-em.	1	12.5	72.5	78.8	83.7
BROSE	Post-em.	1	24.8	87.5	86.3	91.3
GAETE	Post-em.	1	6.5	95.0	92.5	95.0
BRSNW	Post-em.	1	9.0	37.5	55.0	67.5
VICCRE	Post-em.	1	10.5	58.8	71.3	81.3
MYOAR	Post-em.	1	6.5	65.0	71.3	81.3
SINAR	Post-em.	1	9.3	62.5	71.3	78.8
Mean of all assessments		24	16.1 (5.3-70.2)	69.1 (35.0-95.0)	76.7 (43.8-97.5)	85.3 (60.0-97.7)

**Table 3.2-14:** Mediterranean zone: Minimum effective dose of Pendimethalin 45.5% CS applied pre- or post-emergence against frequently occurring broadleaved and grass weeds in cereals.

EPP0 Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment Mean (min-max)	Efficacy obtained with Pendimethalin 45.5% CS at:		
				Mean (min-max)		
				2.0 L/ha	2.5 L/ha	3.0 L/ha
<b>Pre-emergence application</b>						
AMARE	Pre-em.	3	12.3 (8.0-16.0)	74.2 (67.5-83.8)	82.5 (73.8-90.0)	98.4 (97.5-98.8)
BEAVX	Pre-em.	1	5.0	83.8	87.5	92.5
CHEAL	Pre-em.	1	20.0	67.5	72.5	97.5
CHEPO	Pre-em.	1	9.0	85.0	91.3	97.5
CYPRO	Pre-em.	1	2.0	37.5	47.5	50.0
DATST	Pre-em.	1	2.0	47.5	50.0	50.0
DIPER	Pre-em.	2	12.0 (8.0-16.0)	72.5 (65.0-80.0)	81.3 (72.5-90.0)	96.3 (95.0-97.5)
MALSI	Pre-em.	1	2.0	47.5	47.5	47.5
SOLNI	Pre-em.	1	17.0	66.3	76.3	98.8
Mean of all assessments		12	9.0	64.6	70.7	80.9
<b>Post-emergence application</b>						
AMARE	Post-em.	6	10.0 (7.0-13.0)	80.0 (76.3-85.0)	85.0 (81.3-90.0)	90.9 (85.0-97.5)
BEAVX	Post-em.	1	5.0	76.3	80.0	82.5
CHEAL	Post-em.	2	15.5 (12.0-19.0)	79.4 (75.0-83.8)	88.8 (86.3-91.3)	96.3 (96.3-96.3)
CHEPO	Post-em.	2	8.0 (5.0-11.0)	84.4 (78.8-90.0)	85.7 (78.8-92.5)	91.9 (86.3-97.5)
CYPRO	Post-em.	2	4.5 (4.0-5.0)	46.3 (42.5-50.0)	45.0 (42.5-47.5)	47.5 (45.0-50.0)
DATST	Post-em.	2	7.0 (5.0-9.0)	40.0 (30.0-50.0)	40.0 (30.0-50.0)	40.0 (30.0-50.0)
DIPER	Post-em.	4	11.3 (9.0-14.0)	81.3 (75.0-93.8)	87.9 (83.8-93.8)	94.1 (91.3-98.8)
MALSI	Post-em.	2	4.5 (4.0-5.0)	45.0 (40.0-50.0)	45.0 (40.0-50.0)	45.0 (40.0-50.0)
MAQVU	Post-em.	1	8.0	78.8	80.0	85.0
SOLNI	Post-em.	2	12.5 (10.0-15.0)	85.7 (77.5-93.8)	91.3 (91.3-91.3)	95.7 (95.0-96.3)
Mean of all assessments		24	8.6	69.7	72.9	76.9

At the timing of the assessments, the recommended dose of 2.5-3.5 L/ha of Pendimethalin 45.5% CS provided a superior control, to the doses of 2.0 L/ha of Pendimethalin 45.5% CS in the trials conducted in the Maritime, the North-east and the Mediterranean EPP0 zone.

Based on results achieved on monocotyledonous and dicotyledonous weeds which were present in 45 cereals trials included in the minimum effective dose section, it can be concluded that the recommended doses are optimal to consistently control frequently occurring grass and broadleaved weeds. Pendimethalin 45.5% CS should be applied pre- or post-emergence under optimal weather- and soil conditions at recommended dose rate.

### Summary and evaluation of Minimum Effective Dose trial results for 2.5-3.5 L/ha Pendimethalin 45.5% CS target rate against broadleaved and grass weeds in Apple

In order to prove and to support the requested dose rate of 2.5-3.5 L/ha Pendimethalin 45.5% CS [1.137-1.59 kg pendimethalin per hectare] applied pre- and post-emergence for the control of broadleaved and grass weeds, the assessment results of 20 efficacy trials with broadleaved and grass weeds, performed in the Maritime, North-east, South-east and Mediterranean EPPO zone in 2019 season, are reported. Pendimethalin 45.5% CS was included in these trials at 2.5-3.0-3.5 L/ha to demonstrate the recommended dose rate as well as at a lower than recommended dose rate (2.0 L/ha [0.91 kg pendimethalin per hectare]). The rates reflect the proposed label rate as well as 66% of the full recommended rate of Pendimethalin 45.5% CS in apple, in accordance with the EPPO standard PP 1/225(2) 'Minimum effective dose' and the Central zone efficacy requirements.

The control of frequently occurring monocotyledonous and dicotyledonous weeds in apple was assessed at different timings throughout the trial period. In the Mediterranean, Maritime, North-east and South-east zone, the data obtained from the assessment carried out after regrowth of the weeds was considered as the most accurate representation of whole plot product performance and this data is therefore presented in the summary tables. Table 3.2-15, Table 3.2-16, Table 3.2-17 and Table 3.2-18 therefore contains a summary of the assessment data obtained by visually estimating control obtained by the applied products at 11-103 days after pre- or post-emergence application in the Maritime, Mediterranean, North-east and South-east EPPO zone.

**Table 3.2-15: Maritime zone: Minimum effective dose of Pendimethalin 45.5% CS applied post-emergence against frequently occurring broadleaved and grass weeds in apple.**

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment Mean (min-max)	Efficacy obtained with Pendimethalin 45.5% CS at:		
				2.0 L/ha	2.5 L/ha	3.5 L/ha
<b>Post-emergence application</b>						
AMARD	Post-em.	3	4.3 (2.5-5.5)	51.3 (46.3-55.0)	83.3 (80.0-87.5)	95.0 (92.5-96.3)
ATXPA	Post-em.	3	12.9 (12.3-14.0)	62.1 (57.5-67.5)	84.6 (82.5-86.3)	89.2 (88.8-90.0)
CAPBP	Post-em.	4	3.4 (2.5-4.0)	48.8 (41.3-55.0)	73.5 (71.3-77.5)	90.4 (86.3-92.5)
CIRAR	Post-em.	6	8.4 (1.0-16.8)	25.9 (21.3-32.5)	55.5 (51.3-60.0)	60.2 (55.0-65.0)
ECHCG	Post-em.	6	8.4 (2.8-14.8)	54.4 (47.5-61.3)	72.9 (67.5-77.5)	88.6 (86.3-92.5)
ERICA	Post-em.	1	1.0	57.5	70.0	92.5
LAMPU	Post-em.	2	7.7 (7.3-8.0)	40.1 (38.8-41.3)	67.5 (67.5-67.5)	77.5 (77.5-77.5)
POAAN	Post-em.	3	3.5 (2.5-4.5)	76.3 (73.8-77.5)	82.5 (80.0-85.0)	94.6 (92.5-97.5)
SETPU	Post-em.	2	2.7 (2.5-2.8)	68.8 (67.5-70.0)	82.5 (82.5-82.5)	88.2 (86.3-90.0)
STEME	Post-em.	2	6.2 (5.8-6.5)	58.8 (58.8-58.8)	72.5 (72.5-72.5)	86.3 (85.0-87.5)
Mean of all assessments		32	5.9	54.4	74.5	86.3

**Table 3.2-16: North-east zone: Minimum effective dose of Pendimethalin 45.5% CS applied post-emergence against frequently occurring broadleaved and grass weeds in apple.**

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment Mean (min-max)	Efficacy obtained with Pendimethalin 45.5% CS at:		
				2.0 L/ha	2.5 L/ha	3.5 L/ha
<b>Post-emergence application</b>						
ARREL	Post-em.	1	8.0	22.5	27.5	37.5
CHEAL	Post-em.	1	12.0	37.5	37.5	68.8
ECHCG	Post-em.	3	16.5 (7.0-25.0)	87.5 (78.8-95.0)	93.4 (88.8-98.8)	98.8 (98.8-100)
GERPU	Post-em.	1	3.0	50.0	57.5	81.3
LAMPU	Post-em.	5	7.0 (3.0-10.0)	66.5 (25.0-87.5)	78.1 (35.0-98.3)	90.7 (73.8-99.5)
MATIN	Post-em.	1	6.0	88.0	96.5	91.3
POAAN	Post-em.	4	9.0 (2.0-13.8)	88.8 (80.0-100)	97.1 (95.0-100)	99.6 (98.5-100)
POLPI	Post-em.	1	15.0	91.3	97.5	100
SENVU	Post-em.	1	3.0	27.5	30.0	32.5
STEME	Post-em.	6	12.0 (5.0-23.0)	78.8 (35.0-100)	85.9 (45.0-100)	94.1 (72.5-100)
TAROF	Post-em.	3	6.3 (5.0-8.0)	35.8 (27.5-45.0)	44.6 (41.3-50.0)	50.8 (47.5-52.5)
VERPE	Post-em.	2	6.5 (6.0-7.0)	80.1 (78.8-81.3)	93.2 (88.8-97.5)	96.7 (94.5-98.8)
Mean of all assessments		29	8.7	62.9	69.9	78.5

**Table 3.2-17: South-east zone: Minimum effective dose of Pendimethalin 45.5% CS applied post-emergence against frequently occurring broadleaved and grass weeds in apple.**

EPP Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment Mean (min-max)	Efficacy obtained with Pendimethalin 45.5% CS at:		
				Mean (min-max)		
				2.0 L/ha	2.5 L/ha	3.5 L/ha
<b>Post-emergence application</b>						
ANGAR	Post-em.	1	5.5	100	100	100
APESV	Post-em.	1	15.6	82.5	95.0	100
CABBP	Post-em.	2	7.9 (7.0-8.7)	88.2 (76.3-100)	100 (100-100)	98.8 (97.5-100)
DAUCA	Post-em.	1	16.1	82.5	81.3	90.0
DIGSA	Post-em.	1	7.8	92.5	92.5	97.5
ECHCG	Post-em.	1	13.2	81.3	87.5	98.8
ERIAN	Post-em.	1	12.0	100	100	100
GALAP	Post-em.	1	3.1	100	100	100
POAAN	Post-em.	1	5.5	87.5	90.0	100
RANRE	Post-em.	1	4.0	87.5	95.0	100
SETSS	Post-em.	2	11.5 (11.5-11.5)	91.9 (88.8-95.0)	91.9 (87.5-96.3)	98.8 (98.8-98.8)
SONOL	Post-em.	1	4.6	97.1	94.0	100
VERSS	Post-em.	1	9.9	87.5	97.5	100
Mean of all assessments		15	9.0	90.7	94.2	98.8

**Table 3.2-18: Mediterranean zone: Minimum effective dose of Pendimethalin 45.5% CS applied post-emergence against frequently occurring broadleaved and grass weeds in apple.**

EPP Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment Mean (min-max)	Efficacy obtained with Pendimethalin 45.5% CS at:		
				Mean (min-max)		
				2.0 L/ha	2.5 L/ha	3.0 L/ha
<b>Post-emergence application</b>						
AMARE	Post-em.	1	9.0	88.8	88.8	92.5
BEAVX	Post-em.	1	8.0	81.3	87.5	92.5
CHEAL	Post-em.	1	7.0	76.3	82.5	86.3
CIRAR	Post-em.	1	5.0	73.8	76.3	77.5
CONAR	Post-em.	1	9.0	85.0	92.5	92.5
CRUBO	Post-em.	1	7.0	76.3	76.3	86.3
DIPER	Post-em.	1	5.0	67.5	75.0	77.5
SENVU	Post-em.	1	6.0	80.0	83.8	86.3
SOLNI	Post-em.	2	6.0 (6.0-6.0)	77.5 (75.0-80.0)	81.3 (81.3-81.3)	85.0 (85.0-85.0)
SONOL	Post-em.	1	1.0	76.3	72.5	81.3
Mean of all assessments		11	6.3	78.3	81.7	85.8

At the timing of the assessments, the recommended dose of 2.5-3.5 L/ha of Pendimethalin 45.5% CS provided a superior control, to the doses of 2.0 L/ha of Pendimethalin 45.5% CS in the trials conducted in the Maritime, North-east, South-east and Mediterranean EPP zone.

Based on results achieved on monocotyledonous and dicotyledonous weeds which were present in 18 apple trials included in the minimum effective dose section, it can be concluded that the recommended doses are optimal to consistently control frequently occurring grass and broadleaved weeds. Pendimethalin 45.5% CS should be applied post-emergence under optimal weather- and soil conditions at recommended dose rate.

#### Summary of all uses claimed on the label

Pendimethalin 45.5% CS applied pre- and post-emergence at 2.5-3.5 L/ha to control annual grasses and broadleaved weeds achieved excellent control of all target weeds. Reducing the application rate of Pendimethalin 45.5% CS from the proposed dose rate, resulted in lower levels of efficacy. To ensure that a satisfactory level of control is achieved with the dose rate recommended, it is recommended that Pendimethalin 45.5% CS is applied under optimal conditions, i.e. pre- or post-emergence of the weeds as well as optimal weather- and soil conditions.

As weeds often occur as a complex of several weeds with different susceptibility towards pendimethalin, one application of Pendimethalin 45.5% CS at the recommended rate should be used to efficiently control all weeds claimed on the label.

The same weeds are controlled by pendimethalin in the different crops. When treating the weeds at similar growth stages, the same level of control would be expected, in all GAP claimed crops and this has been seen in the trials. Therefore, for any label claims not adequately supported for one crop type, Sharda Cropchem España requests that the Zonal Evaluators reads across to the data on the other crop types and application timings.

As will be demonstrated in the following section, this document clearly demonstrates that the efficacy and crop safety of Pendimethalin 45.5% CS is equivalent to that of the standard pendimethalin reference products (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 to which it was compared. The applicant therefore wishes to cite the original registrant's data on pendimethalin now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	<p>The applicant has proposed doses of PENSHUI (product code: SHA 2600 E) that reflect those of currently-authorized pendimethalin products across the EU.</p> <p>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).</p> <p>During field tests Applicant used different doses of herbicide PENSHUI (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).</p> <p>SHA 2600 E was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with PENSHUI applied at:</p> <ul style="list-style-type: none"><li>• 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;</li><li>• 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;</li><li>• 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.</li></ul> <p>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 – PENSHUI 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 – PENSHUI. However, in our opinion, the higher of the doses should be used under conditions of high weed infestation or worse weather conditions. Most weed species were characterized by a higher sensitivity to the dose of 3.5 L/ha than 2,5 L/ha. But dose 2,5 L/ha was also characterized by good efficiency.</p>
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### 3.2.3 Efficacy tests (KCP 6.2)

Thirty-six efficacy trials and twelve selectivity trials conducted in the Maritime EPPO zone, 33 efficacy trials and 12 selectivity trials conducted in the North-east EPPO and 6 efficacy trials in South-east EPPO zone to support the proposed label claims of Pendimethalin 45.5% CS in the Central zone. The trials were conducted in Czech Republic (48), Poland (35), Estonia (3), Lithuania (7), Slovakia (2) and Romania (4) in cereals, apple and maize.

To give additional support to the proposed label claims in the Central zone, data obtained in 22 efficacy trials and 7 selectivity trials conducted in the Mediterranean EPPO zone have been included. The trials were conducted in Spain (22) and Italy (7) in cereals, maize and apple.

Data from the Mediterranean trials has been added as the same mono- and dicotyledonous weed species that are affecting cereals, apple and maize in the South zone may affect the cultivation of cereals, apple and maize in the Central zone as well. Furthermore, the climatic conditions during the application window in the South zone may be similar to the climatic conditions prevalent in the Central zone during the proposed application window. Therefore, to demonstrate the wide range of control obtained with pendimethalin, the Mediterranean data has been added to the current evaluation.

The 97 efficacy trials were conducted in cereals, apple and maize which was treated with Pendimethalin 45.5% CS before emergence of the crop.

The efficacy trials were conducted to prove the following label claim:

- Single pre- and post-emergence application to winter cereals, maize, bulb vegetables, for control of annual grass- and broadleaved weeds, target rate: 2.5-3.5 L/ha
- Single pre- and post-emergence application to leek for control of annual grass- and broadleaved weeds, target rate: 3.5 L/ha
- Single pre-emergence application to strawberry, potato for control of annual grass- and broadleaved weeds, target rate: 2.5-3.5 L/ha
- Single pre-emergence application to pome fruits, stone fruits, asparagus, currants, parsnip, grapevine, ornamentals, artichoke, fennel and cucurbits for control of annual grass- and broadleaved weeds, target rate: 3.5 L/ha
- Single pre-transplanting application to brassicas for control of annual grass- and broadleaved weeds, target rate 3.5 L/ha
- Single pre-emergence application to bean, pea, carrot, parsley for control of annual grass- and broadleaved weeds, target rate: 2.5-3.5 L/ha
- Single pre-emergence application to sunflower, soybean, lupine for control of annual grass- and broadleaved weeds, target rate 2.6 L/ha
- Single pre- and post-emergence application to winter oilseed rape for control of annual grass- and broadleaved weeds, target rate: 1.0-2.0 L/ha
- Single pre-transplanting application to lettuce and endive for control of annual grass- and broadleaved weeds, target rate: 3.5 L/ha
- Single post-emergence application to clover and alfalfa for control of annual grass- and broadleaved weeds, target rate: 2.2 L/ha
- Single pre-emergence application to raspberry for control of annual grass- and broadleaved weeds, target rate: 3.0 L/ha

In the 97 trials, the level of control obtained by Pendimethalin 45.5% CS was assessed on annual grasses and broadleaved weeds present in the trials. Data on each individual weed species is only included from trials in which a minimum of 3 plants per m<sup>2</sup> or 1% ground cover were seen at the spring assessments. In the autumn assessments, it was sufficient that the weed was present in the trial to be included in the summary.

**Table 3.2-19: Details on trial methodology**

<b>Guidelines</b>	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/50(3), PP 1/90(3), PP 1/93(3)
<b>Experimental design</b>	Plot design	RCBD (97)
	Plot size	10-60 m <sup>2</sup>
	Number of replications	4 (97)
<b>Crop</b>	Trials per crop	Cereals (45), Apple (20), Maize (32)
	Varieties per crop	<u>Cereals</u> : Nogal (2), Filon (2), Artur nick (2), Botticelli (2), Yuriko, Cometa, Vinagrosa, Volley, Tobak (2), Bohemia (3), Sonnengold, Meridian (2), Leopard, Viriato, Annie (3), Toras, Santiago, Frisky, Triumph, Kosmos, Zenek, Vireni, Julius (2), Arkadia (2), Kallas, Owacja, Euforia, Skagen, Hondia, Concordia, Baracoda, Ada (2). <u>Apple</u> : Golden (6), Starking, Royal gala, Spartan, Idared (2), Champion, Jonagold (3), Prince, Szampion (2), Jonathan, Modi. <u>Maize</u> : SY Antex, P1921 (2), SY Zoan, LG3216 (2), Xxilo, Es Amulet, LG31233, Cebesto C (2), Perrero, LG 30215 (2), LG 30222 (2), Rosomak, Ulan (3), PoesiCS, P0927, Agiraxx (2), Enigma (2), MAS 26 K (2), P9874, Susann, DKC 54670.
	Sowing period	<u>Cereals</u> : 18/02/19-20/10/19 <u>Maize</u> : 13/03/19-01/06/19 <u>Apple</u> : 03/03/95-20/09/15
<b>Application</b>	Crop stage (BBCH)* at application	BBCH 00-09 (range: BBCH 00-09) pre-emergence BBCH 11-77 (range: BBCH 11-77) post-emergence
	Timing Pest stage at appl. (1)	<u>Cereals</u> : 08/03/19-04/10/19 <u>Maize</u> : 27/03/19-11/06/19 <u>Apple</u> : 21/03/19-15/07/19
	Number of appl. Intervals between appl.	1 (97) n.a.
	Spray volumes	200-400 L/ha
<b>Assessment</b>	Assessment types	- Visual estimation of biomass reduction per plot compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) or calculated, based on weed counts (COUPLA) or weed ground cover (GROUND) in a defined area, as compared to the untreated check. - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms. - Crop vigour
	Assessment dates	Efficacy: 10 to 233 DAT
<b>Other relevant information</b>	Soil type	Light to heavy soils
	Natural / artificial inoculation...	Natural
	Field / Greenhouse...	Field

**Use 001: Control of grasses and broadleaved weeds in Maize with a single application of 2.5-3.5 L/ha Pendimethalin 45.5% CS**

The efficacy trials were conducted to prove the following label claims:

### Description of Use 001

Crop, stage	Maize, pre-emergence BBCH 00-08 Maize, post-emergence BBCH 11-13
Use rate Use frequency Application timing	2.5-3.5 L/ha Pendimethalin 45.5% CS 1x Pre- or post-emergence to weeds and crop
Target weeds	Annual grass weeds, e.g. <i>Poa annua</i> Annual broadleaved weeds, e.g. <i>Cirsium</i> , <i>Veronica</i> , a.o.

The effectiveness of applying Pendimethalin 45.5% CS pre- and post-emergence against mono- and dicotyledonous weeds was evaluated in 32 efficacy trials conducted in maize. These trials were carried out in 2019 season in the Maritime (12, i.e. Czech Republic (12)), North-east (12, i.e. Poland (10) and Lithuania (2)), South-east EPPO zone (4, i.e. Romania (2) and Slovakia (2)) and Mediterranean (4, i.e. Italy (4)). The objective was to confirm the performance of Pendimethalin 45.5% CS at 2.5-3.5 L/ha (i.e. 1137-1590 g pendimethalin per hectare) and compare this to reference products registered for similar uses. In the trials, one application was applied.

Pendimethalin 45.5% CS was tested alongside an EU approved pendimethalin formulation.

#### Maritime zone

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following pre- and post-emergence application in maize as well as compare it to the reference product included in the trials, results are presented in

**Table 3.2-20.**

When applied at 2.5-3.5 L/ha pre- and post-emergence in the Maritime zone, Pendimethalin 45.5% CS achieved moderate to excellent control of annual grasses and broadleaved weeds commonly found in the crops. In all species evaluated, the effect achieved with Pendimethalin 45.5% CS was similar to the effect obtained with the pendimethalin reference product applied in the trials at comparable dose rate. Statistical evaluation supports this statement.

**Table 3.2-20:** Maritime zone, Maize – Annual grasses and broadleaved weed control results by Pendimethalin 45.5% CS applied at 2.5-3.5 L/ha pre- and post-emergence and compared against control obtained with Pendimethalin reference product applied at 3.0-3.5-4.0 L/ha at registered rate in the efficacy tests 2019 (13-42 DAA; mean and variation in % control as compared to untreated check).

Eppo Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment min-max	Efficacy obtained with					No. of trials where Pendimethalin 45.5% CS at 1590 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall
				Pendimethalin 45.5% CS	Pendimethalin 45.5% CS	Stomp Aqua	Pendimethalin 33% EC	Pendimethalin 40% SC				
				Mean (min-max)					>	=	<	
				2.5 L/ha	3.5 L/ha	3.0 L/ha	4.0 L/ha	3.5 L/ha				
<b>Pre-emergence application</b>												
APESV	Pre-em.	1	10.0	100	100	98.0	95.0	98.0		1		=
CAPBP	Pre-em.	4	23.4 (6.0-63.8)	93.0 (81.3-100)	95.3 (88.8-100)	99.3 (94.0-100)	98.8 (95.0-100)	100 (99.8-100)		4		=
CHEAL	Pre-em.	2	8.6 (1.3-15.8)	100 (100-100)	100 (100-100)	100 (100-100)	97.5 (95.0-100)	100 (100-100)		2		=
ECHCG	Pre-em.	5	25.7 (5.5-100)	100 (100-100)	100 (100-100)	99.0 (95.0-100)	97.5 (95.0-100)	100 (100-100)		5		=
FUMOF	Pre-em.	2	15.7 (13.5-17.8)	96.9 (93.8-100)	98.3 (96.5-100)	92.9 (90.0-95.8)	100 (100-100)	100 (100-100)		2		=
GAETE	Pre-em.	1	8.0	97.8	98.8	97.8	93.8 (90.0-97.5)	97.9 (97.8-98.0)		1		=
GALAP	Pre-em.	1	5.3	99.8	100	93.8	99.5	99.5		1		=
MATIN	Pre-em.	5	18.1 (7.8-31.0)	85.4 (80.0-97.0)	90.8 (85.0-98.8)	94.5 (90.0-100)	72.5	80.0		5		=
POLCO	Pre-em.	3	8.2 (4.5-12.3)	90.5 (80.0-96.5)	94.6 (85.0-100)	97.7 (96.8-98.8)	93.5 (85.0-97.0)	97.3 (91.3-100)		3		=
POLLA	Pre-em.	1	5.3	100	100	100	91.1 (75.0-99.5)	97.9 (94.8-100)		1		=
STEME	Pre-em.	2	13.9 (8.3-19.5)	100 (100-100)	100 (100-100)	98.9 (98.0-99.8)	100	100		2		=
THLAR	Pre-em.	3	15.2 (5.5-26.0)	100 (100-100)	100 (100-100)	100 (100-100)	100 (100-100)	100 (100-100)		3		=
VERPE	Pre-em.	1	2.5	100	100	100	100	100		1		=
VIOAR	Pre-em.	3	11.2 (1.5-17.0)	92.9 (78.8-100)	95.0 (85.0-100)	100 (100-100)	100 (100-100)	100 (100-100)		3		=
Mean, all assessments		34	12.2	96.9	98.1	98.1	95.7	97.9		12		=
<b>Post-emergence application</b>												
APESV	Post-em.	1	9.0	95.0	98.0	100	70.0	80.0		1		=
CAPBP	Post-em.	5	21.4 (8.5-59.8)	55.0 (32.5-90.0)	68.5 (37.5-95.0)	68.3 (40.0-100)	69.3 (41.3-97.3)	69.5 (41.3-97.3)		5		=
CHEAL	Post-em.	3	14.7 (8.0-21.0)	87.1 (81.3-95.0)	90.0 (82.5-95.0)	94.9 (91.3-100)	89.5 (70.0-99.8)	91.7 (80.0-97.5)		3		=
ECHCG	Post-em.	5	18.3 (10.8-26.0)	61.0 (25.0-96.0)	77.8 (60.0-99.0)	87.6 (77.5-99.0)	88.4 (81.3-99.3)	78.0 (62.5-98.8)		5		=
FUMOF	Post-em.	2	15.3 (10.0-20.5)	60.0 (25.0-96.0)	75.0 (55.0-95.0)	77.5 (55.0-100)	84.4 (70.0-98.8)	87.8 (80.0-95.5)		2		=
GAETE	Post-em.	1	6.3	100	100	100	100	100		1		=
GALAP	Post-em.	2	5.2 (5.0-5.3)	72.5 (70.0-75.0)	90.7 (87.5-93.8)	96.8 (93.5-100)	95.1 (93.8-96.3)	100 (100-100)		2		=
POLCO	Post-em.	3	11.7 (7.8-19.0)	17.5 (0.0-27.5)	41.7 (37.5-50.0)	68.3 (55.0-75.0)	53.9 (35.0-91.8)	58.8 (42.5-83.8)		3		=
POLLA	Post-em.	2	7.3 (5.0-9.5)	47.5 (0.0-95.0)	87.5 (77.5-97.5)	82.5 (75.0-90.0)	97.8 (95.5-100)	97.5 (95.0-100)		2		=
STEME	Post-em.	2	12.8 (9.0-16.5)	96.0 (95.0-97.0)	98.8 (98.0-99.5)	100 (100-100)	85.0 (70.0-100)	90.0 (80.0-100)		2		=
THLAR	Post-em.	4	16.9 (8.3-37.5)	67.5 (50.0-88.8)	76.0 (57.5-96.3)	72.2 (55.0-87.5)	75.2 (51.3-98.5)	76.0 (58.8-93.8)		4		=
VERPE	Post-em.	2	15.2 (14.3-16.0)	96.7 (92.5-100)	98.2 (96.3-100)	96.3 (92.5-100)	99.9 (99.8-100)	98.0 (96.0-100)		2		=
Mean, all assessments		18	12.8	71.3	83.5	87.0	84.0	85.6		24		=

### **North-east zone**

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following pre- and post-emergence application in maize as well as compare it to the reference product included in the trials, results are presented in

**Table 3.2-21.**

When applied at 2.5-3.5 L/ha pre- and post-emergence in the North-east zone, Pendimethalin 45.5% CS achieved moderate to excellent control of annual grasses and broadleaved weeds commonly found in the crops. In all species evaluated, the effect achieved with Pendimethalin 45.5% CS was similar to the effect obtained with the pendimethalin reference product applied in the trials at comparable dose rate. Statistical evaluation supports this statement.

**Table 3.2-21:** North-east zone, maize – Annual grasses and broadleaved weed control results by Pendimethalin 45.5% CS applied at 2.5-3.5 L/ha pre- and post-emergence and compared against control obtained with Pendimethalin reference product applied at 3.0-3.5-4.0 L/ha at registered rate in the efficacy tests 2019 (13-61 DAA; mean and variation in % control as compared to untreated check).

Eppo Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment min-max	Efficacy obtained with					No. of trials where Pendimethalin 45.5% CS at 1365 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall
				Pendimethalin 45.5% CS	Pendimethalin 45.5% CS	Stomp Aqua	Pendimethalin 33% EC	Pendimethalin 40% SC				
				Mean (min-max)					>	=	<	
				2.5 L/ha	3.0 L/ha	3.0 L/ha	4.0 L/ha	3.5 L/ha				
<b>Pre-emergence application</b>												
AMARE	Pre-em.	2	11.8 (8.3-15.3)	68.8 (52.5-85.0)	77.5 (62.5-92.5)	79.4 (66.3-92.5)	78.2 (62.5-93.8)	76.9 (60.0-93.8)		2		=
CAPBP	Pre-em.	1	9.3	92.5	95.0	96.3	95.0	92.5		1		=
CHEAL	Pre-em.	5	10.7 (6.5-16.3)	81.3 (72.5-92.5)	90.3 (82.5-100)	91.4 (83.8-100)	90.7 (82.5-100)	89.5 (81.3-100)		5		=
ECHCG	Pre-em.	5	16.3 (7.3-34.5)	78.6 (63.8-86.5)	88.3 (73.8-100)	89.2 (70.0-100)	88.9 (75.0-100)	87.9 (72.5-100)		5		=
EPHHE	Pre-em.	1	5.0	50.0	87.5	92.5	87.3	88.8		1		=
GASPA	Pre-em.	1	9.0	7.8	21.0	20.8	20.0	20.5		1		=
LAMPUR	Pre-em.	1	6.0	78.5	88.7	87.8	87.8	86.8		1		=
POLCO	Pre-em.	3	7.5 (5.0-10.0)	68.0 (60.3-73.8)	79.8 (67.0-90.0)	80.5 (67.8-92.5)	76.9 (67.0-82.5)	80.2 (67.5-90.5)		3		=
SENVU	Pre-em.	1	5.8	30.0	38.7	38.8	38.8	36.3		1		=
SINAR	Pre-em.	1	14.8	50.5	57.5	60.0	63.8	60.0		1		=
STEME	Pre-em.	3	7.6 (6.5-8.8)	86.0 (80.0-91.3)	92.4 (87.5-96.3)	94.8 (91.3-98.8)	91.6 (83.8-96.3)	82.5 (87.5-97.5)		3		=
THLAR	Pre-em.	1	8.0	64.3	81.8	82.3	81.3	82.0		1		=
VERPE	Pre-em.	1	7.5	85.5	97.0	97.3	96.3	96.0		1		=
VIOAR	Pre-em.	3	6.4 (5.8-7.5)	72.5 (70.0-75.0)	82.5 (81.3-85.0)	85.4 (81.3-90.0)	79.2 (77.5-81.3)	81.3 (81.3-81.3)		3		=
Mean, all assessments		29	9.0	65.3	77.0	78.3	76.8	75.8		12		=
<b>Post-emergence application</b>												
AMARE	Post-em.	1	11.5	65.0	75.0	72.5	73.8	73.8		1		=
BRSNW	Post-em.	1	10.0	71.0	73.8	63.8	66.3	71.3		1		=
CAPBP	Post-em.	1	6.3	71.0	82.6	78.8	78.8	77.8		1		=
CHEAL	Post-em.	6	13.8 (7.0-31.3)	74.4 (65.0-88.8)	83.6 (72.5-91.8)	83.9 (75.1-87.5)	83.8 (73.8-93.8)	83.7 (73.8-92.0)		6		=
ECHCG	Post-em.	5	12.0 (8.5-16.0)	71.3 (55.0-78.8)	82.2 (68.8-87.5)	81.5 (72.5-86.3)	82.4 (72.5-87.5)	81.3 (71.3-85.3)		5		=
LAMPUR	Post-em.	2	6.5 (6.5-6.5)	64.8 (64.8-64.8)	74.8 (74.8-74.8)	74.3 (74.3-74.3)	75.5 (75.5-75.5)	75.5 (75.5-75.5)		2		=
POLCO	Post-em.	4	9.8 (9.5-10.3)	58.4 (50.5-72.5)	65.7 (56.3-77.5)	64.2 (55.3-80.0)	65.6 (57.3-78.8)	66.0 (57.0-78.8)		4		=
SETVI	Post-em.	1	9.0	71.3	80.0	83.8	81.3	81.3		1		=
SINAR	Post-em.	1	33.8	70.0	72.5	83.8	72.3	72.3		1		=
SOLNI	Post-em.	1	5.5	70.0	81.3	82.5	77.5	80.0		1		=
STEME	Post-em.	1	8.3	77.5	87.5	87.5	87.5	88.8		1		=
VERPE	Post-em.	2	7.5 (7.5-7.5)	74.3 (74.3-74.3)	82.8 (82.8-82.8)	83.0 (83.0-83.0)	82.5 (82.5-82.5)	82.8 (82.8-82.8)		2		=
VIOAR	Post-em.	1	7.0	71.3	73.8	81.3	66.3	73.8		1		=
Mean, all assessments		27	10.8	70.0	78.1	78.1	77.3	77.6		24		=

### **South-east zone**

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following pre- and post-emergence application in maize as well as compare it to the reference product included in the trials, results are presented in [Table 3.2-22](#).

When applied at 2.5-3.5 L/ha pre- and post-emergence in the South-east zone, Pendimethalin 45.5% CS achieved moderate to excellent control of annual grasses and broadleaved weeds commonly found in the crops. In all species evaluated, the effect achieved with Pendimethalin 45.5% CS was similar to the effect obtained with the pendimethalin reference product applied in the trials at comparable dose rate. Statistical evaluation supports this statement.

**Table 3.2-22:** South-east zone, maize – Annual grasses and broadleaved weed control results by Pendimethalin 45.5% CS applied at 2.5-3.5 L/ha pre- and post-emergence and compared against control obtained with Pendimethalin reference product applied at 3.0-3.5-4.0 L/ha at registered rate in the efficacy tests 2019 (10-29 DAA; mean and variation in % control as compared to untreated check).

Eppo Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment min-max	Efficacy obtained with					No. of trials where Pendimethalin 45.5% CS at 1365 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall
				Pendimethalin 45.5% CS	Pendimethalin 45.5% CS	Stomp Aqua	Pendimethalin 33% EC	Pendimethalin 40% SC				
				Mean (min-max)					>	=	<	
				2.5 L/ha	3.5 L/ha	3.0 L/ha	4.0 L/ha	3.5 L/ha				
<b>Pre-emergence application</b>												
AMARE	Pre-em.	1	5.5	100	100	100	100	100		1		=
AMBEL	Pre-em.	1	4.0	100	100	100	100	100		1		=
CHEAL	Pre-em.	2	35.5 (7.0-64.0)	98.7 (97.4-100)	99.1 (98.1-100)	99.4 (98.7-100)	99.2 (98.4-100)	99.7 (99.4-100)		2		=
CHEHY	Pre-em.	1	47.0	100	100	100	100	100		1		=
DIGSA	Pre-em.	1	10.5	92.3	95.0	95.0	96.5	94.0		1		=
ECHCG	Pre-em.	2	20.4 (15.8-25.0)	88.6 (80.8-96.3)	92.7 (85.3-100)	84.4 (85.0-98.8)	90.7 (85.0-96.3)	92.0 (86.5-97.5)		2		=
MERAN	Pre-em.	1	38.0	98.0	100	100	99.5	100		1		=
SETSS	Pre-em.	1	10.0	98.0	100	100	98.8	100		1		=
STEME	Pre-em.	1	18.0	100	100	100	100	100		1		=
XANSI	Pre-em.	1	4.5	97.3	98.9	100	97.5	97.5		1		=
Mean, all assessments		12	19.3	97.3	98.6	97.9	98.2	98.3		12		=
<b>Post-emergence application</b>												
AMARE	Post-em.	1	9.8	94.6	96.0	100	98.5	97.1		1		=
AMBEL	Post-em.	1	9.8	94.1	97.8	95.0	97.5	94.8		1		=
CAPBP	Post-em.	1	10.0	20.0	30.0	20.0	98.0	96.5		1		=
CHEAL	Post-em.	2	21.7 (13.3-30.0)	80.8 (72.8-88.8)	90.9 (88.0-93.8)	89.8 (88.0-91.5)	95.2 (93.8-96.5)	92.7 (90.8-94.5)		2		=
DIGSA	Post-em.	1	9.3	88.9	94.7	94.9	97.2	96.9		1		=
ECHCG	Post-em.	2	11.8 (7.0-16.5)	88.6 (32.8-88.6)	78.2 (62.0-94.4)	78.1 (59.3-96.8)	93.6 (90.0-97.2)	91.9 (87.3-96.4)		2		=
GALAP	Post-em.	1	6.0	39.5	80.8	81.5	95.0	96.5		1		=
MATIN	Post-em.	1	8.0	17.3	27.3	22.8	78.8	72.0		1		=
POLCO	Post-em.	1	5.0	46.0	57.5	48.5	80.0	72.8		1		=
SETSS	Post-em.	1	10.0	89.0	96.4	96.5	96.8	93.8		1		=
THLAR	Post-em.	1	20.0	86.0	95.3	94.5	100	100		1		=
VIOAR	Post-em.	1	3.0	95.8	96.5	96.5	98.0	98.0		1		=
XANSI	Post-em.	1	5.5	93.8	93.8	92.5	94.0	94.5		1		=
Mean, all assessments		15	10.0	71.9	79.6	77.7	94.0	92.1		24		=

### **Mediterranean zone**

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following pre- and post-emergence application in maize as well as compare it to the reference product included in the trials, results are presented in

**Table 3.2-23.**

When applied at 2.5-3.0 L/ha pre- and post-emergence in the Mediterranean zone, Pendimethalin 45.5% CS achieved moderate to excellent control of annual grasses and broadleaved weeds commonly found in the crops. In all species evaluated, the effect achieved with Pendimethalin 45.5% CS was similar to the effect obtained with the pendimethalin reference product applied in the trials at comparable dose rate. Statistical evaluation supports this statement.

**Table 3.2-23:** Mediterranean zone, maize – Annual grasses and broadleaved weed control results by Pendimethalin 45.5% CS applied at 2.5-3.0 L/ha pre- and post-emergence and compared against control obtained with Pendimethalin reference product applied at 3.0-3.5-4.0 L/ha at registered rate in the efficacy tests 2019 (14-49 DAA; mean and variation in % control as compared to untreated check).

Eppo Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment min-max	Efficacy obtained with					No. of trials where Pendimethalin 45.5% CS at 1365 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall
				Pendimethalin 45.5% CS	Pendimethalin 45.5% CS	Stomp Aqua	Pendimethalin 33% EC	Pendimethalin 40% SC				
				Mean (min-max)					>	=	<	
				2.5 L/ha	3.0 L/ha	3.0 L/ha	4.0 L/ha	3.5 L/ha				
<b>Pre-emergence application</b>												
AMARE	Pre-em.	2	10.6 (7.3-13.8)	94.5 (93.0-96.0)	98.3 (97.5-99.0)	97.0 (94.0-100)	96.2 (95.3-97.0)	97.9 (96.8-99.0)		2		=
CHEAL	Pre-em.	1	5.5	99.5	100	100	99.5	99.5		1		=
ECHCG	Pre-em.	1	2.8	91.3	90.0	86.3	80.0	91.3		1		=
SOLNI	Pre-em.	1	6.3	99.0	99.5	100	99.0	100		1		=
DIGSA	Pre-em.	1	37.5	91.8	96.3	99.0	92.5	96.5		1		=
Mean, all assessments		6	12.5	95.2	96.8	96.5	93.4	97.0		6		=
<b>Post-emergence application</b>												
ABUTH	Post-em.	1	10.0	80.0	85.0	82.5	80.0	87.5		1		=
AMARE	Post-em.	1	12.5	92.5	97.3	92.5	96.8	98.3		1		=
CHEAL	Post-em.	1	5.0	98.0	98.0	98.0	98.0	98.0		1		=
ECHCG	Post-em.	2	4.3 (4.3-4.3)	93.5 (93.3-94.0)	94.5 (94.0-95.0)	94.7 (93.3-96.0)	96.0 (96.0-96.0)	93.9 (91.8-96.0)		2		=
SETVI	Post-em.	1	12.5	92.5	94.0	96.5	95.9	95.3		1		=
SOLNI	Post-em.	1	25.0	96.5	97.8	98.3	99.5	99.0		1		=
Mean, all assessments		7	11.6	92.2	94.4	93.8	94.4	95.3		7		=

In **Table 3.2-24**, the weed species are classified according to their average sensitivity at the assessment to 3.5 L/ha of Pendimethalin 45.5% CS in the Maritime, North-east, South-east and Mediterranean EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

**Table 3.2-24: Weed control spectrum of Pendimethalin 45.5% CS at 2.5-3.5 L/ha in the Maritime, North-east, South-east and Mediterranean zone**

Scientific name	English common name	EPPO code
<b>Highly Susceptible (≥95 %)</b>		
<i>Amaranthus retroflexus</i>	Redroot pigweed	AMARE
<i>Ambrosia artemisiifolia</i>	American wormwood	AMBEL
<i>Apera spica-venti</i>	Loose silky-bent	APESV
<i>Capsella bursa-pastoris</i>	Shepherd's purse	CAPBP
<i>Chenopodium album</i>	Common lambsquarters	CHEAL
<i>Lipandra polysperma</i>	Many-seeded poosefoot	CHEHY
<i>Digitaria sanguinalis</i>	Large crabgrass	DIGSA
<i>Echinochloa crus-galli</i>	Common barnyard grass	ECHCG
<i>Galeopsis tetrahit</i>	Common hemp nettle	GAETE
<i>Mercurialis annua</i>	Annual mercury	MERAN
<i>Fallopian convolvulus</i>	Bearbind	POLCO
<i>Persicaria lapathifolia</i>	Green smartweed	POLLA
<i>Setaria verticillata</i>	Bristly foxtail	SETVI
<i>Stellaria media</i>	Common chickweed	STEME
<i>Solanum nigrum</i>	Black nightshade	SOLNI
<i>Thlaspi arvense</i>	Field pennycress	THLAR
<i>Veronica persica</i>	Common field speedwell	VERPE
<i>Xanthium orientale</i>	Californian burr	XANSI
<b>Susceptible (85 – 94.9 %)</b>		
<i>Euphorbia helioscopia</i>	Sun spurge	EPHHE
<i>Fumaria officinalis</i>	Common fumitory	FUMOF
<i>Gallium aparine</i>	Cleavers	GALAP
<i>Lamium purpureum</i>	Red deadnettle	LAMPU
<i>Tripleurospermum inodorum</i>	Scentless mayweed	MATIN
<b>Moderately Susceptible (70 – 84.9 %)</b>		
<i>Abutilon theophrasti</i>	Butter print	ABUTH
<i>Viola arvensis</i>	Field pansy	VIOAR
<b>Moderately tolerant (50 – 69.9 %)</b>		
<i>Sinapis arvensis</i>	Kelk	SINAR
<b>Tolerant (0 – 49.9 %)</b>		
<i>Galinsoga parviflora</i>	Gallant soldier	GASPA
<i>Senecio vulgaris</i>	Common groundsel	SENVU

**Use 002: Control of grasses and broadleaved weeds in Cereals with a single application of 2.5-3.5 L/ha Pendimethalin 45.5% CS**

The efficacy trials were conducted to prove the following label claims:

**Description of Use 002**

Crop, stage	Cereals, pre-emergence BBCH 08 Cereals, post-emergence BBCH 11-12
Use rate	2.5-3.5 L/ha Pendimethalin 45.5% CS
Use frequency	1x
Application timing	Pre- or post-emergence to weeds and crop
Target weeds	Annual grass weeds, e.g. <i>Poa annua</i>

	Annual broadleaved weeds, e.g. <i>Cirsium</i> , <i>Veronica</i> , a.o.
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The effectiveness of applying Pendimethalin 45.5% CS pre- or post-emergence against mono- and dicotyledonous weeds was evaluated in 45 efficacy trials conducted in cereals. These trials were carried out in 2019 and 2020 season in the Maritime (18, i.e. Poland (18)), the North-east (15; Estonia(1), Lithuania (2) and Poland (12)) and the Mediterranean EPPO zone (12, i.e. Spain (12)). The objective was to confirm the performance of Pendimethalin 45.5% CS at 2.5-3.5 L/ha (i.e. 1.137-1.590 g pendimethalin per hectare) and compare this to reference products registered for similar uses. In the trials, one application was applied.

Pendimethalin 45.5% CS was tested alongside an EU approved Pendimethalin formulation.

### **Maritime zone**

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following pre- and post-emergence application in cereals as well as compare it to the reference product included in the trials, results are presented in Table 3.2-25.

When applied at 2.5-3.5 L/ha pre- and post-emergence in the Maritime zone, Pendimethalin 45.5% CS achieved moderate to excellent control of annual grasses and broadleaved weeds commonly found in the crops. In all species evaluated, the effect achieved with Pendimethalin 45.5% CS was similar to the effect obtained with the pendimethalin reference product applied in the trials at comparable dose rate. Statistical evaluation supports this statement.

**Table 3.2-25: Maritime zone, cereals – Annual grasses and broadleaved weed control results by Pendimethalin 45.5% CS applied at 2.5-3.5 L/ha pre- and post-emergence and compared against control obtained with Pendimethalin 45.5% CS reference product applied at 3.0-3.5-4.0 L/ha at registered rate in the efficacy tests 2019 and 2020 (14-233 DAA; mean and variation in % control as compared to untreated check).**

EPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment min-max	Efficacy obtained with					No. of trials where Pendimethalin 45.5% CS at 1590 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall
				Pendimethalin 45.5% CS	Pendimethalin 45.5% CS	Stomp Aqua	Pendimethalin 33% EC	Pendimethalin 40% SC				
				Mean (min-max)					>	=	<	
				2.5 L/ha	3.5 L/ha	3.5 L/ha	4.0 L/ha	3.5 L/ha				
<b>Pre-emergence application</b>												
THLAR	Pre-em.	3	12.4 (7.3-22.5)	49.2 (27.5-60.0)	59.2 (50.0-65.0)	60.0 (50.0-65.0)	99.0 (97.0-100)	98.8 (96.5-100)		3		
VERPE	Pre-em.	3	24.8 (6.0-54.5)	87.6 (85.0-90.0)	93.3 (90.0-100)	93.3 (90.0-100)	93.0 (93.0-96.0)	95.0 (90.0-100)		3		
VIOAR	Pre-em.	3	18.0 (7.0-39.5)	87.9 (86.3-90.0)	91.5 (91.3-92.0)	90.9 (90.0-92.8)	100 (100-100)	100 (100-100)		3		
STEME	Pre-em.	7	10.6 (5.5-17.0)	94.4 (65.0-100)	96.3 (70.0-100)	92.6 (70.0-100)	88.2 (50.0-100)	92.4 (60.0-100)		7		
CAPBP	Pre-em.	7	22.0 (7.0-61.3)	68.8 (30.0-100)	73.9 (50.0-100)	73.2 (50.0-100)	85.6 (50.0-100)	88.7 (60.0-100)		7		
POAAN	Pre-em.	2	6.65 (6.5-6.8)	90.0 (90.0-90.0)	90.0 (90.0-90.0)	90.0 (90.0-90.0)	88.8 (87.5-90.0)	90.0 (90.0-90.0)		2		
ALOMY	Pre-em.	2	8.9 (7.3-10.5)	90.0 (90.0-90.0)	90.0 (90.0-90.0)	90.0 (90.0-90.0)	90.0 (90.0-90.0)	90.0 (90.0-90.0)		2		
APESV	Pre-em.	6	10.3 (7.0-17.0)	86.8 (65.0-100)	89.2 (70.0-100)	88.6 (70.0-100)	83.0 (50.0-100)	83.5 (60.0-100)		6		
GALAP	Pre-em.	5	17.8 (9.0-22.5)	83.8 (65.0-100)	88.0 (70.0-100)	88.0 (70.0-100)	80.6 (50.0-100)	83.0 (60.0-100)		5		
ECHCG	Pre-em.	4	13.6 (8.8-17.0)	83.3 (65.0-100)	85.0 (70.0-100)	85.0 (70.0-100)	75.8 (50.0-98.0)	79.5 (60.0-100)		4		
MATIN	Pre-em.	2	15.4 (12.0-18.8)	83.0 (68.0-98.0)	84.0 (70.0-98.0)	82.5 (70.0-95.0)	75.0 (55.0-95.0)	80.0 (60.0-100)		2		
PARPH	Pre-em.	1	55.8	80.0	90.0	90.0	96.3	96.5		1		
FUMOF	Pre-em.	1	40.8	50.0	70.0	70.0	100	100		1		
Mean, all assessments		46	16.5 (5.5-61.3)	84.7 (27.5-100)	88.9 (50.0-100)	84.5 (50.0-100)	86.9 (50.0-100)	89.1 (60.0-100)		46		
<b>Post-emergence application</b>												
VERPE	Post-em.	8	13.8 (7.8-29.0)	91.4 (80.0-100)	96.9 (90.0-100)	97.2 (90.0-100)	96.5 (93.0-100)	100 (100-100)	1	7		
VIOAR	Post-em.	5	8.96 (7.0-12.5)	72.0 (30.0-100)	80.0 (50.0-100)	84.0 (60.0-100)	80.0 (80.0-80.0)	60.0 (60.0-60.0)		3	2	
STEME	Post-em.	9	9.4 (7.0-12.5)	94.4 (80.0-100)	97.0 (90.0-100)	96.8 (90.0-100)	99.3 (97.3-100)	99.2 (96.8-100)		9		
CAPBP	Post-em.	6	22.2 (7.8-66.3)	67.9 (30.0-100)	77.1 (50.0-100)	80.8 (60.0-100)	97.5 (92.5-100)	96.6 (90.0-100)		6		
POAAN	Post-em.	3	16.4 (7.8-33.5)	96.7 (90.0-100)	100 (100-100)	100 (100-100)	100 (100-100)	100 (100-100)		3		
ALOMY	Post-em.	3	13.1 (7.8-23.5)	96.7 (90.0-100)	100 (100-100)	100 (100-100)	100 (100-100)	100 (100-100)		3		
MATIN	Post-em.	5	10.4 (7.0-15.0)	78.6 (45.0-95.0)	86.0 (50.0-100)	85.0 (50.0-100)	66.5 (40.0-93.0)	70.0 (40.0-100)	1	3	1	
THLAR	Post-em.	4	11.9 (7.5-20.3)	93.6 (90.0-99.5)	96.0 (90.0-100)	95.6 (90.0-100)	90.0 (90.0-90.0)	90.0 (90.0-90.0)		4		
LAMPU	Post-em.	3	8.2 (7.8-9.0)	96.7 (90.0-100)	100 (100-100)	100 (100-100)	100 (100-100)	100 (100-100)		3		
APESV	Post-em.	6	18.9 (7.0-27.8)	89.1 (78.8-98.0)	96.7 (90.0-100)	92.8 (88.8-100)	93.4 (88.8-98.0)	87.5 (80.0-95.0)	2	4		
PARPH	Post-em.	2	39.8 (10.5-69.0)	90.0 (90.0-90.0)	91.9 (91.3-92.5)	91.9 (91.3-92.5)	97.0	97.0		2		
FUMOF	Post-em.	2	40.9 (38.3-43.5)	98.9 (98.5-99.3)	99.6 (99.3-99.8)	99.5 (99.0-100)	100	99.8		2		
ARBTH	Post-em.	2	27.9 (25.0-30.8)	88.8 (87.5-90.0)	93.2 (91.3-95.0)	93.2 (92.5-93.8)	92.5	95.0		2		
GALAP	Post-em.	3	9.6 (8.0-12.0)	81.0 (80.0-83.0)	95.0 (90.0-100)	96.0 (90.0-100)	95.0	93.0		3		
ECHCG	Post-em.	2	9.5 (8.0-11.0)	80.0 (80.0-80.0)	95.0 (95.0-95.0)	94.0 (900-98.0)	-	-	1	1		
Mean, all assessments		63	15.3 (7.0-22.5)	86.9 (30.0-100)	92.8 (50.0-100)	93.0 (80.8-100)	93.2 (40.0-100)	91.5 (40.0-100)	5	55	3	

### **North-east zone**

**To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following pre- and post-emergence application in cereals as well as compare it to the reference product included in the trials, results are presented in**

**Table 3.2-26.**

When applied at 2.5-3.5 L/ha pre- and post-emergence in the North-east zone, Pendimethalin 45.5% CS achieved moderate to excellent control of annual grasses and broadleaved weeds commonly found in the crops. In all species evaluated, the effect achieved with Pendimethalin 45.5% CS was similar to the effect obtained with the pendimethalin reference product applied in the trials at comparable dose rate. Statistical evaluation supports this statement.

**Table 3.2-26: North-east zone, cereals – Annual grasses and broadleaved weed control results by Pendimethalin 45.5% CS applied at 2.5-3.5 L/ha pre- and post-emergence and compared against control obtained with Pendimethalin 45.5% CS reference product applied at 3.0-3.5-4.0 L/ha at registered rate in the efficacy tests 2019 and 2020 (14-233 DAA; mean and variation in % control as compared to untreated check).**

Eppo Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment min-max	Efficacy obtained with					No. of trials where Pendimethalin 45.5% CS at 1590 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall
				Pendimethalin 45.5% CS	Pendimethalin 45.5% CS	Stomp Aqua	Pendimethalin 33% EC	Pendimethalin 40% SC				
				Mean (min-max)					>	=	<	
				2.5 L/ha	3.5 L/ha	3.5 L/ha	4.0 L/ha	3.5 L/ha				
<b>Pre-emergence application</b>												
APESV	Pre-em.	3	26.4 (5.0-62.3)	78.3 (75.0-82.5)	85.9 (82.5-88.8)	74.2 (55.0-83.8)	68.8 (38.8-83.8)	72.9 (53.8-83.8)	1	2		
VIOAR	Pre-em.	4	13.6 (9.75-19.8)	77.7 (52.5-91.8)	81.7 (65.0-92.8)	80.6 (66.3-93.8)	78.5 (55.0-91.5)	76.9 (52.5-91.5)	1	3		
STEME	Pre-em.	3	11.1 (9.0-14.3)	78.3 (72.5-83.8)	85.4 (82.5-88.8)	73.7 (46.3-87.5)	69.2 (40.0-87.5)	64.6 (36.3-82.5)	1	2		
CAPBP	Pre-em.	3	10.2 (5.5-19.3)	81.9 (66.3-95.5)	88.7 (78.8-98.5)	85.9 (77.5-96.5)	83.4 (67.5-96.5)	79.9 (58.8-94.5)		3		
ANTAR	Pre-em.	2	10.2 (9.8-10.5)	63.8 (41.3-86.3)	73.8 (61.3-86.3)	74.4 (60.0-88.8)	62.6 (38.8-86.3)	67.6 (46.3-88.8)		2		
POLAV	Pre-em.	1	8.50	78.8	81.3	78.8	78.8	76.3		1		
VERPE	Pre-em.	1	10.0	83.8	77.5	82.5	81.3	80.0		1		
PAPRH	Pre-em.	1	5.8	68.8	81.3	78.8	72.5	71.3		1		
BRSNW	Pre-em.	1	19.5	51.3	67.5	66.3	51.3	50.0		1		
MATIN	Pre-em.	1	8.3	92.8	95.5	95.5	93.0	92.5		1		
GALAP	Pre-em.	1	6.0	91.5	94.5	94.0	92.3	91.8		1		
SINAR	Pre-em.	1	5.8	72.5	82.5	82.5	48.8	52.5		1		
Mean, all assessments		22	14.3 (5.0-62.3)	74.5 (41.3-92.8)	81.7 (61.3-94.5)	79.6 (46.3-96.5)	73.7 (38.8-96.5)	73.1 (36.3-94.5)	3	19		
<b>Post-emergence application</b>												
APESV	Post-em.	4	40.1 (12.3-70.3)	76.6 (71.3-81.3)	83.2 (80.0-85.0)	79.7 (77.5-85.0)	84.4 (78.8-90)	87.6 (81.3-93.8)	1	3		
AGRRE	Post-em.	2	29.1 (19.8-38.3)	80.1 (78.8-81.3)	91.3 (90.0-92.5)	89.4 (87.5-91.3)	83.8	91.3		2		
VIOAR	Post-em.	7	13.4 (7.5-30.5)	66.4 (40.0-92.5)	78.9 (63.8-95.0)	79.1 (60.0-96.0)	79.2 (50.0-100)	77.7 (55.0-93.5)	1	5	1	
STEME	Post-em.	7	9.6 (5.3-25.5)	85.5 (72.5-100)	92.5 (82.5-100)	92.8 (82.5-100)	88.3	87.6		7		
PARPH	Post-em.	2	26.6 (25.3-27.8)	93.2 (92.5-93.8)	98.8 (98.8-98.8)	92.6 (91.3-93.8)				2		
ANTAR	Post-em.	2	28.5 (21.0-36.0)	87.6 (86.3-88.8)	93.8 (93.8-93.8)	88.8 (85.0-92.5)				2		
LAMPU	Post-em.	2	7.7 (6.0-9.3)	83.0 (72.5-93.5)	90.8 (85.0-96.5)	90.8 (85.0-96.5)	95.5	93.0		2		
VERPE	Post-em.	4	11.4 (6.3-23.5)	84.6 (72.5-97.5)	90.5 (83.8-100)	88.6 (80.0-100)	81.9 (71.3-92.0)	81.4 (67.5-93.0)		4		
CAPBP	Post-em.	3	13.0 (6.5-23.0)	66.4 (40.0-92.5)	78.9 (63.8-95.0)	78.3 (73.8-85.0)	76.3	81.3		3		
GALAP	Post-em.	2	9.4 (8.0-10.8)	56.9 (46.3-67.5)	70.7 (66.3-75.0)	68.2 (63.8-73.8)	64.4 (56.3-72.5)	68.8 (47.5-90.0)		2		
MATIN	Post-em.	3	6.6 (5.8-7.5)	64.2 (43.8-96.3)	73.9 (60.0-97.7)	73.0 (62.5-97.7)	68.4 (42.5-94.3)	69.8 (42.5-97.0)		3		
ALOMY	Post-em.	1	31.3	81.3	90.0	87.5				1		
POLAV	Post-em.	1	12.5	78.8	83.7	76.3	77.5	80.0		1		
BROSE	Post-em.	1	24.8	86.3	91.3	92.5	88.8	90.0		1		
GAETE	Post-em.	1	6.5	92.5	95.0	92.5	90.0	95.0		1		
BRSNW	Post-em.	1	9.0	55.0	67.5	68.8	48.8	48.8		1		
VICCRE	Post-em.	1	10.5	71.3	81.3	85.0	71.3	71.3		1		

Eppo Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment min-max	Efficacy obtained with					No. of trials where Pendimethalin 45.5% CS at 1590 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall
				Pendimethalin 45.5% CS	Pendimethalin 45.5% CS	Stomp Aqua	Pendimethalin 33% EC	Pendimethalin 40% SC				
				Mean (min-max)					>	=	<	
				2.5 L/ha	3.5 L/ha	3.5 L/ha	4.0 L/ha	3.5 L/ha				
MYOAR	Post-em.	1	6.5	71.3	81.3	82.5	-	-		1		1
SINAR	Post-em.	1	9.3	71.3	78.8	78.8	-	-		1		1
Mean, all assessments		24	16.1 (5.3-70.2)	76.7 (43.8-97.5)	85.3 (60.0-97.7)	83.7 (60.0-100)	79.2 (42.5-100)	80.1 (47.5-100)	2	21	1	1

### **Mediterranean zone**

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following pre- and post-emergence application in cereals as well as compare it to the reference product included in the trials, results are presented in

**Table 3.2-27.**

When applied at 2.5-3.0 L/ha pre- and post-emergence in the Mediterranean zone, Pendimethalin 45.5% CS achieved moderate to excellent control of annual grasses and broadleaved weeds commonly found in the crops. In all species evaluated, the effect achieved with Pendimethalin 45.5% CS was similar to the effect obtained with the pendimethalin reference product applied in the trials at comparable dose rate. Statistical evaluation supports this statement.

**Table 3.2-27:** Mediterranean zone, cereals – Annual grasses and broadleaved weed control results by Pendimethalin 45.5% CS applied at 2.5-3.0 L/ha pre- and post-emergence and compared against control obtained with Pendimethalin 45.5% CS reference product applied at 3.0-3.5-4.0 L/ha at registered rate in the efficacy tests 2019 (12-108 DAA; mean and variation in % control as compared to untreated check).

Eppo Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment min-max	Efficacy obtained with					No. of trials where Pendimethalin 45.5% CS at 1365 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall
				Pendimethalin 45.5% CS	Pendimethalin 45.5% CS	Stomp Aqua	Pendimethalin 33% EC	Pendimethalin 40% SC				
				Mean (min-max)					>	=	<	
				2.5 L/ha	3.0 L/ha	3.0 L/ha	4.0 L/ha	3.5 L/ha				
<b>Pre-emergence application</b>												
AMARE	Pre-em.	3	12.3 (8.0-16.0)	82.5 (73.8-90.0)	98.4 (97.5-98.8)	97.1 (96.3-97.5)	95.0 (93.8-96.3)	95.9 (93.8-98.8)		3		=
BEAVX	Pre-em.	1	5.0	87.5	92.5	95.0	93.8	93.8		1		=
CHEAL	Pre-em.	1	20.0	72.5	97.5	96.3	96.3	96.3		1		=
CHEPO	Pre-em.	1	9.0	91.3	97.5	96.3	93.8	97.5		1		=
CYPRO	Pre-em.	1	2.0	47.5	50.0	47.5	50.0	47.5		1		=
DATST	Pre-em.	1	2.0	50.0	50.0	50.0	50.0	50.0		1		=
DIPER	Pre-em.	2	12.0 (8.0-16.0)	81.3 (72.5-90.0)	96.3 (95.0-97.5)	95.1 (93.8-96.3)	94.4 (92.5-96.3)	97.5 (97.5-97.5)		2		=
MALSI	Pre-em.	1	2.0	47.5	47.5	47.5	47.5	47.5		1		=
SOLNI	Pre-em.	1	17.0	76.3	98.8	97.5	93.8	96.3		1		=
Mean, all assessments		12	9.0	70.7	80.9	80.3	79.4	80.3		12		=
<b>Post-emergence application</b>												
AMARE	Post-em.	6	10.0 (7.0-13.0)	85.0 (81.3-90.0)	90.9 (85.0-97.5)	91.9 (86.3-98.8)	88.4 (81.3-95.0)	90.4 (85.0-95.0)		6		=
BEAVX	Post-em.	1	5.0	80.0	82.5	82.5	82.5	80.0		1		=
CHEAL	Post-em.	2	15.5 (12.0-19.0)	88.8 (86.3-91.3)	96.3 (96.3-96.3)	96.9 (96.3-97.5)	95.7 (95.0-96.3)	91.3 (86.3-96.3)		2		=
CHEPO	Post-em.	2	8.0 (5.0-11.0)	85.7 (78.8-92.5)	91.9 (86.3-97.5)	90.0 (82.5-97.5)	91.9 (87.5-96.3)	86.9 (82.5-91.3)		2		=
CYPRO	Post-em.	2	4.5 (4.0-5.0)	45.0 (42.5-47.5)	47.5 (45.0-50.0)	46.3 (42.5-50.0)	45.0 (42.5-47.5)	47.5 (45.0-50.0)		2		=
DATST	Post-em.	2	7.0 (5.0-9.0)	40.0 (30.0-50.0)	40.0 (30.0-50.0)	40.0 (30.0-50.0)	40.0 (30.0-50.0)	40.0 (30.0-50.0)		2		=
DIPER	Post-em.	4	11.3 (9.0-14.0)	87.9 (83.8-93.8)	94.1 (91.3-98.8)	92.5 (91.3-95.0)	91.6 (88.8-95.0)	92.2 (85.0-97.5)		4		=
MALSI	Post-em.	2	4.5 (4.0-5.0)	45.0 (40.0-50.0)	45.0 (40.0-50.0)	45.0 (40.0-50.0)	45.0 (40.0-50.0)	45.0 (40.0-50.0)		2		=
MAQVU	Post-em.	1	8.0	80.0	85.0	80.0	85.0	78.8		1		=
SOLNI	Post-em.	2	12.5 (10.0-15.0)	91.3 (91.3-91.3)	95.7 (95.0-96.3)	97.5 (97.5-97.5)	92.5 (92.5-92.5)	96.3 (95.0-97.5)		2		=
Mean, all assessments		24	8.6	72.9	76.9	76.3	75.8	74.8		24		=

In Table 3.2-28, the weed species are classified according to their average sensitivity at the assessment to 2.5-3.5 L/ha of Pendimethalin 45.5% CS in the Maritime, the North-east and the Mediterranean EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

**Table 3.2-28: Weed control spectrum of Pendimethalin 45.5% CS at 2.5-3.5 L/ha in the Maritime, the North-east and the Mediterranean zone**

Scientific name	English common name	EPPO code
<b>Highly Susceptible (≥95 %)</b>		
<i>Amaranthus retroflexus</i>	Redroot pigweed	AMARE
<i>Stellaria media</i>	Common chickweed	STEME
<i>Veronica persica</i>	Common field speedwell	VERPE
<i>Lamium purpureum</i>	Red deadnettle	LAMPU
<i>Papaver rhoeas</i>	field poppy	PAPRH
<i>Beta vulgaris</i>	Beet	BEAVX
<i>Chenopodium album</i>	Common lambsquarters	CHEAL
<i>Lipandra polysperma</i>	Many-seeded poosefoot	CHEPO
<i>Diplotaxis erucoides</i>	Garden wall-rocket	DIPER
<i>Solanum nigrum</i>	Black nightshade	SOLNI
<b>Susceptible (85 – 94.9 %)</b>		
<i>Arabidopsis thaliana</i>	common wallcress	ARBTH
<i>Viola arvensis</i>	Field pansy	VIOAR
<i>Poa annua</i>	goosegrass	POAAN
<i>Alopecurus myosuroides</i>	black twitch	ALOMY
<i>Apera spica-venti</i>	Loose silky-bent	APESV
<i>Gallium aparine</i>	Cleavers	GALAP
<i>Echinochloa crus-galli</i>	Common barnyard grass	ECHCG
<i>Bromus secalinus</i>	chess brome grass	BROSE
<i>Setaria verticillata</i>	Bristly foxtail	SETVI
<i>Elymus repens</i>	couchgrass	AGRRE
<i>Galeopsis tetrahit</i>	common hemp nettle	GAETE
<b>Moderately Susceptible (70 – 84.9 %)</b>		
<i>Marrubium vulgare</i>	Common horehound	MAQVU
<i>Capsella bursa-pastoris</i>	Shepherd's purse	CAPBP
<i>Tripleurospermum inodorum</i>	Scentless mayweed	MATIN
<i>Fumaria officinalis</i>	common fumitory	FUMOF
<i>Sinapis arvensis</i>	kedlock	SINAR
<i>Myosotis arvensis</i>	common scorpiongrass	MYOAR
<b>Moderately tolerant (50 – 69.9 %)</b>		
<i>Datura stramonium</i>	False castor oil-plant	DATST
<i>Thlaspi arvense</i>	Field pennycress	THLAR
<i>Anthemis arvensis</i>	corn chamomile	ANTAR
<b>Tolerant (0 – 49.9 %)</b>		
<i>Cyperus rotundus</i>	Purple nutsedge	CYPRO
<i>Malva sylvestris</i>	High mallow	MALSI

**Use 003: Control of grasses and broadleaved weeds in apple with a single application of 2.5-3.5 L/ha Pendimethalin 45.5% CS**

The efficacy trials were conducted to prove the following label claims:

**Description of Use 003**

Crop, stage	Apple, post-emergence BBCH 10-77
Use rate	2.5-3.5 L/ha Pendimethalin 45.5% CS
Use frequency	1x
Application timing	Post-emergence to weeds and crop

Target weeds	Annual grass weeds, e.g. <i>Poa annua</i> Annual broadleaved weeds, e.g. <i>Cirsium</i> , <i>Veronica</i> , a.o.
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The effectiveness of applying Pendimethalin 45.5% CS post-emergence against mono- and dicotyledonous weeds was evaluated in 20 efficacy trials conducted in apple. These trials were carried out in 2019 season in the Maritime (6, i.e. Czech Republic (6)), North-east (6, i.e. Poland (6)), South-east EPPO zone (2, i.e. Romania (2)) and Mediterranean (6, i.e. Spain (4) and Italy (2)). The objective was to confirm the performance of Pendimethalin 45.5% CS at 2.5-3.0 L/ha (i.e. 1137-1590g pendimethalin per hectare) and compare this to reference products registered for similar uses. In the trials, one application was applied.

Pendimethalin 45.5% CS was tested alongside an EU approved Pendimethalin formulation.

### **Maritime zone**

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following post-emergence application in onion as well as compare it to the reference product included in the trials, results are presented in

**Table 3.2-29.**

When applied at 2.5-3.5 L/ha post-emergence in the Maritime zone, Pendimethalin 45.5% CS achieved moderate to excellent control of annual grasses and broadleaved weeds commonly found in the crops. In all species evaluated, the effect achieved with Pendimethalin 45.5% CS was similar to the effect obtained with the pendimethalin reference product applied in the trials at comparable dose rate. Statistical evaluation supports this statement.

**Table 3.2-29:** Maritime zone, apple – Annual grasses and broadleaved weed control results by Pendimethalin 45.5% CS applied at 2.5-3.5 L/ha post-emergence and compared against control obtained with Pendimethalin reference product applied at 3.0-3.5-4.0 L/ha at registered rate in the efficacy tests 2019 (11-14 DAA; mean and variation in % control as compared to untreated check).

Eppo Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment min-max	Efficacy obtained with					No. of trials where Pendimethalin 45.5% CS at 1365 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall
				Pendimethalin 45.5% CS	Pendimethalin 45.5% CS	Stomp 400 SC	Pendimethalin 33% EC	Pendimethalin 40% SC				
				Mean (min-max)					>	=	<	
				2.5 L/ha	3.5 L/ha	3.0 L/ha	4.0 L/ha	3.5 L/ha				
<b>Post-emergence application</b>												
AMARD	Post-em.	3	4.3 (2.5-5.5)	83.3 (80.0-87.5)	95.0 (92.5-96.3)	95.0 (93.8-96.3)	87.9 (85.0-92.5)	91.3 (90.0-92.5)		3		=
ATXPA	Post-em.	3	12.9 (12.3-14.0)	84.6 (82.5-86.3)	89.2 (88.8-90.0)	94.2 (93.8-95.0)	89.2 (83.8-93.8)	87.1 (85.0-88.8)		3		=
CAPBP	Post-em.	4	3.4 (2.5-4.0)	73.5 (71.3-77.5)	90.4 (86.3-92.5)	89.1 (87.5-91.3)	86.0 (80.0-88.8)	80.7 (78.8-83.8)		4		=
CIRAR	Post-em.	6	8.4 (1.0-16.8)	55.5 (51.3-60.0)	60.2 (55.0-65.0)	58.6 (51.3-65.0)	52.3 (42.5-57.5)	49.8 (36.3-57.5)		6		=
ECHCG	Post-em.	6	8.4 (2.8-14.8)	72.9 (67.5-77.5)	88.6 (86.3-92.5)	90.6 (86.3-95.0)	83.4 (75.0-86.3)	89.4 (83.8-92.5)		6		=
ERICA	Post-em.	1	1.0	70.0	92.5	90.0	90.0	87.5		1		=
LAMPU	Post-em.	2	7.7 (7.3-8.0)	67.5 (67.5-67.5)	77.5 (77.5-77.5)	85.7 (85.0-86.3)	75.7 (75.0-76.3)	71.9 (71.3-72.5)		2		=
POAAN	Post-em.	3	3.5 (2.5-4.5)	82.5 (80.0-85.0)	94.6 (92.5-97.5)	93.4 (91.3-95.0)	90.9 (88.8-92.5)	93.8 (92.5-95.0)		3		=
SETPU	Post-em.	2	2.7 (2.5-2.8)	82.5 (82.5-82.5)	88.2 (86.3-90.0)	94.4 (93.8-95.0)	87.5 (85.0-90.0)	93.2 (92.5-93.8)		2		=
STEME	Post-em.	2	6.2 (5.8-6.5)	72.5 (72.5-72.5)	86.3 (85.0-87.5)	93.8 (93.8-93.8)	82.5 (82.5-82.5)	77.5 (77.5-77.5)		2		=
Mean, all assessments		32	5.9	74.5	86.3	88.5	82.5	82.2		32		=

### **North-east zone**

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following post-emergence application in apple as well as compare it to the reference product included in the trials, results are presented in

**Table 3.2-30.**

When applied at 2.5-3.5 L/ha post-emergence in the North-east zone, Pendimethalin 45.5% CS achieved moderate to excellent control of annual grasses and broadleaved weeds commonly found in the crops. In all species evaluated, the effect achieved with Pendimethalin 45.5% CS was similar to the effect obtained with the pendimethalin reference product applied in the trials at comparable dose rate. Statistical evaluation supports this statement.

**Table 3.2-30:** North-east zone, apple – Annual grasses and broadleaved weed control results by Pendimethalin 45.5% CS applied at 2.5-3.5 L/ha post-emergence and compared against control obtained with Pendimethalin reference product applied at 3.0-3.5-4.0 L/ha at registered rate in the efficacy tests 2019 (21-40 DAA; mean and variation in % control as compared to untreated check).

Eppo Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment min-max	Efficacy obtained with					No. of trials where Pendimethalin 45.5% CS at 1365 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall
				Pendimethalin 45.5% CS	Pendimethalin 45.5% CS	Stomp Aqua	Pendimethalin 33% EC	Pendimethalin 40% SC				
				Mean (min-max)					>	=	<	
				2.5 L/ha	3.5 L/ha	3.0 L/ha	4.0 L/ha	3.5 L/ha				
<b>Post-emergence application</b>												
ARREL	Post-em.	1	8.0	22.5	37.5	25.0	42.5	32.5	1			>
CHEAL	Post-em.	1	12.0	37.5	68.8	35.0	78.8	50.0	1			>
ECHCG	Post-em.	3	16.5 (7.0-25.0)	93.4 (88.8-98.8)	98.8 (98.8-100)	88.3 (70.0-100)	97.8 (96.0-100)	90.3 (75.0-100)		3		=
GERPU	Post-em.	1	3.0	57.5	81.3	81.3	78.8	83.8		1		=
LAMPU	Post-em.	5	7.0 (3.0-10.0)	78.1 (35.0-98.3)	90.7 (73.8-99.5)	76.2 (45.0-95.8)	87.7 (67.5-97.5)	76.3 (47.5-96.5)	3	2		>, =
MATIN	Post-em.	1	6.0	96.5	91.3	75.0	96.3	75.0	1			>
POAAN	Post-em.	4	9.0 (2.0-13.8)	97.1 (95.0-100)	99.6 (98.5-100)	85.1 (70.0-100)	96.8 (92.5-100)	86.3 (73.8-100)	2	2		>, =
POLPI	Post-em.	1	15.0	97.5	100	100	100	100		1		=
SENVU	Post-em.	1	3.0	30.0	32.5	31.3	32.5	32.5		1		>, =
STEME	Post-em.	6	12.0 (5.0-23.0)	85.9 (45.0-100)	94.1 (72.5-100)	80.3 (45.0-100)	90.9 (65.0-100)	79.8 (35.0-100)	3	3		=
TAROF	Post-em.	3	6.3 (5.0-8.0)	44.6 (41.3-50.0)	50.8 (47.5-52.5)	50.8 (45.0-55.0)	46.7 (40.0-52.5)	46.7 (32.5-57.5)		3		=
VERPE	Post-em.	2	6.5 (6.0-7.0)	93.2 (88.8-97.5)	96.7 (94.5-98.8)	65.7 (60.0-71.3)	89.4 (88.8-90.0)	72.6 (68.8-76.3)	1	1		>, =
Mean, all assessments		29	8.7	69.5	78.5	66.2	78.2	68.8	12	17		>, =

### **South-east zone**

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following post-emergence application in apple as well as compare it to the reference product included in the trials, results are presented in

**Table 3.2-31.**

When applied at 2.5-3.5 L/ha post-emergence in the South-east zone, Pendimethalin 45.5% CS achieved moderate to excellent control of annual grasses and broadleaved weeds commonly found in the crops. In all species evaluated, the effect achieved with Pendimethalin 45.5% CS was similar to the effect obtained with the pendimethalin reference product applied in the trials at comparable dose rate. Statistical evaluation supports this statement.

**Table 3.2-31:** South-east zone, apple – Annual grasses and broadleaved weed control results by Pendimethalin 45.5% CS applied at 2.5-3.5 L/ha post-emergence and compared against control obtained with Pendimethalin reference product applied at 3.5-4.0 L/ha at registered rate in the efficacy tests 2019 (14-28 DAA; mean and variation in % control as compared to untreated check).

Eppo Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment min-max	Efficacy obtained with					No. of trials where Pendimethalin 45.5% CS at 1365 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall
				Pendimethalin 45.5% CS	Pendimethalin 45.5% CS	Sharpen 40EC	Pendimethalin 33% EC	Pendimethalin 40% SC				
				Mean (min-max)					>	=	<	
				2.5 L/ha	3.5 L/ha	4.0 L/ha	4.0 L/ha	3.5 L/ha				
<b>Post-emergence application</b>												
ANGAR	Post-em.	1	5.5	100	100	100	100	100		1		=
APESV	Post-em.	1	15.6	95.0	100	92.5	98.8	100		1		=
CAPBP	Post-em.	2	7.9 (7.0-8.7)	100 (100-100)	98.8 (97.5-100)	100 (100-100)	100 (100-100)	99.4 (98.7-100)		2		=
DAUCA	Post-em.	1	16.1	81.3	90.0	93.8	97.5	95.0		1		=
DIGSA	Post-em.	1	7.8	92.5	97.5	100	100	100		1		=
ECHCG	Post-em.	1	13.2	87.5	98.8	83.8	96.3	95.0		1		=
ERIAN	Post-em.	1	12.0	97.5	100	95.8	100	97.5		1		=
GALAP	Post-em.	1	3.1	100	100	100	100	100		1		=
POAAN	Post-em.	1	5.5	90.0	100	100	100	100		1		=
RANRE	Post-em.	1	4.0	95.0	100	100	100	100		1		=
SETSS	Post-em.	2	11.5 (11.5-11.5)	91.9 (87.5-96.3)	98.8 (98.8-98.8)	100 (100-100)	99.4 (98.8-100)	100 (100-100)		2		=
SONOL	Post-em.	1	4.6	94.0	100	97.1	98.7	100		1		=
VERSS	Post-em.	1	9.9	97.5	100	100	97.5	100		1		=
Mean, all assessments		15	9.0	94.0	98.8	97.2	99.1	99.0		15		=

### **Mediterranean zone**

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following post-emergence application in apple as well as compare it to the reference product included in the trials, results are presented in

**Table 3.2-32.**

When applied at 2.5-3.0 L/ha post-emergence in the Mediterranean zone, Pendimethalin 45.5% CS achieved moderate to excellent control of annual grasses and broadleaved weeds commonly found in the crops. In all species evaluated, the effect achieved with Pendimethalin 45.5% CS was similar to the effect obtained with the pendimethalin reference product applied in the trials at comparable dose rate. Statistical evaluation supports this statement.

**Table 3.2-32:** Mediterranean zone, apple – Annual grasses and broadleaved weed control results by Pendimethalin 45.5% CS applied at 2.5-3.0 L/ha post-emergence and compared against control obtained with Pendimethalin reference product applied at 3.0-3.5-4.0 L/ha at registered rate in the efficacy tests 2019 (14-103 DAA; mean and variation in % control as compared to untreated check).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessment min-max	Efficacy obtained with					No. of trials where Pendimethalin 45.5% CS at 1365 g pendimethalin /ha is >, < or =, compared to the Pendimethalin reference product. = : ± 5% control			Overall
				Pendimethalin 45.5% CS	Pendimethalin 45.5% CS	Stomp Aqua	Pendimethalin 33% EC	Pendimethalin 40% SC				
				Mean (min-max)					>	=	<	
				2.5 L/ha	3.0 L/ha	3.0 L/ha	4.0 L/ha	3.5 L/ha				
<b>Post-emergence application</b>												
AMARE	Post-em.	1	9.0	88.8	92.5	91.3	82.5	85.0		1		=
BEAVX	Post-em.	1	8.0	87.5	92.5	92.5	88.8	88.8		1		=
CHEAL	Post-em.	1	7.0	82.5	86.3	85.0	78.8	82.5		1		=
CIRAR	Post-em.	1	5.0	76.3	77.5	78.8	72.5	73.8		1		=
CONAR	Post-em.	1	9.0	92.5	92.5	100	86.3	85.0		1		=
CRUBO	Post-em.	1	7.0	76.3	86.3	71.3	66.3	82.5		1		=
DIGSA	Post-em.	1	17.5	91.8	96.8	96.5	96.0	97.3		1		=
DIPER	Post-em.	1	5.0	75.0	77.5	77.5	72.5	76.3		1		=
ECHCG	Post-em.	1	6.8	95.0	96.8	96.5	96.8	97.5		1		=
LOLMU	Post-em.	2	16.3 (10.0-22.5)	100 (100-100)	99.9 (99.8-100)	100 (100-100)	99.3 (98.5-100)	99.8 (99.5-100)		2		=
MATCH	Post-em.	1	8.8	100	100	100	100	100		1		=
POAAN	Post-em.	1	4.3	100	100	100	100	100		1		=
SENVU	Post-em.	1	6.0	83.8	86.3	86.3	80.0	85.0		1		=
SOLNI	Post-em.	2	6.0 (6.0-6.0)	81.3	85.0 (85.0-85.0)	83.2 (81.3-85.0)	78.8 (78.8-78.8)	84.4 (83.8-85.0)		2		=
SONOL	Post-em.	1	1.0	72.5	81.3	78.8	86.3	85.0		1		=
Mean, all assessments		17	6.3	86.9	85.8	84.5	85.7	88.2		17		=

In **Table 3.2-33**, the weed species are classified according to their average sensitivity at the assessment to 3.0 L/ha of Pendimethalin 45.5% CS in the Mediterranean, Maritime, North-east and South-east EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

**Table 3.2-33: Weed control spectrum of Pendimethalin 45.5% CS at 2.5-3.5 L/ha in the Maritime, North-east, South-east and Mediterranean zone**

Scientific name	English common name	EPPO code
<b>Highly Susceptible (≥95 %)</b>		
<i>Amaranthus retroflexus</i>	Redroot pigweed	AMARD
<i>Anagallis arvensis</i>	Common pimpernel	ANGAR
<i>Apera spica-venti</i>	Loose silky-bent	APESV
<i>Capsella bursa-pastoris</i>	Shepherd's purse	CAPBP
<i>Digitaria sanguinalis</i>	Large crabgrass	DIGSA
<i>Echinochloa crus-galli</i>	Common barnyard grass	ECHCG
<i>Erigeron annuus</i>	Annual fleabane	ERIAN
<i>Gallium aparine</i>	Cleavers	GALAP
<i>Poa annua</i>	Annual bluegrass	POAAN
<i>Persicaria maculosa</i>	Red shank	POLPI
<i>Ranunculus sardous</i>	Hairy buttercup	RANRE
<i>Setaria sphacelata</i>	Common bristlegrass	SETSS
<i>Sonchus oleraceus</i>	Annual sowthistle	SONOL
<i>Veronica persica</i>	Common field speedwell	VERPE
<b>Susceptible (85 – 94.9 %)</b>		
<i>Amaranthus retroflexus</i>	Redroot pigweed	AMARE
<i>Atriplex patula</i>	Common orache	ATXPA
<i>Beta vulgaris</i>	Beet	BEAVX
<i>Chenopodium album</i>	Common lambsquarters	CHEAL
<i>Convolvulus arvensis</i>	Field bindweed	CONAR
<i>Carduus bourgeanus</i>	Cardo borriquero	CRUBO
<i>Daucus carota</i>	Bee's nest	DAUCA
<i>Erigeron canadensis</i>	Canada horseweed	ERICA
<i>Lamium purpureum</i>	Red deadnettle	LAMPU
<i>Tripleurospermum inodorum</i>	Scentless mayweed	MATIN
<i>Senecio vulgaris</i>	Common groundsel	SENVU
<i>Setaria verticillata</i>	Bristly foxtail	SETPU
<i>Stellaria media</i>	Common chickweed	STEME
<i>Solanum nigrum</i>	Black nightshade	SOLNI
<b>Moderately Susceptible (70 – 84.9 %)</b>		
<i>Cirsium arvense</i>	Canada thistle	CIRAR
<i>Diplotaxis erucoides</i>	Garden wall-rocket	DIPER
<i>Geranium pusillum</i>	Small-flower geranium	GERPU
<b>Moderately tolerant (50 – 69.9 %)</b>		
<i>Taraxacum officinale</i>	Blowball	TAROF
<b>Tolerant (0 – 49.9 %)</b>		
<i>Arrhenatherum elatius</i>	False oat	ARREL

### Summary and conclusion

Based on the results of 97 field efficacy trials carried out in 2019 and 2020 season, the following can be concluded for the intended use 'Control of annual grasses and broadleaved weeds' with Pendimethalin 45.5% CS applied pre- or post-emergence at the rate of 2.5-3.5 L/ha in cereals, maize and apple:

- Pendimethalin 45.5% CS applied pre- or post-emergence at the proposed dose rate of 2.5-3.5 L/ha provides a high level of control of a range of annual grasses and broadleaved weeds commonly found in cereals, maize and apple. As weeds often occur as a complex of several weeds with different susceptibil-

ity towards pendimethalin, one application of Pendimethalin 45.5% CS at 2.5-3.5 L/ha rate in cereals, maize and apple should be used to efficiently control all weeds claimed on the label.

- Compared to the pendimethalin reference product, the efficacy obtained with Pendimethalin 45.5% CS is comparable against all weed species.
- The trial results are considered valid for all intended Central zone countries.

Pendimethalin 45.5% CS applied pre- or post-emergence is suitable for the control of annual grasses and broadleaved weeds in winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peas, carrot, parsley, strawberry, potato, asparagus, brassicas, currants, leek, parsnip, lettuce, endive, grapevine, ornamentals, artichoke, fennel, cucurbits, raspberry, sunflower, soybean, lupine, clover and alfalfa and winter oilseed rape.

Due to Pendimethalin 45.5% CS is applied pre-emergence or early post-emergence, the crop does not influence the effectiveness of the herbicide. Therefore, although the results have been presented divided by crops, they could be considered all together. The effectiveness of Pendimethalin 45.5% CS is independent of the crop.

When treating the weeds at similar growth stages, the same level of control would be expected, irrespective of applied in the autumn or in the spring. Therefore, for any label claims not adequately supported for one crop type, Sharda Cropchem España requests that the Zonal Evaluators reads across to the data on the other crop types and application timings.

This BAD also clearly demonstrates that the efficacy and cropsafetyness of Pendimethalin 45.5% CS is equivalent to the efficacy and cropsafetyness of the standard pendimethalin reference products against which Pendimethalin 45.5% CS was compared. The applicant therefore wishes to cite the original registrant's data on pendimethalin now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

The proposed label claims across uses, based on control achieved with Pendimethalin 45.5% CS applied at 2.5-3.5 L/ha. The classification is made according to Appendix I of regulation SAN-CO/10055/2013 Rev. 4 (October 3<sup>rd</sup>, 2013), however this does not replace individual MS systems for expressing control on national labels:

Susceptibility	Abbreviation	Level of control
Highly Susceptible	HS	95-100 %
Susceptible	S	85 – 94.9 %
Moderately Susceptible	MS	70 – 84.9 %
Moderately tolerant	MT	50 – 69.9 %
Tolerant	T	0 – 49.9 %

Applicant would like to refer to the EPPO standard PP 1/226(3) where is indicated that full number of trials in different years is required “particularly for plant protection products or active substances which not have been on the market in the EPPO region in which authorization is sought”. It is important to remark that the EPPO standard is referring to the region where registration is sought and not to a specific country, thus applicant considers that presence of standards has to be evaluated taking into account the registers in the whole Central Zone. The same EPPO PP 1/226(3) indicates that reduced number of trials can be presented “where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance on closely related pests or against the same pests on different crops”. Pendimethalin formulations have been registered in Central Zone and in countries where trials were conducted for various years like Stomp Aqua 455 CS (reg nr R-90/2014) registered in Poland in 2014, Stomp Aqua (reg nr 34330-32/10/3 registered in Slovenia in 2012, Stomp Aqua (reg nr 005958-00) reg-

istered in Germany, Stomp Aqua (reg nr 3107-0) registered in Austria in 2012, Stomp Aqua (reg no 5003-0) registered in the Czech Republic in 2018, Stomp Aqua (reg nr 015PC, 14/12/2012) registered in Romania in 2012. Pendimethalin 445 g/L CS was also registered in North-East EP-PO Zone belonging to North Zone countries like Stomp Aqua (reg no AS2-15H(2019)) registered in Lithuania in 2012, Stomp SC (reg no 0431) registered in Latvia in 2013 or Stomp CS (reg no 427) registered in Estonia in 2012. According to this, formulation has been widely proved in Central and North Zone where registration is sought, thus applicant considers that number of trials are enough to register formulation.

Comments of zRMS:	<p>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).</p> <p>The field experiments of the herbicide – PENSHUI (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).</p> <p>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 used different scale: S (susceptible) &gt; 85%; MS (moderately susceptible) 70-85%; MT (moderately tolerant) 60-70%; T (tolerant) &lt; 60%.</p> <p>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 (&gt;5%) of weed infestation in all studies was sufficient. Only trials with greater than 5 weeds/m<sup>2</sup> or over 2% ground cover have been included.</p> <p><u>Applicant submitted following number of trials for:</u></p> <ul style="list-style-type: none"><li>• <b>maize:</b> 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.</li><li>• <b>cereals:</b> 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.</li><li>• <b>apple:</b> for post-emergence use in total 20 trials were presented (MAR: 6 -CZ,</li></ul>
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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 consider 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), CYPRO (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 EP-

	<p><u>PO zone</u>: CAPBP (2) and SETSS (2); <u>MED EPPO zone</u>: LOLMU (2) and SOLNI (2).</p> <p>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.</p> <p><u>Following weed species should be excluded due to not enough number of trials (only 1 trial was presented):</u></p> <ul style="list-style-type: none"><li>• <b>maize:</b><ul style="list-style-type: none"><li>- <u>pre-emergence use</u>: <u>Maritime</u>: APESV, GAETE, GALAP, POLLA, VERPE; <u>N-E EPPO zone</u>: CAPBP, EPHHE, GASPA, LAMPU, SENVU, SINAR, THLAR, VERPE; <u>S-E EPPO zone</u>: AMARE, AMBEL, CHEHY, GIGSA, MERAN, SETSS, STEME, XANSI; <u>MED EPPO zone</u>: CHEAL, ECHCG, SOLNI, DIGSA.</li><li>- <u>post-emergence use</u>: <u>Maritime</u>: APESV, GAETE; <u>N-E EPPO zone</u>: AMARE, BRSNW, CAPBP, SETVI, SINAR, SOLNI, STEME, VIOAR; <u>S-E EPPO zone</u>: AMARE, AMBEL, CAPBP, DIGSA, GALAP, MATIN, POLCO, SETSS, THLAR, VIOAR, XANSI; <u>MED EPPO zone</u>: ABUTH, AMARE, CHEAL, SETVI, SOLNI.</li></ul></li><li>• <b>cereals:</b><ul style="list-style-type: none"><li>- <u>pre-emergence use</u>: <u>Maritime</u>: PAPRH, FUMOF; <u>N-E EPPO zone</u>: POLAV, VERPE, PAPRH, BRSNW, MATIN, GALAP, SINAR; <u>MED EPPO zone</u>: BEAVX, CHEAL, CHEPO, CYPRO, DATST, MALSI, SOLNI.</li><li>- <u>post-emergence use</u>: <u>N-E EPPO zone</u>: ALOMY, POLAV, BROSE, GAETE, BRSNW, VICCRE, MYOAR, SINAR; <u>MED EPPO zone</u>: BEAVX, MAQVU.</li></ul></li><li>• <b>apple:</b><ul style="list-style-type: none"><li>- <u>post-emergence use</u>: <u>Maritime</u>: ERICA, <u>N-E EPPO zone</u>: AREEL, CHEAL, GERPU, MATIN, POLPI, SENVU; <u>S-E EPPO zone</u>: ANGAR, APESV, DAUCA, DIGSA, ECHCG, ERIAN, GALAP, POAAN, RANRE, SONOL, VERSS; <u>MED EPPO zone</u>: AMARE, BEAVX, CHEAL, CIRAR, CONAR, CRUBO, DIGSA, DIPER, ECHCG, MATCH, POAAN, SENVU, SONOL.</li></ul></li></ul> <p>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.</p> <p>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.</p> <p>Presented the effectiveness of PENSHUI in apple according to LWA approach is not required, in the opinion of Evaluator. Because applications are made <b>between rows to the intra rows (inner strips between the trees within a row)</b>, application rates per ha are expressed per 'unit of treated surface area.</p> <p>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</p>
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	<p>and alfalfa and raspberry for control of annual grass- and broadleaved weeds.</p> <p>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.</p> <p>For pear no efficacy studies were presented, however according to extrapolation tables, results from apple can be extrapolated on pear.</p> <p>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).</p> <p><b>ASSESSMENT FOR POLAND (N-E EPPO ZONE):</b></p> <p>For Poland (N-E) we can take into consideration results from neighbouring countries (DE, CZ)</p> <ul style="list-style-type: none"><li>• <b>maize:</b> 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.</li></ul> <p><b>Pre-emergence use:</b></p> <p>Following weed species can be accepted in the Polish label:</p> <ul style="list-style-type: none"><li>- CAPBP – 5 trials (CZ-4, PL-1) – minor weed- at 2,5 l/ha and 3,5 l/ha – S;</li><li>- CHEAL – 7 trials (CZ-2, PL-5) – major weed – at 2,5 l/ha – MS and at 3,5 l/ha – S;</li><li>- ECHCG – 10 trials (CZ-5, PL-5) – major weed – at 2,5 l/ha – MS and at 3,5 l/ha – S;</li><li>- FUMOF – 2 trials (CZ) – minor weed – at 2,5 l/ha and 3,5 l/ha – S;</li><li>- MATIN – 5 trials (CZ) – major weed – at 2,5 l/ha and 3,5 l/ha – S</li><li>- POLCO – 6 trials (CZ-3, PL-3) – minor weeds – at 2,5 l/ha – MT and at 3,5 l/ha – MS;</li><li>- STEME – 5 trials (CZ-2, PL-3) – minor weed – at 2,5 l/ha and 3,5 l/ha – S</li><li>- THLAR – 4 trials (CZ-3, PL-1) – minor weed – at 2,5 l/ha – MS and 3,5 l/ha – S;</li><li>- VERPE - 2 trials (CZ, PL) – minor weed – at 2,5 l/ha and 3,5 l/ha – S;</li><li>- VIOAR – 6 trials (CZ-3, PL-3) – minor weed – at 2,5 l/ha and 3,5 l/ha – MS;</li><li>- 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.</li></ul> <p><b>Post – emergence use:</b></p> <p>Following weed species can be accepted in the Polish label:</p> <ul style="list-style-type: none"><li>- CAPBP – 6 trials (CZ-5, PL-1) – minor weed- at 2,5 l/ha – MT and 3,5 l/ha – MS;</li><li>- CHEAL – 9 trials (CZ-3, PL-6) – major weed – at 2,5 l/ha and at 3,5 l/ha – S;</li><li>- ECHCG – 10 trial (CZ-5, PL-5) – major weed – at 2,5 l/ha and 3,5 l/ha – MS</li><li>- FUMOF – 2 trials (CZ) – minor weed – at 2,5 l/ha – MT and 3,5 l/ha – MS;</li><li>- 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.</li><li>- POLCO – 7 trials (CZ-3, PL-4) – minor weed – at 2,5 l/ha – T and 3,5 l/ha – MT;</li><li>- 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.</li><li>- STEME – 3 trials (CZ, PL-2) – minor weed – at 2,5 l/ha – MS and 3,5 l/ha –</li></ul>
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	<p>S'</p> <ul style="list-style-type: none"><li>- THLAR – 4 trials (CZ) – minor weed – at 2,5 l/ha – MT and 3,5 l/ha – MS;</li><li>- VERPE – 4 trials (CZ-2, PL-2) – minor weed – at 2,5 l/ha and 3,5 l/ha – MS;</li><li>- LAMPU – 2 trials (PL) – minor weed – at 2,5 l/ha – MT and 3,5 l/ha – MS.</li></ul> <p><b>Based on the summarized data, it is therefore considered that claims for control of weeds in maize by PENSHUI (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.</b></p> <ul style="list-style-type: none"><li>• <b>cereals:</b> 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.</li></ul> <p><b>Pre-emergence use</b> (trials were carried out on winter wheat): Following weed species can be accepted in the Polish label:</p> <ul style="list-style-type: none"><li>- 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.;</li><li>- VERPE – 4 trials (CZ-3, PL-1) – major weed – at 2,5 l/ha – MS and at 3,5 l/ha – S;</li><li>- VIOAR – 7 trials (CZ-3, PL-4) – major weed – at 2,5 l/ha and 3,5 l/ha – MS;</li><li>- STEME – 10 trials (CZ-7, PL-3) – major weed – at 2,5 l/ha – MS and at 3,5 l/ha – S;</li><li>- CAPBP – 10 trials (CZ-7, PL-3) – major weed – at 2,5 l/ha – MS and 3,5 l/ha – S;</li><li>- POAAN – 2 trials (CZ) – minor weed – at 2,5 l/ha and 3,5 l/ha – S;</li><li>- 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;</li><li>- APESV – 9 trials (CZ-6, PL-3) – major weed – at 2,5 l/ha – MS and 3,5 l/ha – S;</li><li>- GALAP – 5 trials (CZ) – major weed – at 2,5 l/ha – MS and 3,5 l/ha – S;</li><li>- ECHCG – 4 trials (CZ) – minor weed – at 2,5 l/ha – MS and 3,5 l/ha – S;</li><li>- MATIN – 2 trials (CZ) – major weeds – at 2,5 l/ha and 3,5 l/ha – MS;</li><li>- 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.;</li><li>- ANTAR -2 trials (PL) – minor weed - at 2,5 l/ha – MT and 3,5 l/ha – MS.</li></ul> <p><b>Post – emergence use</b> (trials were carried out on winter wheat and winter barley): Following weed species can be accepted in the Polish label:</p> <ul style="list-style-type: none"><li>VERPE – 12 trials (CZ-8, PL-4) – major weed- at 2,5 l/ha and 3,5 l/ha –S;</li><li>VIOAR – 12 trials (CZ-5, PL-7) – major weed – at 2,5 l/ha – MT and at 3,5 l/ha –MS;</li><li>STEME – 16 trials (CZ-9, PL-7) – major weed – at 2,5 l/ha and 3,5 l/ha – S;</li><li>CAPBP – 9 trials (CZ-6, PL-3) – major weed – at 2,5 l/ha and 3,5 l/ha -MS;</li><li>POAAN - 3 trials (CZ) – minor weed – at 2,5 l/ha and 3,5 l/ha -S;</li><li>ALOMY – 4 trials (CZ-3, PL-1) – major weed – at 2,5 l/ha – MS and at 3,5 l/ha – S;</li><li>MATIN – 9 trials (CZ_5, PL-3) – major weed – at 2,5 l/ha – MS and at 3,5 l/ha -S);</li><li>THLAR – 4 trials (CZ) – major weed – at 2,5 l/ha and 3,5 l/ha – S;</li><li>LAMPU – 5 trials (CZ-3, PL-2) – minor weed – at 2,5 l/ha – MS and at 3,5</li></ul>
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	<p>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 dose 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.</p> <p><b>Based on the summarized data, it is therefore considered that claims for control of weeds in cereals by PENSHUI (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 results from winter wheat.</b></p> <ul style="list-style-type: none"><li>• <b>apple:</b> 12 valid trials (CZ-6, PL-6) for use post-emergence in Poland – number of trials is acceptable according to EPPO and national rules.</li></ul> <p>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.</p> <p><b>Post – emergence use:</b></p> <p>Following weed species can be accepted in the Polish label:</p> <ul style="list-style-type: none"><li>- 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;</li><li>- ATXPA – 3 trials (CZ) – at 2,5 l/ha – MS and at 3,5 l/ha – S;</li><li>- 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;</li><li>- 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;</li><li>- 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;</li><li>- LAMPU – 5 trials (CZ-2, PL-3) – at dose 2,5 l/ha – MS and at dose 3,5 l/ha – S.</li><li>- POAAN – 7 trials (CZ-3, PL-4) – in four trials the level of infestation was not</li></ul>
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	<p>acceptable – at dose 2,5 l/ha and 3,5 l/ha – S;</p> <ul style="list-style-type: none"><li>- 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;</li><li>- STEME – 7 trials (CZ-2, PL-5) – at dose 2,5 l/ha and 3,5 l/ha – S;</li><li>- LAMAM – 2 trials (PL) – at dose 2,5 l/ha and 3,5 l/ha – MS;</li><li>- TAROF – 3 trials (PL) – at dose 2,5 l/ha and 3,5 l/ha – T;</li><li>- VERPE – 2 trials (PL) – at dose 2,5 l/ha and 3,5 l/ha – S.</li></ul> <p><b>Based on the summarized data, it is therefore considered that claims for control of weeds in apple by PENSHUI (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 Applicant presented additional selectivity trials carried out on apple during commenting period, this sentence was excluded, and apple can be accepted.</b></p> <p><b>Lack of trials for pear – at least 2 selectivity trials are required (then – extrapolation efficacy results from apple is possible).</b></p> <p><b>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.</b></p> <p><b>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.</b></p> <p><u>In Polish label following weeds species can be included as:</u></p> <ul style="list-style-type: none"><li>• <i>Susceptible:</i> 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 (in 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);</li><li>• <i>Moderately susceptible:</i> POLCO (in dose 2,5 l/ha – moderately tolerant), VI-OAR, ANTAR (in dose 2,5 l/ha – moderately tolerant), LAMPU (in dose 2,5 l/ha – moderately tolerant), LAMAM</li><li>• <i>Moderately tolerant:</i> CIRAR (in dose 2,5 l/ha – tolerant)</li><li>• <i>Tolerant:</i> TAROF</li></ul>
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### **3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)**

#### **3.3.1 Summary and Conclusions**

Herbicide-resistant biotypes have been, and are currently, the subject of extensive study by weed scientists and plant physiologists. While the actual biochemical mechanisms of resistance are complicated, the general process of evolution of resistance to herbicides is fairly simple. Herbicide resistance is defined as the naturally occurring, inheritable ability of some weed biotypes within a weed population to survive an herbicide treatment that would, under normal conditions of use, effectively control that weed population. The terms "naturally occurring" and "inheritable" are key terms in understanding the development of resistance.

"Naturally occurring" refers to weed biotypes with the genetic makeup to be resistant to a particular herbicide already existing in the weed population. In other words, the herbicide does not genetically change (mutate) weeds to make them resistant to a herbicide; the weeds resistant to the herbicide occur naturally in the wild population (Duke *et al.*, 1991). Weed population is extremely diverse, even though they are similar in appearance, minor differences exist in genetic level. Sometimes, it so happens that this minor genetic variation confers some of these variants the inherent ability to resist some of the herbicides. However, frequency of such variants in a normal weed population is very less, one in a million or even one in a billion. But if we apply an herbicide to this population, to which the naturally occurring variants are immune, the entire picture changes and majority of the susceptible species are killed. This provides the resistant species, which are normally less competitive than the susceptible species, with a unique opportunity to proliferate themselves. So if we are using the same herbicide continuously for many years, in the natural weed population, the number of susceptible biotypes decreases drastically and resistant biotypes increases dramatically. Since it is difficult to distinguish susceptible from resistant biotypes morphologically, we will not notice any difference between the initial susceptible and final resistant population. But the only difference we notice is that a particular herbicide that was able to control a particular weed species is no more able to control it. So we say that the weed species have developed resistance against the particular herbicide.

"Inheritable" means that these naturally occurring resistant biotypes reproduce and pass the genes conferring resistance from one generation of weeds to the next. It is necessary to understand these points to develop effective management strategies to delay or eliminate the development of herbicide-resistant weed problems.

According to Art. 43 for renewal of a formulation, it is required to update resistance section with possible new resistances and cross resistances that appeared since the last evaluation.

In below table at evidence of resistance section for status can be observed resistances reported according to weedscience.org. As can be observed, only few new situations were observed resistance for pendimethalin. These were detected in the USA.

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

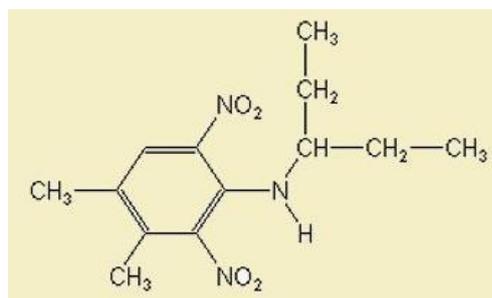
The Registration of Pendimethalin 45.5% CS is endorsed.

#### **3.3.2 Mode of Action**

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 broad-leaved weeds. In the post-emergence application, Pendimethalin is predominantly effective on broad-leaved weeds.

The chemical structure of clomazone is shown in Figure 3.3-1.

**Figure 3.3-1: Structure of pendimethalin**



Pendimethalin inhibits cell division by binding to  $\beta$ -tubuline and preventing assembly of tubuline heterodimers into microtubules (primary mode of action). In addition Pendimethalin inhibits RNA, DNA and protein synthesis and at higher concentrations an uncoupling of the oxidative phosphorylation was observed.

Due to the primary target site and the chemical subgroup, Pendimethalin is classified as a HRAC group K1 herbicide (microtubule assembly inhibition). In the WSSA resistance classification system the dinitroanilines are classified as group 3. The other chemical groups in HRAC group K1 are: phosphoroamidates, pyridines, benzamides and benzoic acids.

Chemical families	Herbicides/active ingredient
Phosphoroamidates	Amiprofos-methyl, butamifos
Pyridines	Dithiopyr, thiazopyr
Benzamides	Propyzamide, tebutam
Benzoic acids	Chlorthal-dimethyl
Dinitroanilines	e.g. pendimethalin, trifluralin, butralin

### 3.3.3 Mechanism(s) of resistance

The reason for the reduced sensitivity of resistant weed biotypes against HRAC group K1 herbicides can be metabolic resistance due to enhanced metabolism (e.g. *Alopecurus myosuroides*) as well as an altered site of action (e.g. *Eleusine indica*; *Setaria viridis*).

### 3.3.4 Evidence of resistance

HRAC group K1 herbicides are used for weed control in agricultural crops for more than 30 years. Despite this long term use only very few resistant weed populations were reported. However, group K1 resistance was observed in the important grass species *Alopecurus myosuroides* and *Lolium rigidum*. This is a fact which has to be accounted for when evaluating the resistance risk for Pendimethalin due to the tendency of this species to develop cross resistance.

To date, ten different monocotyledonous weed species and two dicotyledonous weed species has been reported in a total of 39 cases to have evolved resistance towards one HRAC group K1 herbicide (Heap, 2019). The first report of K1/15 herbicide resistance was reported from USA in 1973 where *Eleusine indica* (Goosegrass) showed resistance towards trifluralin in cotton fields. Since then, a number of cases of K1 resistance has been reported, whereof the majority are from outside Europe, i.e. USA, Australia and Canada.

Out of the ten cases of pendimethalin resistance, six cases were from the US and the remaining four cases were from within Europe. The first of the four European cases of pendimethalin resistance came from the UK, in 1987, where a population of Blackgrass (*Alopecurus myosuroid-*

es) had evolved resistance specifically towards pendimethalin. The second case was reported from Bulgaria, in 1992, where a population of Barnyardgrass (*Echinochloa crus-galli*) was reported to be resistant to pendimethalin. The third case was reported in 1996 from Belgium where Blackgrass (*Alopecurus myosuroides*) had evolved multiple resistance towards pendimethalin as well as herbicides with other sites of action (A/1, B/2, C1/5 and C2/7). Finally, in 2001, a population of Blackgrass (*Alopecurus myosuroides*) in Denmark had evolved multiple resistance towards pendimethalin, ALS inhibitors (B/2) and ACCase inhibitors (A/1). The ten cases of pendimethalin resistance reported are presented in the table below.

Year	Species	Country	MoA
1987	<i>Alopecurus myosuroides</i>	United Kingdom	K1/3
1988	<i>Eleusine indica</i>	USA (Tennessee)	K1/3
1992	<i>Sorghum halepense</i>	USA (Mississippi)	K1/3
1992	<i>Echinochloa crus-galli</i>	Bulgaria	K1/3
1994	<i>Eleusine indica</i>	USA (Mississippi)	K1/3
1996	<i>Alopecurus myosuroides</i>	Belgium	A/1, B/2, K1/3, C1/5, C2/7
1997	<i>Poa annua</i>	USA (North Carolina)	K1/3
2001	<i>Alopecurus myosuroides</i>	Denmark	A/1, B/2, K1/3
2007	<i>Poa annua</i>	USA (Tennessee)	K1/3
2012	<i>Poa annua</i>	USA (Alabama)	K1/3
2016	<i>Amaranthus palmeri</i>	USA (Arkansas)	B/2, G/9, K3/15, K1/3, E/14

MoA: A=ACCase inhibitors, B=ALS inhibitors; C1=Photosystem II inhibitors, C2=PSII inhibitors (Ureas and amides), E=PPO inhibitors, K1=Microtubule inhibitors, N=Lipid inhibitors, F4=DOXP inhibitors

The latest case of K1/3 resistance was reported from various places in Australia in 2017, where Annual bluegrass (*Poa annua*) had evolved resistance to K1/3 (propyzamide). In one of the four latest cases, the Annual bluegrass had also developed multiple resistance towards other herbicides with different sites of action (B/2, C1/5, G/9 and Z/27).

Further information and updates regarding resistance and weed populations can be found on [www.weedscience.org](http://www.weedscience.org).

### 3.3.5 Cross-resistance

“When a plant expressing resistance to an herbicide also demonstrates resistance to other herbicides that target the same plant process even though the plant has not been exposed to the other herbicides, the resistance is termed cross-resistance” (Prather et al. 2000).

Based on the HRAC classification, cross resistance could be expected to be likely between Pendimethalin and other HRAC group K1 herbicides. Cases of multiple resistance including HRAC group K1 herbicides are reported for biotypes of *Alopecurus myosuroides* (ALOMY), *Lolium rigidum* (LOLRI) and *Setaria viridis* (SETVI).

### 3.3.6 Sensitivity data

Baseline sensitivity data of the target weed species are not available and are not considered to be relevant since HRAC group K1 herbicides have already been used for many years. Therefore, it would probably be impossible to find origins of the target weed species in major crop production areas which have not been treated with these herbicides before.

### **3.3.7 Use pattern**

Pendimethalin 45.5% CS is used for pre-emergence and early post-emergence to control grass weeds as well as some broadleaved weeds in a long range of different crops.

Pendimethalin 45.5% CS is applied pre-emergence or early post-emergence.

Pendimethalin has been used as straight product as well as in mixtures for many years.

### **3.3.8 Resistance Risk Assessment of unrestricted use patterns**

To avoid resistance it is important to have a reasonable crop rotation and respect the label recommended application rates and doses. Resistance has often developed where monocropping, reduced tillage and subsequent use of K1 herbicides has been practiced. The risk of resistance to Pendimethalin is believed to be low for the following reasons:

- High level of control is achieved when used in recommended dose rates.
- There is a maximum of one application each year.
- In most areas, there is a rotation of crops as well as different cultivation and drilling times.

Pendimethalin has residual effect and therefore high soil activity.

### **3.3.9 Acceptability of the resistance risk**

Without any precautions, the resistance risk is unacceptable. However; taking the right precautions and following Good Agricultural Practice, the risk is acceptable. Should resistant populations arise, control could be achieved through use of alternative products.

### **3.3.10 Management strategy for Pendimethalin 45.5% CS**

Good Agricultural Practices and Good Plant Protection Practices (EPPO Standard 2/1 (2)) should be followed in the weed management strategy.

Pendimethalin 45.5% CS should be used in alternation with herbicides comprising different modes of action to avoid the build-up of resistant biotypes and cross resistance. Do not make more than one application.

Uses of mixtures with herbicides with different modes of action and weed spectrum is recommended, in order to obtain a high degree of weed control and get rid of eventually resistant weeds in the field and prevent resistance build up.

Follow the label recommendations regarding application rate (max. 1 application per year), growth stage, doses etc.

#### **Apply pendimethalin:**

- Apply the dose rate as recommended

#### **Avoid:**

- Late applications – when the weeds are too developed.
- Use of reduced rates particularly where late applications are made.

#### **Do Not:**

- Apply to weeds where target site resistance to K1 herbicides has been confirmed.

Remember herbicide usage should only form part of a strategy to manage herbicide resistance. Where appropriate seed samples should be tested to establish the type and severity of resistance present as this will aid decisions on future herbicide control programmes. Always follow the recommendations of the Weed Resistance Action Group ([WRAG](#)) with respect to the integration of chemical and cultural control measures.

### Cultural practices:

Since cross resistance between different modes of action cannot be excluded, application limitations and the alternation of herbicides should be supported by additional agricultural measures. To minimize the weed pressure, deep soil cultivation (plough) and late sowing are recommended.

### 3.3.11 Implementation of the management strategy

Management strategies are implemented through label advice, backed up by local recommendations from distributors and advisers. In general, the strategies are already implemented in good farm practice.

### 3.3.12 Monitoring, reporting and reaction to changes in performance

Allegations of weeds control failures in Europe and around the world are monitored.

Sharda Cropchem España will inform the regulatory authorities of any new confirmed occurrence of resistance regarding the use of Pendimethalin 45.5% CS.

Comments of zRMS:	<p>PENSHUI (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 broad-leaved weeds. In the post-emergence application, Pendimethalin is predominantly effective on broad-leaved weeds. PENSHUI is a pre- and post-emergence herbicide for the control of weeds in many different crops.</p> <p>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 <del>K1</del> 3 herbicide (microtubule assembly inhibition). To group 3 we can included also: Propyzamide=pronamide, Chlorthal-dimethyl=DCPA, Benefin=benfluralin, Butralin, Dinitramine, Ethalfluralin, Fluchloralin, Isopropalin, Nitralin, 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: phosphoroamidates, pyridines, benzamides and benzoic acids.</p> <p>Due to a low to medium resistance risk, the restriction of PENSHUI (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.</p> <p>The following table shows the current worldwide resistance weeds specifically to the herbicide glyphosate (according to <a href="http://www.weedscience.org">http://www.weedscience.org</a>):</p>						
	#	Year	Species	Country	MOAs	Actives	Situations
	1	1996	<i>Alopecurus myosuroides</i>	Belgium	ACCase inhibitors (A/1), ALS inhibitors	clodinafop-propargyl, propaquizafop, fenoxaprop-	Winter wheat

				(B/2), Microtubule Assembly inhibitors (K1/3), Photosystem II- Serine 264 Binders (C1/5), PSII inhibitors - Serine 264 Binders (C2/7)	P-ethyl, flupyr-sulfuron-methyl-sodium, atrazine, chlorotoluron, pendimethalin	
2	1992	<a href="#">Echinochloa crus-galli var. crus-galli</a>	Bulgaria	Microtubule Assembly inhibitors (K1/3)	pendimethalin	Orchards
3	2001	<a href="#">Alopecurus myosuroides</a>	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	<a href="#">Alopecurus myosuroides</a>	United Kingdom	Microtubule Assembly inhibitors (K1/3)	pendimethalin	Wheat
5	2012	<a href="#">Poa annua</a>	United States (Alabama)	Microtubule Assembly inhibitors (K1/3)	prodiamine, pendimethalin, dithiopyr	Turf
6	2016	<a href="#">Amaranthus palmeri</a>	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, fluthiac-et-methyl, carfentrazone-ethyl, glyphosate, pendimethalin, pyraflufen-ethyl, trifloxysulfuron-sodium, S-metolachlor	Cotton, Soybean
7	1992	<a href="#">Sorghum halepense</a>	United States (Mississippi)	Microtubule Assembly inhibitors (K1/3)	pendimethalin	Cotton
8	1994	<a href="#">Eleusine indica</a>	United States (Mississippi)	Microtubule Assembly inhibitors (K1/3)	pendimethalin, trifluralin	Cotton
9	1997	<a href="#">Poa annua</a>	United States (North Carolina)	Microtubule Assembly inhibitors (K1/3)	prodiamine, pendimethalin	Golf courses, Turf
10	1988	<a href="#">Eleusine indica</a>	United States (Tennessee)	Microtubule Assembly inhibitors (K1/3)	prodiamine, pendimethalin, trifluralin	Cotton, Golf courses, Turf
11	2007	<a href="#">Poa annua</a>	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.

### 3.4 Adverse effects on treated crops (KCP 6.4)

Data from 36 efficacy and 18 selectivity trials conducted in the Maritime EPPO zone (48, i.e. Czech Republic (36 eff. and 12 sel.)), the North-east EPPO zone (44, 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 (6, 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 (3, 2 eff. and 1 sel.)) in 2019, 2020 and 2021 season have been included in this biological as-

assessment dossier to support the label claims and recommendations on selectivity in the EU Central Registration zone.

The trials were conducted in cereals, maize and apple where Pendimethalin 45.5% CS was applied pre- and post-emergence, when the majority of the crop was at BBCH 00-14 (range: BBCH 00-14).

### Information on trials submitted

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The GEP-requirement and the Uniform Principles are therefore taken care of.

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. In general, the trials were conducted according to the respective EPPO guidelines.

**Table 3.4-1: Presentation of selectivity trials**

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MAR	MED	S-E	N-E			
TRZAW	Spain	Q + Y + S		3			2019	GEP	Post/Pre-emergence
	Czech Rep.	Q + Y + S	2				2019	GEP	Post/Pre-emergence
		Q + Y + S	2				2020	GEP	Post/Pre-emergence
	Estonia	Q + Y + S				1	2019	GEP	Post/Pre-emergence
	Lithuania	Q + Y + S				1	2020	GEP	Post/Pre-emergence
	Poland	Q + Y + S				2	2020	GEP	Post/Pre-emergence
	<b>Total, Winter wheat</b>			<b>4</b>	<b>3</b>		<b>4</b>		
HORVW	Spain	Q + Y + S		3			2019	GEP	Post/Pre-emergence
	Czech Rep.	Q + Y + S	2				2019	GEP	Post/Pre-emergence
		Q + Y + S	2				2020	GEP	Post/Pre-emergence
	Estonia	Q + Y + S				1	2019	GEP	Post/Pre-emergence
	Lithuania	Q + Y + S				1	2020	GEP	Post/Pre-emergence
	Poland	Q + Y + S				2	2020	GEP	Post/Pre-emergence
	<b>Total, Winter barley</b>			<b>4</b>	<b>3</b>		<b>4</b>		
ZEAMX	Czech Republic	Q + Y + S	4				2019	GEP	Pre-emergence
	Poland	Q + Y + S				3	2019	GEP	Pre-emergence
	Lithuania	Q + Y + S				1	2019	GEP	Pre-emergence
	Italy	Q + Y + S		1			2019	GEP	Pre-emergence
	<b>Total, Maize</b>			<b>4</b>	<b>1</b>		<b>4</b>		
MABSD	Hungary	Q + Y + S			2		2021	GEP	Post-emergence
	Poland	Q + Y + S				4	2021	GEP	Post-emergence
	<b>Total, Apple</b>					<b>2</b>	<b>4</b>		
<b>Total</b>			<b>12</b>	<b>7</b>		<b>2</b>	<b>16</b>		

**Table 3.4-2: Details on selectivity trial methodology**

<b>Guidelines</b>	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/50(3), PP 1/93(3)
<b>Experimental design</b>	Plot design	RCBD (37)
	Plot size	12-30 m <sup>2</sup>
	Number of replications	4 (37)
<b>Crop</b>	Trials per crop	Winter wheat (11), Winter barley (11), Maize (9), Apple (6)
	Varieties per crop	Winter wheat: Fredis, Galerist, Honda, Famulus, Tobak, Bohemia, Toras, Frisky, Nogal, Filon, Artur nick Winter barley: Anja, Quadriga, Sandra, KWS Tenor, Sonnegold, Meridian (2), Triumph, Yuriko, Cometa, Vinagrosa Maize: SY Antex, LG 3216, LG 31233, LG 30215, Perrero, LG 31225, KWS Carolinio, Luigi CS, Salgado. Apple: Prince, Gala, Golden delicious, Idared, Gloster
	Sowing period	Winter wheat: 04/Oct/19-22/Oct/19 Winter barley: 13/Oct/19-10/Nov/19 Maize: 03/04/19-05/05/19 Apple: 22/10/97 -10/05/12
<b>Application</b>	Crop stage (BBCH)* at application	BBCH 00-13 (range: BBCH 00-13)
	Timing Pest stage at appl. (1)	Winter wheat: 01/Aug/19-23/Nov/19 Winter barley: 18/Feb/19-19/Nov/19 Maize: 08/04/19-03/06/19
	Number of appl. Intervals between appl.	1 (37) n.a.
	Spray volumes	200-400 L/ha
<b>Assessment</b>	Assessment types	- Visual estimation of biomass reduction per plot compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) or calculated, based on weed counts (COUPLA) or weed ground cover (GROUND) in a defined area, as compared to the untreated check. - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms. - Crop vigour
	Assessment dates	Selectivity: 4 to 237 DAT
<b>Other relevant information</b>	Soil type	Light to heavy soils
	Natural / artificial inoculation...	Natural
	Field / Greenhouse...	Field

In 97 efficacy trials and 37 selectivity trials, the performance of Pendimethalin 45.5% CS was measured against a commercial Pendimethalin standard formulation currently on the market in Central and Southern Europe.

The reference products used in the trials are listed in Table 3.4-3.

**Table 3.4-3: Presentation of reference standards used in trials (selectivity trials, transformation trials...)**

Trade name	Formulation	Active Ingredient	AI content	Use rates	Countries where used and targets
<b>Test products</b>					
PENDIMETHALIN 45.5% CS	CS	Pendimethalin	455 g/l	2.0 l/ha 2.5 l/ha 3.0 l/ha 3.5 l/ha 7.0 l/ha	Spain, Italy, Czech Republic, Poland, Lithuania, Slovakia, Romania, Hungary, Lithuania and Estonia. Grasses and broadleaved weeds
<b>Pendimethalin reference product</b>					
STOMP AQUA	CS	Pendimethalin	455 g/L	2.5 l/ha 3.0 l/ha 7.0 l/ha	Slovakia, Poland, Czech Republic, Spain, Italy, Estonia, Lithuania, Hungary, Grasses and broadleaved weed
STOMP 400SC	SC	Pendimethalin	400 g/L	3.5 l/ha	Czech Republic, Poland. Grasses and broadleaved weed
ACTIVUS SC	SC	Pendimethalin	400 g/L	4.0 l/ha 8.0 l/ha	Romania, Poland Grasses and broadleaved weed
PENDIMETHALIN 33 EC	EC	Pendimethalin	330 g/L	4.0 l/ha 5.0 l/ha	Spain, Italy, Czech Republic, Poland, Lithuania, Slovakia, Romania, Lithuania and Estonia. Grasses and broadleaved weeds
PENDIMETHALIN 40 SC	SC	Pendimethalin	400 g/L	3.5 l/ha 4.0 l/ha	Spain, Italy, Czech Republic, Poland, Lithuania, Slovakia, Romania, Lithuania and Estonia. Grasses and broadleaved weeds

### 3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

The crop safety of Pendimethalin 45.5% CS was assessed in Maize, Cereals and Apple in 97 efficacy trials (36 MAR, 33 NE, 6 SE and 22 MED) and 37 selectivity trials (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 (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.

#### 3.4.1.1 Summary and evaluation of trials treated pre-emergence

The crop safety of applying Pendimethalin 45.5% CS in Cereals and Maize was evaluated in 53 efficacy trials (24 MAR, 21 NE, 2 SE and 6 MED) and 31 crop safety trials (12 MAR, 12 NE and 7 MED).

##### (a) Winter wheat, pre-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Pendimethalin 45.5% CS was applied pre-emergence, at growth stages of BBCH 00-09, at the rate of 2.0 to 7.0 L/ha in cereals. The dose rate of 7.0 L/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to termination of the trial.

### Phytotoxicity in winter wheat trials, Maritime EPPO zone

Eight efficacy trials and four selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in winter wheat, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 16 trials conducted in the Maritime EPPO zone.

**Table 3.4-4: Varieties where no adverse effects were observed in Maritime cereal trials following pre-emergence application**

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.5 L/ha</b>			
CZ	H1815-TRZAW-DOM11	Tobak	00
CZ	H1815-TRZAW-DOM12	Bohemia	00
CZ	SWEPL-CZE20-PDM-TRZAW-TRU15	Viriato	05
CZ	SWEPL-H1815-RYMA	Toras	09
CZ	SWEPL-H1815-RYMB	Santiago	09
CZ	SWEPL-H1816-RYMA	Frisky	09
CZ	SWEPL-H1816-RYMB	Bohemia	09
CZ	SWEPL-KUJ20-TRZAW-H1815	Annie	00
<b>Selectivity trials, 3.5 and 7.0 L/ha</b>			
CZ	H1817-TRZAW-DOM15	Tobak	00
CZ	H1817-TRZAW-DOM16	Bohemia	09
CZ	SWEPL-H1817-RYMA	Toras	09
CZ	SWEPL-H1817-RYMB	Frisky	09

Thus, no adverse effects were observed in the trials.

### Phytotoxicity in winter wheat trials, North-east EPPO zone

Five efficacy trials and four selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in winter wheat, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 9 trials conducted in the North-east EPPO zone

**Table 3.4-5: Varieties where no adverse effects were observed in North-east cereal trials following pre-emergence application**

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.5 L/ha</b>			
PL	SH20-SHA03	Julius	00
PL	SH20-SHA04	Arkadia	00
PL	SH20-SHA01	Owacja	00
PL	SH20-SHA02	Euforia	09
LT	LTZI19H15023TRZAW	Ada	08
<b>Selectivity trials, 3.5 and 7.0 L/ha</b>			
EE	EE19H1817WW	Fredis	03
PL	SH20-SHA09	Galerist	00
PL	SH20-SHA10	Honda	00
LT	LTZI19H15025TRZAW	Famulus	05

Thus, no adverse effects were observed in the trials.

### Phytotoxicity in winter wheat trials, Mediterranean EPPO zone

Four efficacy trials and six selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in cereals, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 10 trials conducted in the Mediterranean EPPO zone.

**Table 3.4-6: Varieties where no adverse effects were observed in Mediterranean cereal trials following pre-emergence application**

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.0 L/ha</b>			
ES	E19-033-01	Nogal	08
ES	E19-033-02	Filon	08
ES	E19-033-03	Artur nick	08
ES	E19-033-04	Botticelli	08
<b>Selectivity trials, 3.0 and 6.0 L/ha</b>			
ES	E19-035-01	Nogal	08
ES	E19-035-02	Filon	08
ES	E19-035-03	Artur nick	08
ES	E19-037-01	Yuriko	09
ES	E19-037-02	Cometa	08
ES	E19-037-03	Vinagrosa	09

Thus, no adverse effects were observed in the trials.

### (b) Winter barley, pre-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Pendimethalin 45.5% CS was applied pre-emergence, at growth stages of BBCH 09, at the rate of 2.0 to 6.0 L/ha in cereals. The dose rate of 6.0 L/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to termination of the trial.

### Phytotoxicity in cereals trials, Mediterranean EPPO zone

Four efficacy trials and six selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in cereals, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 10 trials conducted in the Mediterranean EPPO zone.

**Table 3.4-7: Varieties where no adverse effects were observed in Mediterranean cereal trials following pre-emergence application**

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.0 L/ha</b>			
ES	E19-033-01	Nogal	08
ES	E19-033-02	Filon	08
ES	E19-033-03	Artur nick	08
ES	E19-033-04	Botticelli	08
<b>Selectivity trials, 3.0 and 6.0 L/ha</b>			
ES	E19-035-01	Nogal	08
ES	E19-035-02	Filon	08
ES	E19-035-03	Artur nick	08
ES	E19-037-01	Yuriko	09
ES	E19-037-02	Cometa	08

ES	E19-037-03	Vinagrosa	09
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Thus, no adverse effects were observed in the trials.

### (c) Maize, pre-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Pendimethalin 45.5% CS was applied pre-emergence, at growth stages of BBCH 00-07, at the rate of 2.0 to 7.0 L/ha in maize. The dose rate of 7.0 L/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to termination of the trial.

#### Phytotoxicity in maize trials, Maritime EPPO zone

Six efficacy trials and four selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in maize, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 10 trials conducted in the Maritime EPPO zone.

**Table 3.4-8:** Varieties where no adverse effects were observed in Mediterranean maize trials following pre-emergence application

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.5 L/ha</b>			
CZ	H1823-ZEAMX-DOM21	LG3216	00
CZ	H1823-ZEAMX-DOM22	Xxilo	00
CZ	SWEPL-CZE19-PDM-ZEAMA-TRU23	Cebesto C	00
CZ	SWEPL-H1823-RYM	Perrero	00
CZ	SWEPL-KUJ20-ZEAMX-H1823a	LG 30215	00
CZ	SWEPL-KUJ20-ZEAMX-H1823b	LG 30222	07
<b>Selectivity trials, 3.5 and 7.0 L/ha</b>			
CZ	H1825-ZEAMX-DOM25	LG3216	00
CZ	H1825-ZEAMX-DOM26	LG31233	00
CZ	SWEPL-H1825-RYM	Perrero	00
CZ	SWEPL-KUJ20-ZEAMX-H1825	LG 30215	00

Thus, no adverse effects were observed in the trials.

#### Phytotoxicity in maize trials, North-east EPPO zone

Six efficacy trials and four selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in maize, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 10 trials conducted in the North-east EPPO zone.

**Table 3.4-9:** Varieties where no adverse effects were observed in North-east maize trials following pre-emergence application

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.5 L/ha</b>			
PL	72-01-F19-137	Rosomak	00
PL	72-02-F19-138	Ulan	00
PL	72-03-F19-139	Poesi CS	00
LU	LTZIHE2019ZEAM1	Agiraxx	00
PL	SH19-SHA05	Enigma	05
PL	SH19-SHA06	MAS 26 K	08

Selectivity trials, 3.5 and 7.0 L/ha			
PL	FH19-SHA26	LG31225	05
PL	FH19-SHA27	KWS Carolinio	05
PL	74-01-F19-143	Luigi CS	00
LU	LTZIHS2019ZEAMI	Slagado	00

Thus, no adverse effects were observed in the trials.

#### Phytotoxicity in maize trials, South-east EPPO zone

Two efficacy trials were conducted in the South-east EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in maize, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 2 trials conducted in the South-east EPPO zone.

**Table 3.4-10:** Varieties where no adverse effects were observed in South-east maize trials following pre-emergence application

Country	Trial no.	Variety	GS at appl.
Efficacy trials, 2.0, 2.5 and 3.5 L/ha			
SK	13/BAHR/19	P9874	00
RO	RO-19-6E-03	DKC 54670	07

Thus, no adverse effects were observed in the trials.

#### Phytotoxicity in maize trials, Mediterranean EPPO zone

Two efficacy trials and one selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in maize, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 3 trials conducted in the Mediterranean EPPO zone.

**Table 3.4-11:** Varieties where no adverse effects were observed in Mediterranean maize trials following pre-emergence application

Country	Trial no.	Variety	GS at appl.
Efficacy trials, 2.0, 2.5 and 3.5 L/ha			
IT	H1823-01	SY Antex	07
IT	H1823-02	P1921	00
Selectivity trials, 3.5 and 7.0 L/ha			
IT	H1825-02	SY Antex	00

Thus, no adverse effects were observed in the trials.

### 3.4.1.2 Summary and evaluation of trials treated post-emergence

The crop safety of applying Pendimethalin 45.5% CS in Cereals, Maize and Apple was evaluated in 62 efficacy trials (22 MAR, 22 NE, 4 SE, 14 MED) and 31 crop safety trials (12 MAR, 12 NE, 7 MED).

### (a) Winter wheat, post-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Pendimethalin 45.5% CS was applied post-emergence, at growth stages of BBCH 11-15, at the rate of 2.0 to 7.0 L/ha in cereals. The dose rate of 7.0 L/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to termination of the trial.

#### Phytotoxicity in winter wheat trials, Maritime EPPO zone

Four efficacy trials and four selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in winter wheat, i.e. post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 8 trials conducted in the Maritime EPPO zone.

**Table 3.4-12: Varieties where no adverse effects were observed in Maritime winter wheat trials following post-emergence application**

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.5 L/ha</b>			
CZ	H1816-TRZAW-DOM13	Tobak	15
CZ	H1816-TRZAW-DOM14	Bohemia	12
CZ	SWEPL-CZE20-PDM-TRZAW-TRU16	Annie	12
CZ	SWEPL-KUJ20-TRZAW-H1816	Annie	13
<b>Selectivity trials, 3.5 and 7.0 L/ha</b>			
CZ	H1817-TRZAW-DOM15	Tobak	12
CZ	H1817-TRZAW-DOM16	Bohemia	12
CZ	SWEPL-H1817-RYMA	Toras	12
CZ	SWEPL-H1817-RYMB	Frisky	09

Thus, no adverse effects were observed in the trials.

#### Phytotoxicity in winter wheat trials, North-east EPPO zone

Six efficacy trials and four selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in winter wheat, i.e. post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 10 trials conducted in the North-east EPPO zone.

**Table 3.4-13: Varieties where no adverse effects were observed in North-east winter wheat trials following post-emergence application**

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.5 L/ha</b>			
PL	SH20-SHA07	Julius	12
PL	SH20-SHA08	Arkadia	12
EE	EE19H1816WW	Kallas	12
PL	SH20-SHA05	Skagen	10
PL	SH20-SHA06	Hondia	11
LT	LTZI19H15024TRZAW	Ada	11
<b>Selectivity trials, 3.5 and 7.0 L/ha</b>			
EE	EE19H1817WW	Fredis	03
PL	SH20-SHA09	Galerist	00
PL	SH20-SHA10	Honda	00
LT	LTZI19H15025TRZAW	Famulus	05

Thus, no adverse effects were observed in the trials.

### Phytotoxicity in cereals trials, Mediterranean EPPO zone

Eight efficacy trials and six selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in cereals, i.e. post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 14 trials conducted in the Mediterranean EPPO zone.

**Table 3.4-14: Varieties where no adverse effects were observed in Mediterranean cereal trials following post-emergence application.**

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.0 L/ha</b>			
ES	E19-034-01	Nogal	11
ES	E19-034-02	Filon	12
ES	E19-034-03	Artur nick	11
ES	E19-034-04	Botticelli	11
ES	E19-036-01	Yuriko	11
ES	E19-036-02	Cometa	12
ES	E19-036-03	Vinagrosa	11
ES	E19-036-04	Volley	11
<b>Selectivity trials, 3.0 and 6.0 L/ha</b>			
ES	E19-035-01	Nogal	12
ES	E19-035-02	Filon	12
ES	E19-035-03	Artur nick	12
ES	E19-037-01	Yuriko	12
ES	E19-037-02	Cometa	12
ES	E19-037-03	Vinagrosa	12

Thus, no adverse effects were observed in the trials.

### (b) Winter barley, post-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Pendimethalin 45.5% CS was applied pre-emergence, at growth stages of BBCH 10-12, at the rate of 2.0 to 7.0 L/ha in cereals. The dose rate of 7.0 L/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to termination of the trial.

### Phytotoxicity in winter barley trials, Maritime EPPO zone

Six efficacy trials and four selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in winter barley, i.e. post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 10 trials conducted in the Maritime EPPO zone.

**Table 3.4-15: Varieties where no adverse effects were observed in Maritime winter barley trials following post-emergence application**

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.5 L/ha</b>			
CZ	H1819-HORVW-DOM17	Sonnengold	13
CZ	H1819-HORVW-DOM18	Meridian	13
CZ	SWEPL-CZE20-PDM-HORVW-TRU19	Leopard	13
CZ	SWEPL-H1819-RYMA	Meridian	10
CZ	SWEPL-H1819-RYMB	Triumph	10
CZ	SWEPL-KUJ20-HORVW-H1819	Kosmos	13

Selectivity trials, 3.0 and 7.0 L/ha			
CZ	H1820-HORVW-DOM19	Sonnengold	13
CZ	H1820-HORVW-DOM20	Meridian	13
CZ	SWEPL-H1820-RYMA	Triumph	12
CZ	SWEPL-H1820-RYMB	Meridian	12

Thus, no adverse effects were observed in the trials.

#### Phytotoxicity in winter barley trials, North-east EPPO zone

Four efficacy trials and four selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in winter barley, i.e. post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 8 trials conducted in the North-east EPPO zone.

**Table 3.4-16: Varieties where no adverse effects were observed in North-east winter barley trials following post-emergence application**

Country	Trial no.	Variety	GS at appl.
Efficacy trials, 2.0, 2.5 and 3.5 L/ha			
PL	SH20-SHA13	Zenek	13
PL	SH20-SHA14	Vireni	13
PL	SH20-SHA11	Concordia	10
PL	SH20-SHA12	Baracooda	10
Selectivity trials, 3.0 and 7.0 L/ha			
EE	EE19H1820WB	Anja	11
PL	SH20-SHA15	Quadriga	12
PL	SH20-SHA16	Sandra	12
LT	LTZI19H15027HORVW	KWS Tenor	05

Thus, no adverse effects were observed in the trial.

#### (c) Maize, post-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Pendimethalin 45.5% CS was applied post-emergence, at growth stages of BBCH 11-13, at the rate of 2.0 to 7.0 L/ha in maize. The dose rate of 7.0 L/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to termination of the trial.

#### Phytotoxicity in maize trials, Maritime EPPO zone

Six efficacy trials and four selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in maize, i.e. post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 10 trials conducted in the Maritime EPPO zone.

**Table 3.4-17: Varieties where no adverse effects were observed in Maritime maize trials following post-emergence application**

Country	Trial no.	Variety	GS at appl.
Efficacy trials, 2.0, 2.5 and 3.5 L/ha			
CZ	H1824-ZEAMX-DOM23	Es Amulet	13

CZ	H1824-ZEAMX-DOM24	LG31233	13
CZ	SWEPL-CZE19-PDM-ZEAMA-TRU24	Cebesto C	12
CZ	SWEPL-H1824-RYM	LG3216	11
CZ	SWEPL-KUJ20-ZEAMX-H1824a	LG 30215	13
CZ	SWEPL-KUJ20-ZEAMX-H1824b	LG 30222	13
<b>Selectivity trials, 3.5 and 7.0 L/ha</b>			
CZ	H1825-ZEAMX-DOM25	LG3216	13
CZ	H1825-ZEAMX-DOM26	LG31233	13
CZ	SWEPL-H1825-RYM	Perrero	11
CZ	SWEPL-KUJ20-ZEAMX-H1825	LG 30215	12

Thus, no adverse effects were observed in the trials.

#### Phytotoxicity in maize trials, North-east EPPO zone

Six efficacy trials and four selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in maize, i.e. post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 10 trials conducted in the North-east EPPO zone.

**Table 3.4-18:** Varieties where no adverse effects were observed in North-east maize trials following post-emergence application

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.5 L/ha</b>			
PL	73-01-F19-140	Ulan	12
PL	73-02-F19-141	P0927	13
PL	73-03-F19-142	Ulan	12
LU	LTZIHE2019ZEAM2	Agiraxx	12
PL	SH19-SHA07	Enigma	11
PL	SH19-SHA08	MAS 26K	11
<b>Selectivity trials, 3.5 and 7.0 L/ha</b>			
PL	FH19-SHA26	LG31225	11
PL	FH19-SHA27	KWS Carolinio	11
PL	74-01-F19-143	Luigi CS	11
LU	LTZIHS2019ZEAM1	Slagado	12

Thus, no adverse effects were observed in the trials.

#### Phytotoxicity in maize trials, South-east EPPO zone

Two efficacy trials were conducted in the South-east EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in maize, i.e. post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 2 trials conducted in the South-east EPPO zone.

**Table 3.4-19:** Varieties where no adverse effects were observed in South-east maize trials following post-emergence application

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.5 L/ha</b>			
SK	2-ZVH-19	Susann	13
RO	RO-19-6E-04	DKC 54670	13

Thus, no adverse effects were observed in the trials.

### Phytotoxicity in maize trials, Mediterranean EPPO zone

Two efficacy trials and one selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in maize, i.e. post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 3 trials conducted in the Mediterranean EPPO zone.

**Table 3.4-20:** Varieties where no adverse effects were observed in Mediterranean maize trials following post-emergence application

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.0 L/ha</b>			
IT	H1824-01	P1921	11
IT	H1824-02	SY Zoan	11
<b>Selectivity trials, 3.5 and 7.0 L/ha</b>			
IT	H1825-02	SY Antex	12

Thus, no adverse effects were observed in the trials.

### (d) Apple, post-emergence

Crop phytotoxicity was evaluated in efficacy- ~~and selectivity~~ trials where Pendimethalin 45.5% CS was applied post-emergence, at growth stages of BBCH 19-65, at the rate of 2.0 to 3.5 L/ha in apple. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to termination of the trial.

### Phytotoxicity in apple trials, Maritime EPPO zone

Six efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in apple, i.e. post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 6 trials conducted in the Maritime EPPO zone.

**Table 3.4-21:** Varieties where no adverse effects were observed in Maritime apple trials following post-emergence application

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.5 L/ha</b>			
CZ	CZOR-SWE19-MABSD-001	Golden	65
CZ	CZOR-SWE19-MABSD-002	Golden	62
CZ	CZOR-SWE19-MABSD-003	Spartan	19
CZ	CZOR-SWE19-MABSD-004	Idared	62
CZ	CZOR-SWE19-MABSD-005	Golden	19
CZ	CZOR-SWE19-MABSD-006	Champion	32

Thus, no adverse effects were observed in the trials.

### Phytotoxicity in apple trials, North-east EPPO zone

Six efficacy trials and **four selectivity trials** were conducted in the North-east EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in apple, i.e. post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 5 trials conducted in the North-east EPPO zone.

**Table 3.4-22:** Varieties where no adverse effects were observed in North-east apple trials following post-emergence application

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.5 L/ha</b>			
PL	SGS/2019/004/PL01	Jonagold	36
PL	SGS/2019/004/PL02	Prince	19
PL	SGS/2019/004/PL03	Szampion	52
PL	SGS/2019/004/PL04	Jonagold	52
PL	SGS/2019/004/PL05	Idared	51
PL	SRPL19-235-034HE	Szampion	77
<b>Selectivity trials, 3.5 and 7.0 L/ha</b>			
PL	129_01_F21_280	Prince	09
PL	129_02_F21_281	Gloster	09
PL	129_03_F21_282	Gala	09
PL	129_04_F21_283	Idared	09

Thus, no adverse effects were observed in the trials.

#### Phytotoxicity in apple trials, South-east EPPO zone

Two efficacy trials and two selectivity trials were conducted in the South-east EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in apple, i.e. post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 4 trials conducted in the South-east EPPO zone.

**Table 3.4-23:** Varieties where no adverse effects were observed in South-east apple trials following post-emergence application

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.5 L/ha</b>			
RO	RO-19-6E-01	Jonathan	10
RO	RO-19-6E-02	Jonagold	15
<b>Selectivity trials, 3.5 and 7.0 L/ha</b>			
RO	SEL-Pendim-MABSD-XIII-PLA-2021	Golden Delicious	09
RO	SEL-Pendim-MABSD-XIX-PLA-2021	Gala	09

Thus, no adverse effects were observed in the trials.

#### Phytotoxicity in apple trials, Mediterranean EPPO zone

Six efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Pendimethalin 45.5% CS when applied as recommended in apple, i.e. post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the 6 trials conducted in the Mediterranean EPPO zone.

**Table 3.4-24:** Varieties where no adverse effects were observed in South-east maize trials following post-emergence application

Country	Trial no.	Variety	GS at appl.
<b>Efficacy trials, 2.0, 2.5 and 3.0 L/ha</b>			

ES	E19-041-01	Golden	65
ES	E19-041-02	Starking	62
ES	E19-041-03	Golden	19
ES	E19-041-04	Royal Gala	32
IT	H1824-03	Modi	69
IT	H1824-04	Golden	67

Thus, no adverse effects were observed in the trials.

### 3.4.1.3 Overall conclusion

Winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peas, carrot, parsley, strawberry, potato, asparagus, brassicas, currants, leek, parsnip, lettuce, endive, grapevine, ornamentals, artichoke, fennel, cucurbits, raspberry, sunflower, soybean, lupine, clover and alfalfa and winter oilseed rape are supported with a total of 113 trials conducted in Czech Republic, Italy, Spain, Poland, Estonia, Slovakia, Romania and Lithuania in 2019 and 2020. In all trials, Pendimethalin 45.5% CS proved to be crop safe and in all trials did not significantly affect the crop adversely when applied at a range of growth stages within and occasionally beyond the label recommended range, at the proposed label recommended rates. The same was observed in the treatments where Pendimethalin 45.5% CS was applied at twice the recommended rates or more, representative of sprayer overlap.

Pre- and post-emergence application in winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peas, carrot, parsley, strawberry, potato, asparagus, brassicas, currants, leek, parsnip, lettuce, endive, grapevine, ornamentals, artichoke, fennel, cucurbits, raspberry, sunflower, soybean, lupine, clover and alfalfa and winter oilseed rape is claimed on the label. For recommendations claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in cereals, maize and apple where pre- and post-emergence applications were tested. This document also clearly demonstrates that the efficacy and crop safety of Pendimethalin 45.5% CS is equivalent to the reference pendimethalin products to which it was compared in all trials. The applicant therefore wishes to cite the original registrant's data on pendimethalin now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

**Table 3.4-25: Phytotoxicity of product**

Number of trials with...		Selectivity trials (37 trials)				Efficacy trials (97 trials)	
		Test product		Standard		Test product	Standard
		3.0-3.5 L/ha	6.0-7.0 L/ha	1N	2N	3.0-3.5 L/ha	1N
Maximum of phytotoxicity recorded during the trials	0% to 5%	37	37	37	37	97	97
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	37	37	37	37	97	97
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

Comments of zRMS:	The selectivity tests about herbicide PENSHUI (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).
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Selectivity studies on herbicide were performed in 2019 and 2020 and 2021 on winter wheat, winter barley, apple and maize 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 PENSHUI 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 PENSHUI 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 PENSHUI 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 PENSHUI 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 PENSHUI.

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. Peshui 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.
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### 3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

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).

#### 3.4.2.1 Summary and evaluation of crop yield on field trials treated pre-emergence

A summary of the mean yield assessments expressed as %-relative of the untreated, from cereals, maize and apple trials treated with pre-emergence applications in the Maritime zone, the North-east and the Mediterranean zone EPPO zone.

##### Winter wheat (Pre-emergence)

Eight selectivity trials conducted in cereals were harvested. The trials were conducted in Czech Republic, Estonia, Lithuania and Poland in 2019 and 2020. In these trials, Pendimethalin 45.5% CS was applied pre-emergence at 3.5 L/ha and 7.0 L/ha. The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 00-09.

**Table 3.4-26: Crop yield (t/ha) of winter wheat treated with Pendimethalin 45.5% CS, single application pre-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no. of trials)			
			3.5 L/ha	7.0 L/ha	1N	2N
<b>Winter wheat, selectivity trials, pre-emergence</b>						
Maritime zone (t/ha)	4	7.7 (6.5-9.2)	101 (100-101)	99.6 (98.8-100)	100 (100-101)	100 (99.3-101)
North-east (t/ha)	4	6.01 (5.08-7.36)	101 (96.4-108)	98.8 (94.4-103)	98.1 (96.4-100)	100 (96.4-103)

##### Winter barley (Pre-emergence)

Eight selectivity trials conducted in cereals were harvested. The trials were conducted in Czech Republic, Estonia, Lithuania and Poland in 2019 and 2020. In these trials, Pendimethalin 45.5% CS was applied pre-emergence at 3.5 L/ha and 7.0 L/ha. The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 00-09.

**Table 3.4-27: Crop yield (t/ha) of winter barley treated with Pendimethalin 45.5% CS, single application pre-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no. of trials)			
			3.5 L/ha	7.0 L/ha	1N	2N
<b>Winter barley, selectivity trials, pre-emergence</b>						
Maritime zone (t/ha)	4	7.93 (6.5-9.0)	101 (99.2-102)	101 (100-102)	101 (98.9-103)	101 (99.0-102)
North-east (t/ha)	4	5.59 (3.7-6.06)	97.8 (91.8-102)	98.8 (97.0-103)	100 (87.7-111)	99.7 (95.9-108)

### **Cereals (Pre-emergence)**

Six selectivity trials conducted in cereals were harvested. The trials were conducted in Spain (6) in 2019. In these trials, Pendimethalin 45.5% CS was applied pre-emergence at 3.0 L/ha and 6.0L/ha. The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 08-09.

**Table 3.4-28: Mediterranean zone – Crop yield (t/ha) of cereals treated with Pendimethalin 45.5% CS, single application pre-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no. of trials)			
Cereals, selectivity trials, pre-emergence						
Mediterranean zone (t/ha)						
	6	2.3 (2.1-2.4)	100.8 (96.1-104)	100.2 (96.7-103.4)	101.5 (93.7-108.8)	101.6 (97.2-109.5)

### **Maize (Pre-emergence)**

Eight selectivity trials conducted in maize were harvested. The trials were conducted in Italy (1), Poland (3), Czech Republic (3) and Lithuania (1) in 2019. In these trials, Pendimethalin 45.5% CS was applied pre-emergence at 3.0-3.5 L/ha and 6.0-7.0 L/ha. The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 00-05.

**Table 3.4-29: Maritime, North-east and Mediterranean zone – Crop yield (t/ha) of maize treated with Pendimethalin 45.5% CS, single application pre-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no. of trials)			
Maize, selectivity trials, pre-emergence						
Maritime zone (T-ha)	3	41.8 (25.2-51.4)	100.5 (98.1-105.2)	100.3 (96.7-103.2)	101.5 (96.9-106.7)	100 (97.1-102.4)
North-east zone (T-MET)	4	20.6 (9.5-48.8)	100.6 (94.1-110.5)	106.1 (98.3-127.3)	111.3 (101.7-109)	100.6 (98.3-103.3)
Mediterranean zone (T-MET)	1	15.9	93.7	92.5	96.9	91.2

In the 30 selectivity trials, Pendimethalin 45.5% CS performed in most cases like the reference products, i.e. the Pendimethalin reference products included in trials. The results obtained in the 30 selectivity trials supports the label claim that Pendimethalin 45.5% CS is safe to be applied pre- and post-emergence at the recommended dose rate in winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peas, carrot, parsley, strawberry, potato, asparagus, brassicas, currants, leek, parsnip, lettuce, endive, grapevine, ornamentals, artichoke, fennel, cucurbits, raspberry, sunflower, soybean, lupine, clover and alfalfa and winter oilseed rape at the recommended application interval.

### **3.4.2.2 Summary and evaluation of crop yield on field trials treated post-emergence**

A summary of the mean yield assessments expressed as %-relative of the untreated, are presented in following tables. The summary table is based on yield data presented in Appendix 6 for results obtained in cereals and maize trials treated post-emergence in the Maritime zone, North-east zone and the Mediterranean zone.

#### **Winter wheat (Post-emergence)**

Eight selectivity trials conducted in cereals were harvested. The trials were conducted in Czech Republic, Estonia, Lithuania and Poland in 2019 and 2020. In these trials, Pendimethalin 45.5% CS was applied post-emergence at 3.5 L/ha and 7.0 L/ha. The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 09-13.

**Table 3.4-30: Crop yield (t/ha) of winter wheat treated with Pendimethalin 45.5% CS, single application post-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no. of trials)			
			3.5 L/ha	7.0 L/ha	1N	2N
<b>Winter wheat, selectivity trials, post-emergence</b>						
Maritime zone (t/ha)	4	7.7 (6.5-9.2)	101 (98.9-103)	100 (100-101)	101 (100-102)	100 (100-101)
North-east (t/ha)	4	6.01 (5.08-7.36)	97.4 (89.8-106)	101 (96.4-109)	101 (94.7-106)	98.7 (94.9-106)

### Winter barley (Post-emergence)

Eight selectivity trials conducted in cereals were harvested. The trials were conducted in Czech Republic, Estonia, Lithuania and Poland in 2019 and 2020. In these trials, Pendimethalin 45.5% CS was applied post-emergence at 3.5 L/ha and 7.0 L/ha. The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 09-12.

**Table 3.4-31: Crop yield (t/ha) of winter barley treated with Pendimethalin 45.5% CS, single application post-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no. of trials)			
			3.5 L/ha	7.0 L/ha	1N	2N
<b>Winter barley, selectivity trials, post-emergence</b>						
Maritime zone (t/ha)	4	7.93 (6.5-9.0)	101 (98.2-102)	101 (100-102)	101 (100-102)	101 (100-103)
North-east (t/ha)	4	5.59 (3.7-6.06)	103 (97.9-108)	95.9 (85.7-100)	99.8 (96.0-104)	101 (97.4-111)

### Cereals (Post-emergence)

Six selectivity trials conducted in cereals were harvested. The trials were conducted in Spain (6) in 2019. In these trials, Pendimethalin 45.5% CS was applied post-emergence at 3.0 L/ha and 6.0L/ha. The trials were sprayed when the majority of the crop was at growth stages BBCH 12.

**Table 3.4-32: Mediterranean zone – Crop yield (t/ha) of cereals treated with Pendimethalin 45.5% CS, single application post-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no. of trials)			
			3.0 L/ha	6.0 L/ha	1N	2N
<b>Cereals, selectivity trials, post-emergence</b>						
Mediterranean zone (t/ha)	6	2.3 (2.1-2.4)	100.6 (96.1-105.9)	103.1 (96.7-110.1)	103.1 (93.7-111.3)	101.2 (96.9-112.3)

### Maize (Post-emergence)

Eight selectivity trials conducted in maize were harvested. The trials were conducted in Czech Republic (3), Italy (1), Poland (3) and Lithuania (1) in 2019. In these trials, Pendimethalin 45.5% CS was applied pre-emergence at 3.0-3.5 L/ha and 6.0-7.0 L/ha. The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 11-13.

**Table 3.4-33: Maritime, North-east and Mediterranean zone – Crop yield (t/ha) of maize treated with Pendimethalin 45.5% CS, single application post-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no. of trials)			
			3.0 L/ha	6.0 L/ha	1N	2N
<b>Maize, selectivity trials, post-emergence</b>						
Maritime zone (T-ha)	3	41.8 (25.2-51.4)	99.2 (97.9-100.4)	100.1 (97.6-101.8)	100.2 (99.6-100.8)	98.2 (97.6-99.0)
North-east zone (T-MET)	4	20.6 (9.5-48.8)	103.6 (95.8-107.8)	98.4 (94.9-100.8)	104.6 (95.8-109.8)	112.7 (94.9-138.9)

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no. of trials)			
			3.0 L/ha	6.0 L/ha	1N	2N
Mediterranean zone (T-MET)	1	15.9	98.7	103.8	97.5	99.4

### Apple (Post-emergence)

Six selectivity trials conducted in Apple were harvested. The trials were conducted in Poland (4) and Hungary (2) in 2021. In these trials, Pendimethalin 45.5% CS was applied pre-emergence at 3.5 L/ha and 7.0 L/ha. The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 09-10.

**Table 3.4-34: North-east and South-East zone – Crop yield (t/ha) of apple treated with Pendimethalin 45.5% CS, single application post-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no. of trials)			
			3.0 L/ha	6.0 L/ha	1N	2N
<b>Apple, selectivity trials</b>						
North-east zone (Kg/plot)	4	105 (82-160)	105 (81-159)	104 (82-159)	105 (84-159)	106 (88-159)
South-east zone (Kg/plot)	2	60.1(52.4-73.8)	67.5(61.0-66.0)	64.6(57.7-71.6)	58.7(53.5-63.9)	60.7(55.0-66.4)

In the 36 selectivity trials, Pendimethalin 45.5% CS performed in most cases like the reference products, i.e. the Pendimethalin reference products included in trials. The results obtained in the 36 selectivity trials supports the label claim that Pendimethalin 45.5% CS is safe to be applied pre- and post-emergence at the recommended dose rate in winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peas, carrot, parsley, strawberry, potato, asparagus, brassicas, currants, leek, parsnip, lettuce, endive, grapevine, ornamentals, artichoke, fennel, cucurbits, raspberry, sunflower, soybean, lupine, clover and alfalfa and winter oilseed repeat the recommended application interval.

### 3.4.2.3 Conclusion

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

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.

As this document clearly demonstrates, the efficacy and crop safety of Pendimethalin 45.5% CS is equivalent to the reference pendimethalin products to which it was compared. The applicant therefore wishes to cite the original registrant’s data on pendimethalin now out of protection in additional support of those recommendations on the draft label that are not adequately supported by the applicant’s data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	Applicant submitted selectivity trials carried out in N-E, S-E, MED and Maritime EPPO zone. During those field trials the impact of PENSHUI on the yield of maize and cereals (winter wheat and winter barley) and apples was studied. Lack of trials for pear. 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 PENSHUI 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.
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	<del>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.</del>
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### 3.4.2.4 Relationship between phytotoxicity and yield

No severe adverse effects were observed in all 37 selectivity trials in which crop yields were assessed.

In the tables presented in section **Błąd! Nie można odnaleźć źródła odwołania.**, the maximum level of phytotoxic symptoms, recorded as reduced crop vigour and reduction in general crop health (PHYGEN), are presented as well as the cereals, maize and apple yield achieved from untreated and treated plots in the affected trials.

No significant reductions in crop yield were recorded in any of the plots treated with Pendimethalin 45.5% CS at dose rates representative of the recommended dose rate or the 2N rate in the vast majority of the trials in which adverse effects were observed. Thus, the differences observed are considered to be due to natural variation, despite the significant differences.

Comments of zRMS:	PENSHUI (product code: 2600 E) can be consider as safe for maize and cereals crops (winter wheat and winter barley) and apples on the basis on the submitted documentation by Applicant. Lack of trials for pear. Relationship between phytotoxicity and yield for apples could not be assessed due to lack of trials.
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### 3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Thirty-six selectivity trials treated pre- and post-emergence with Pendimethalin 45.5% CS were harvested and yields recorded. Besides recording yield, assessments were also carried out on the potential impact of treatment on a range of quality parameters including dry matter, starch content, gluten content, sugar content, firmness and oil content. The summary table is based on yield quality data presented in Appendix 6 for trials conducted in the Maritime, North-east and Mediterranean zone.

The materials and methods of these trials are described in Section 3.4.

#### Winter wheat (Pre-emergence)

The results obtained from assessments on the quality of the harvested cereals seeds are presented in Table 3.4-35.

In the trials evaluated, Pendimethalin 45.5% CS had no detrimental effect on the quality parameters assessed on the harvested winter wheat seeds in the vast majority of the trials. When comparing the results obtained with Pendimethalin 45.5% CS against the results obtained with the Pendimethalin reference products at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

**Table 3.4-35: Quality of harvested winter wheat seeds – crop treated with Pendimethalin 45.5% CS, single application pre-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no of trials)			
			3.5 L/ha	7.0 L/ha	1N	2N

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no of trials)			
			3.5 L/ha	7.0 L/ha	1N	2N
<b>Selectivity trials – Maritime zone, pre-emergence</b>						
TKW	4	41.9 (34.7-47.4)	100 (99.9-100)	100 (100-100)	101 (100-101)	100 (99.1-100)
HLW	2	75.1 (70.3-79.8)	99.3 (98.6-100)	99.4 (98.7-100)	99.7 (98.3-101)	99.5 (99.0-100)
Moicon	4	13.9 (13.4-14.5)	98.2 (95.9-100)	98.8 (95.9-100)	98.9 (97.8-100)	98.9 (95.9-100)
<b>Selectivity trials – North-east zone, pre-emergence</b>						
TKW	4	42.4 (35.4-48.0)	101 (97.5-103)	100 (98.4-102)	98.7 (95.5-103)	99.0 (96.0-102)
HLW	4	74.4 (63.4-80.5)	100 (99.0-101)	101 (100-101)	99.9 (99.2-101)	99.9 (99.0-101)
Moicon	4	12.2 (11.1-13.3)	102 (95.1-109)	100 (95.4-106)	101 (96.8-106)	103 (95.4-104)
GLNCON	1	28.3	103	108	102	102
STACON	1	65.4	100	100	100	100

### Winter wheat (Post-emergence)

The results obtained from assessments on the quality of the harvested winter wheat seeds are presented in Table 3.4-36.

In the trials evaluated, Pendimethalin 45.5% CS had no detrimental effect on the quality parameters assessed on the harvested winter wheat seeds in the vast majority of the trials. When comparing the results obtained with Pendimethalin 45.5% CS against the results obtained with the Pendimethalin reference products at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

**Table 3.4-36: Quality of harvested winter wheat seeds – crop treated with Pendimethalin 45.5% CS, single application post-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no of trials)			
			3.5 L/ha	7.0 L/ha	1N	2N
<b>Selectivity trials – Maritime zone, post-emergence</b>						
TKW	4	42.5 (38.1-45.6)	101 (100-101)	101 (100-101)	100 (97.9-102)	102 (100-103)
HLW	2	61.0 (60.5-61.5)	98.4 (97.9-98.9)	99.0 (97.9-100)	99.6 (99.2-100)	97.8 (96.7-98.9)
Moicon	4	12.9 (11.8-14.0)	101 (95.7-101)	100 (96.6-100)	100 (95.7-101)	100 (100-101)
<b>Selectivity trials – North-east zone, post-emergence</b>						
TKW	4	42.4 (35.4-48.0)	100 (96.2-103)	101 (98.2-103)	101 (97.1-102)	100 (96.0-103)
HLW	4	74.4 (63.4-80.5)	100 (99.0-101)	101 (100-101)	99.9 (99.2-101)	99.9 (99.0-101)
Moicon	4	12.2 (11.1-13.3)	96.8 (88.7-103)	101 (96.0-104)	100 (95.0-103)	99.6 (93.8-108)
GLNCON	1	28.3	103	104	103	102
STACON	1	65.4	99.8	100	100	100

### Winter barley (Pre-emergence)

The results obtained from assessments on the quality of the harvested winter barley seeds are presented in Table 3.4-37.

In the trials evaluated, Pendimethalin 45.5% CS had no detrimental effect on the quality parameters assessed on the harvested winter barley seeds in the vast majority of the trials. When comparing the results obtained with Pendimethalin 45.5% CS against the results obtained with the Pendimethalin reference products at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

**Table 3.4-37: Quality of harvested winter barley seeds – crop treated with Pendimethalin 45.5% CS, single application pre-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no of trials)			
			3.5 L/ha	7.0 L/ha	1N	2N
<b>Selectivity trials – Maritime zone, pre-emergence</b>						
TKW	4	42.5 (38.1-45.6)	101 (100-102)	101 (100-102)	101 (100-103)	101 (100-102)

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no of trials)			
			3.5 L/ha	7.0 L/ha	1N	2N
HLW	2	61.0 (60.5-61.5)	99.3 (98.9-99.6)			
Moicon	4	12.9 (11.8-14.0)	101 (99.2-102)	100 (100-101)	100 (98.3-101)	100 (98.3-101)
<b>Selectivity trials – North-east zone, pre-emergence</b>						
TKW	4	48.1 (42.0-54.8)	100 (99.0-102)	99.3 (98.4-100)	97.8 (95.3-101)	99.6 (98.2-102)
HLW	4	59.5 (54.4-62.6)	101 (98.0-108)	98.9 (96.6-104)	98.2 (92.6-103)	98.7 (96.2-100)
Moicon	4	12.2 (11.3-12.9)	101 (96.1-110)	101 (94.9-106)	100 (94.4-107)	101 (98.6-108)

### Winter barley (Post-emergence)

The results obtained from assessments on the quality of the harvested winter barley seeds are presented in Table 3.4-38.

In the trials evaluated, Pendimethalin 45.5% CS had no detrimental effect on the quality parameters assessed on the harvested winter barley seeds in the vast majority of the trials. When comparing the results obtained with Pendimethalin 45.5% CS against the results obtained with the Pendimethalin reference products at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

**Table 3.4-38: Quality of harvested winter barley seeds – crop treated with Pendimethalin 45.5% CS, single application post-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no of trials)			
			3.5 L/ha	7.0 L/ha	1N	2N
<b>Selectivity trials – Maritime zone, post-emergence</b>						
TKW	4	42.5 (38.1-45.6)	101 (100-101)	101 (100-101)	100 (97.9-102)	102 (100-103)
HLW	2	61.0 (60.5-61.5)	98.4 (97.9-98.9)	99.0 (97.9-100)	99.6 (99.2-100)	97.8 (96.7-98.9)
Moicon	4	12.9 (11.8-14.0)	101 (95.7-101)	100 (96.6-100)	100 (95.7-101)	100 (100-101)
<b>Selectivity trials – North-east zone, post-emergence</b>						
TKW	4	48.1 (42.0-54.8)	100 (98.0-103)	98.5 (95.8-101)	101 (98.6-105)	92.9 (71.7-101)
HLW	4	59.5 (54.4-62.6)	101 (97.8-107)	99.3 (95.0-104)	101 (97.5-105)	98.5 (93.9-101)
Moicon	4	12.2 (11.3-12.9)	100 (95.2-108)	101 (94.9-110)	96.3 (89.9-100)	102 (99.0-109)

### Cereals (Pre-emergence)

The results obtained from assessments on the quality of the harvested cereals seeds are presented in Table 3.4-38.

In the trials evaluated, Pendimethalin 45.5% CS had no detrimental effect on the quality parameters assessed on the harvested cereals seeds in the vast majority of the trials. When comparing the results obtained with Pendimethalin 45.5% CS against the results obtained with the Pendimethalin reference products at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

**Table 3.4-39: Mediterranean zone – Quality of harvested cereals seeds – crop treated with Pendimethalin 45.5% CS, single application pre-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no of trials)			
			3.0 L/ha	6.0 L/ha	1N	2N
<b>Selectivity trials – Mediterranean zone, pre-emergence</b>						
MOICON	6	11.0 (8.7-13.7)	95.2 (77.1-106.3)	100 (84.4-115.3)	98.7 (90.6-108.3)	97.6 (87.2-106.4)

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no of trials)			
			3.0 L/ha	6.0 L/ha	1N	2N
TLW	6	34.9 (33.8-35.9)	99.8 (94.9-102.3)	100.9 (97.4-105.5)	102.9 (96.7-106.5)	101.1 (98.0-104.3)
HLW	6	52.1 (46.8-59.4)	103.4 (95.8-112.7)	96.7 (90.9-103.3)	100.2 (93.1-112.5)	106.5 (89.8-119.3)

### Cereals (Post-emergence)

The results obtained from assessments on the quality of the harvested cereals seeds are presented in [Table 3.4-39](#).

In the trials evaluated, Pendimethalin 45.5% CS had no detrimental effect on the quality parameters assessed on the harvested cereals seeds in the vast majority of the trials. When comparing the results obtained with Pendimethalin 45.5% CS against the results obtained with the Pendimethalin reference products at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

**Table 3.4-40: Mediterranean zone – Quality of harvested cereals seeds – crop treated with Pendimethalin 45.5% CS, single application post-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no of trials)			
			3.0 L/ha	6.0 L/ha	1N	2N
<b>Selectivity trials – Mediterranean zone, post-emergence</b>						
MOICON	6	11.0 (8.7-13.7)	97.5 (77.1-108.4)	98.8 (84.4-108.7)	101.1 (92.7-110.3)	96.7 (87.2-113.1)
TLW	6	34.9 (33.8-35.9)	101.1 (97.0-104.7)	101 (98.0-104.9)	102 (95.3-107.8)	102.4 (101.2-105.6)
HLW	6	52.1 (46.8-59.4)	93.8 (86.5-102)	102.5 (86.5-117.8)	97.0 (85.4-104.8)	96.0 (81.8-103.9)

### Maize (Pre-emergence)

The results obtained from assessments on the quality of the harvested maize are presented in [Table 3.4-40](#).

In the trials evaluated, Pendimethalin 45.5% CS had no detrimental effect on the quality parameters assessed on the harvested maize in the vast majority of the trials. When comparing the results obtained with Pendimethalin 45.5% CS against the results obtained with the Pendimethalin reference products at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

**Table 3.4-41: Maritime, North-east and Mediterranean zone – Quality of harvested maize – crop treated with Pendimethalin 45.5% CS, single application pre-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no of trials)			
			3.0 L/ha	6.0 L/ha	1N	2N
<b>Selectivity trials – Maritime zone, pre-emergence</b>						
MOICON	1	26.3	100	99.2	99.2	101.1
Dry matter	2	100 (100-100)	97.7 (97.4-98.0)	97.5 (96.9-98.1)	97.7 (95.4-99.9)	99.0 (97.1-100.9)
WEIFRE	1	331.3	100.6	100.4	100.5	100.5
WEIDRY	1	75.6	100	100	100.1	100
<b>Selectivity trials – North-east zone, pre-emergence</b>						
MOICON	3	23.7 (15.7-33.2)	103.7 (98.5-113.3)	104.8 (101.5-110.6)	110.2 (103.6-118.4)	108.7 (102.3-119.3)
TKW	3	300.6 (288-315)	98.4 (96.3-100.3)	100.3 (99.5-101.6)	104.4 (103.6-105.7)	103.7 (99.6-100.7)
HLW	3	70.9 (67.1-74.9)	101.4 (100.7-102.8)	101.0 (98.6-104.1)	102.3 (99.3-107)	101.7 (98.6-105.7)
<b>Selectivity trials – Mediterranean zone, pre-emergence</b>						
MOICON	1	21.1	100.5	99.1	100.5	98.1

### Maize (Post-emergence)

The results obtained from assessments on the quality of the harvested maize are presented in **Table 3.4-41**.

In the trials evaluated, Pendimethalin 45.5% CS had no detrimental effect on the quality parameters assessed on the harvested maize in the vast majority of the trials. When comparing the results obtained with Pendimethalin 45.5% CS against the results obtained with the Pendimethalin reference products at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

**Table 3.4-42: Maritime, North-east and Mediterranean zone – Quality of harvested maize – crop treated with Pendimethalin 45.5% CS, single application post-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no of trials)			
			3.0 L/ha	6.0 L/ha	1N	2N
<b>Selectivity trials – Maritime zone, post-emergence</b>						
MOICON	1	26.3	101.9	101.1	100.4	99.2
Dry matter	2	100 (100-100)	96.7 (95.9-97.4)	98.9 (98.6-99.1)	99.0 (98.2-99.7)	98.4 (97.3-99.5)
WEIFRE	1	331.3	100.2	100.4	100.5	100.5
WEIDRY	1	75.6	100	100.1	100.3	100.4
<b>Selectivity trials – North-east zone, post-emergence</b>						
MOICON	3	23.7 (15.7-33.2)	108.4 (100.9-119.8)	100.6 (97.8-102.2)	110.3(101.8-121.7)	107.5 (101.4-119.3)
TKW	3	300.6 (288-315)	104.1 (101-107.5)	100.6 (98.9-101.8)	105.6 (101.8-110)	102.7 (96.5-109.7)
HLW	3	70.9 (67.1-74.9)	101 (99.9-102.1)	102.1 (100.9-103.3)	100.7 (98.1-103.1)	99.0 (98.1-100.7)
<b>Selectivity trials – Mediterranean zone, post-emergence</b>						
MOICON	1	21.1	100	99.5	100	100

### Apple (Post-emergence)

The results obtained from assessments on the quality of the harvested maize are presented in **Table 3.4-43**

In the trials evaluated, Pendimethalin 45.5% CS had no detrimental effect on the quality parameters assessed on the harvested maize in the vast majority of the trials. When comparing the results obtained with Pendimethalin 45.5% CS against the results obtained with the Pendimethalin reference products at comparable dose rates, both products performed statistically similar on all quality parameters assessed.

**Table 3.4-43: North-east zone – Quality of harvested Apple – crop treated with Pendimethalin 45.5% CS, single application post-emergence, as % of untreated (Untreated = 100%)**

Crop, trial type	No. of trials	Untreated Mean (min-max)	Pendimethalin 45.5% CS at:		Pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max, no of trials)			
			3.0 L/ha	6.0 L/ha	1N	2N
<b>Selectivity trials – North-east zone, post-emergence</b>						
FIRMNESS	1	26.3	101.9	101.1	100.4	99.2
CONSUG	2	100 (100-100)	96.7 (95.9-97.4)	98.9 (98.6-99.1)	99.0 (98.2-99.7)	98.4 (97.3-99.5)

### 3.4.3.1 Conclusion

Pendimethalin 45.5% CS applied at the recommended dose rate did not affect the quality of the harvested yield in any of the 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.

As this BAD clearly demonstrates, the efficacy and crop safety of Pendimethalin 45.5% CS is equivalent to the reference pendimethalin products to which it was compared. The applicant therefore wishes to cite the original registrant's data on pendimethalin now out of protection in additional support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	<p>Submitted trials are sufficient for maize and cereals (winter wheat and winter barley) and apples. Lack of trials for pear. Influence of PENSHUI (product code: SHA 7600 E) on quantity and quality of yield was evaluated during selectivity research. The evaluation was carried out in accordance with EPPO guidelines. In all trials no detrimental effect on the quality of yield was recorded at the proposed dose rate and even at the double dose rate. Application of PENSHUI (product code: SHA 2600 E) provided a quality 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.</p> <p><del>In the opinion of Evaluator, studies for quality of yield for 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.</del></p>
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#### 3.4.4 Effects on transformation processes (KCP 6.4.4)

Pendimethalin 45.5% CS is composed of pendimethalin which has been widely used for several years on a range of crops including winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peas, carrot, parsley, strawberry, potato, asparagus, brassicas, currants, leek, parsnip, lettuce, endive, grapevine, ornamentals, artichoke, fennel, cucurbits, raspberry, sunflower, soybean, lupine, clover and alfalfa and winter oilseed rape without identifying any quality problems on the treated crops.

In winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peas, carrot, parsley, strawberry, potato, asparagus, brassicas, currants, leek, parsnip, lettuce, endive, grapevine, ornamentals, artichoke, fennel, cucurbits, raspberry, sunflower, soybean, lupine, clover and alfalfa and winter oilseed rape, Pendimethalin 45.5% CS is recommended applied pre- and post-emergence. As the treatment is recommended applied early in the season, before inflorescence emergence and heading, and as the active ingredient is not systemic, it is therefore not expected that the active ingredient is transferred to the seeds. For further information on residues, please refer to Part B, Section 7: Metabolism and residues.

Comments of zRMS:	<p>Assuming a long history of safe use of a.s.: pendimethalin no special trials dedicated to evaluation of effects of PENSHUI (product code: SHA 2600 E) on transformation process were undertaken.</p> <p>In the opinion of Evaluator, since applications of PENSHUI are made at an early stage in the crop's development there is no risk that the actives would be translocated to the grain. The germination of seeds (ex. maize, cereals) will be not negatively affected by the application of PENSHUI, in the opinion of Evaluator.</p>
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### 3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Pendimethalin 45.5% CS is composed of pendimethalin, which has been widely used for several years on a range of crops, including winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peas, 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, without identifying any issues in regard to the ability of seeds of treated plants to germinate.

In accordance with the EPPO guideline PP 1/135 (4) “Phytotoxicity assessment”, Table 2, no germination test is required if the herbicide is applied pre-emergence in seed crops, as is the recommendation of use of Pendimethalin 45.5% CS in winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peas, 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.

**The product complies with the Uniform Principles.**

Comments of zRMS:	<p>The active substances: pendimethalin, is commonly used for many years in many countries. No adverse effects on parts of plant used for propagating purposes were reported.</p> <p>No adverse effect on the yield and quality and no phytotoxicity symptoms were recorded in the field trials. Also, no information is available pointing to presence of any limitations to using of pendimethalin in seed crops of winter cereals, maize, pome fruits, stone fruits, bulb vegetables, beans, peas, 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.</p> <p><b>In the opinion of Evaluator, the product PENSHUI has no negative impact on parts of plants used for propagating purposes.</b></p>
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### 3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

#### 3.5.1 Impact on succeeding crops (KCP 6.5.1)

Reference:	KCP 3.5.1-01
Report	A study to determine the effects of Pendimethalin 40% SC (pendimethalin 400 g/L on the seedling emergence and growth of terrestrial plants Deslandes, L. 2013. Study code: 34SRFR12C6. SynTech Research France S.A.S.
Guideline(s):	OECD Guideline No. 208 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

## Materials and methods

PENDIMETHALIN 40% SC (batch No.0007955648) was diluted in distilled water and applied with a spray application volume of 200 L water/ha onto bare soil. Distilled water was used as a control treatment and KATANA (nominal content of flazasulfuron: 250 g/kg) was applied at 50 g a.s./ha as a reference treatment. Multiple rate testing (5 test item rates per plant species) preceded by a non-GLP range-finding test was conducted to establish a rate-response relationship and, where possible to determine values for ER50 (effective rate 50%), LOER (lowest observed effect rate) and NOER (no observed effect rate) for each species tested. The plants (wheat, ryegrass, lettuce, tomato, oil seed rape and pea) were evaluated against distilled water control plants for effects on seedling emergence and early growth once a week between 14 and 28 days after 50% emergence of seedlings in the control groups. The main endpoints measured were seedling emergence and biomass (shoot weight). Shoot height and mortality were measured as well and visible detrimental effects (phytotoxicity) were visually assessed. Data were analysed for significant differences compared to the control group using adequate statistical methods and to determine the ER50, LOER and NOER for each species tested.

## Results

Summary of effects of PENDIMETHALIN 40% SC on the seedling emergence and early growth of terrestrial non-target plants at 28DAE

Test item	PENDIMETHALIN 40% SC (Pendimethalin 400 g/l)					
Test organism /Exposure	Terrestrial non-target plants / Foliar spray application					
<b>Dry weight</b>	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
ER50 [g a.s./ha]	> 1760	> 1760	269.8	425.1	434.0	> 1760
LOER [g a.s./ha]	> 1760	> 1760	196	587	587	> 1760
NOER [g a.s./ha]	1760	1760	66	196	196	1760
<b>Height</b>	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
ER50 [g a.s./ha]	> 1760	> 1760	> 1760	554	> 1760	> 1760
LOER [g a.s./ha]	> 1760	> 1760	> 587	587	1760	> 1760
NOER [g a.s./ha]	1760	1760	587	196	587	1760
<b>Emergence</b>	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
ER50 [g a.s./ha]	> 1760	> 1760	> 1760	> 1760	> 1760	> 1760
LOER [g a.s./ha]	> 1760	> 1760	> 1760	> 1760	> 1760	> 1760
NOER [g a.s./ha]	1760	1760	1760	1760	1760	1760
<b>Mortality</b>	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
LR50 [g a.s./ha]	> 1760	> 1760	339.2	809.8	1088	> 1760
LOER [g a.s./ha]	> 1760	1760	587	1760	1760	> 1760
NOER [g a.s./ha]	1760	587	196	587	587	1760

## Conclusion

The study is valid since the mean seedling emergence was > 70% in the control for each plant species (actual mean values: 100% for tomato, 95% for lettuce, 90 % for wheat, oil seed rape and pea and 80% for ryegrass), mean plant survival in the control was ≥ 90% at the end of the test (actual values: 100% for all species), there was no visible phytotoxic effect in the control and the recovery of the highest test item concentration (1760 g a.s./ha, corresponding to 8.8 g a.s./L) was within the required range of 70-110% of nominal concentration (actual analysed concentration: 7.2 g a.s./L, corresponding to 81.8 % of nominal concentration).

PENDIMETHALIN 40% SC was shown to have rate-related effects on the seedling emergence and early growth of terrestrial non-target plants.

Lettuce (*Lactuca sativa*) was the most sensitive species in term of effects on biomass (dry weight), with a NOER biomass of 66 g a.s./ha, a LOER biomass of 196 g a.s./ha and an ER50 biomass calculated to be 269.8 g a.s./ha (95% confidence limits not calculable). The least sensitive species were found to be wheat, ryegrass and pea with a NOER biomass of 1760 g a.s./ha and both LOER biomass and ER50 biomass estimated to be > 1760 g a.s./ha.

Tomato (*Solanum lycopersicum*) was the most sensitive species in term of effects on height (shoot length), with a NOER height of 196 g a.s./ha, a LOER height of 587 g a.s./ha and an ER50 height calculated to be 554.0 g a.s./ha (95% confidence limits not calculable). The least sensitive species were wheat, ryegrass and pea with a NOER height of 1760 g a.s./ha and both LOER height and ER50 height estimated to be > 1760 g a.s./ha.

For emergence endpoint, the NOER emergence was 1760 g a.s./ha and both LOER emergence and ER50 emergence were > 1760 g a.s./ha for all species.

Lettuce (*Lactuca sativa*) was the most sensitive species in term of effects on mortality, with a NOER mortality of 196 g a.s./ha, a LOER mortality of 587 g a.s./ha and an LR50 mortality calculated to be 339.2 g a.s./ha (95% confidence limits 307.2 - 374.6 g a.s./ha). The least sensitive species were found to be wheat and pea with a NOER mortality of 1760 g a.s./ha and both LOER mortality and LR50 mortality estimated to be > 1760 g a.s./ha.

The overall lowest ER50 (biomass endpoint; 269.8 g a.s./ha) was observed with the lettuce (*Lactuca sativa*).

Comments of zRMS:	<p>The EU requirements on plant protection products requires, that sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops if studies and evaluations presented in the other part of the dossier, show that significant residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials up to sowing or planting time of possible succeeding crops. Therefore, the Applicant should present the assessment of the possible effect of PENSHUI (product code: SHA 2600 E) on crops grown as rotational or replacement crops following crops treated with that product, prepared in accordance to the EPPO Standard Efficacy evaluation of plant protection products.</p> <p>Effects on succeeding crops (PP 1/207 (2)). This standard is intended as a general standard on the methods used to examine whether the active substance of a plant protection product can cause negative effects on crops grown after a crop treated with that product. These crops can be grown as normal rotational crops as well as replacement crops in case of crop failure.</p> <p>Applicant submitted a study to determine the effects of Pendimethalin 40% SC (pendimethalin 400 g/L on the seedling emergence and growth of terrestrial plant Deslandes, L. 2013. Study code: 34SRFR12C6. SynTech Research France S.A.S. PENDIMETHALIN 40% SC was shown to have rate-related effects on the seedling emergence and early growth of terrestrial non-target plants.</p> <p>Product decomposes in the soil during the growing season without endangering crops. Therefore, it can be assumed that application PENSHUI (product code: SHA 2600 E) in maize and winter cereals will pose no risk for succeeding crops.</p> <p>The half-life (DT<sub>50</sub>) for pendimethalin is 27-186 days. As regards effects on suc-</p>
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	<p>ceeding 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: <i>“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.”</i></p> <p>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: <i>However, leaf discoloration is possible in broadleaf crops and winter oilseed rape.</i></p>
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### 3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

Reference:	KCP 3.5.2-01
Report	A study to determine the effects of Pendimethalin 40% SC (pendimethalin 400 g/L on the vegetative vigour of terrestrial plants Deslandes, L. 2013. Study code: 34SRFR12C7. SynTech Research France S.A.S.
Guideline(s):	OECD Guideline No. 227 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

#### Materials and methods

PENDIMETHALIN 40% SC (batch No. 0007955648) was diluted in distilled water and applied with a spray application volume of 200 L water/ha to leaves and above-ground parts of terrestrial non-target plants. Distilled water was used as a control treatment and ROUNDUP FLASH PLUS (nominal content of glyphosate acid: 450 g/L) was applied at 1350 g a.s./ha as a toxic reference treatment.

Multiple rate testing (5 test item rates per plant species) preceded by a non-GLP range-finding test was conducted to establish a rate-response relationship and, where possible to determine values for ER50 (effective rate 50%), LOER (lowest observed effect rate) and NOER (no observed effect rate) for each species tested.

The plants (wheat, ryegrass, lettuce, tomato, oil seed rape and pea) were evaluated against distilled water control plants for effects on vigour and growth once a week between 7 and 28 days after treatment. The main endpoint measured was biomass (shoot weight). Shoot height and mortality were measured as well and visible detrimental effects (phytotoxicity) were visually assessed.

Data were analysed for significant differences compared to the control group using adequate statistical methods and to determine the ER50, LOER and NOER for each species tested.

#### Results

Summary of effects of PENDIMETHALIN 40% SC on the vegetative vigour of terrestrial non-target plants at day 28

Test item	PENDIMETHALIN 40 % EC (Pendimethalin 400 g/l)
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Test organism /Exposure	Terrestrial non-target plants / Foliar spray application					
<b>Dry weight</b>	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
ER50 [g a.s./ha]	> 1760	> 1760	223.8	149.0	> 1760	> 1760
LOER [g a.s./ha]	> 1760	> 1760	66	66	66	> 1760
NOER [g a.s./ha]	1760	1760	22	22	22	1760
<b>Height</b>	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
ER50 [g a.s./ha]	> 1760	> 1760	> 196	> 196	> 1760	> 1760
LOER [g a.s./ha]	> 1760	> 1760	> 196	196	587	> 1760
NOER [g a.s./ha]	1760	1760	196	66	196	1760
<b>Mortality</b>	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
ER50 [g a.s./ha]	> 1760	> 1760	> 196	> 196	> 1760	> 1760
LOER [g a.s./ha]	> 176	> 1760	> 196	> 196	> 1760	> 1760
NOER [g a.s./ha]	1760	1760	196	196	1760	1760

### Conclusion

The study is valid since the seedling emergence was > 70% for each plant species (actual values: 100% for wheat, lettuce and pea; 96% for oil seed rape; 95% for ryegrass and 92% for tomato), mean plant survival in the control was > 90% at the end of the test (actual values: 100%) for all species, there was no

visible phytotoxic effect in the control and the recovery of the highest test item concentration (1760 g a.s./ha, corresponding to 8.8 g a.s./L) was within the required range of 70-110% of nominal concentration (actual analysed concentration: 6.2 g a.s./L, corresponding to 70.5% of nominal concentration).

PENDIMETHALIN 40% SC was shown to have rate-related effects on the vegetative vigour of terrestrial non-target plants.

Tomato (*Solanum lycopersicum* L.) was the most sensitive species in term of effects on biomass (dry weight), with a NOER biomass of 22 g a.s./ha, a LOER biomass of 66 g a.s./ha and an ER 50 biomass calculated to be 149.0 g a.s./ha (95% confidence limits not calculable). The least sensitive species were found to be wheat, ryegrass and pea with a NOER biomass of 1760 g a.s./ha and both LOER biomass and ER 50 biomass estimated to be > 1760 g a.s./ha.

Tomato (*Solanum lycopersicum* L.) was the most sensitive species in term of effects on height (shoot height), with a NOER height of 66 g a.s./ha, a LOER height of 196 g a.s./ha and an ER50 height estimated to be > 196 g a.s./ha. The least sensitive species were wheat, ryegrass and pea with a NOER height of 1760 g a.s./ha and both LOER height and ER50 height estimated to be > 1760 g a.s./ha.

For mortality parameter, the NOER mortality was 196 g a.s./ha and both LOER mortality and ER50 mortality were estimated to be > 196 g a.s./ha for lettuce and tomato. For all other species, the NOER mortality was 1760 g a.s./ha and both LOER mortality and ER50 mortality were estimated to be > 1760 g a.s./ha.

The overall lowest ER50 (biomass endpoint; 149.0 g a.s./ha with 95% confidence limits not calculable) was observed with the tomato (*Solanum lycopersicum* L.).

### Risk Assessment

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

**Table 3.5-1: Assessment of the risk for non-target plants due to the use of Pendimethalin 45.5% CS in cotton**

<b>Intended use</b>		Cotton		
<b>Active substance/product</b>		Pendimethalin 45.5% CS		
<b>Application rate (g/ha)</b>		1 × 1467 g a.s./ha*		
<b>MAF</b>		1		
<b>Test species</b>	<b>ER<sub>50</sub> (g/ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>TER criterion: TER ≥ 5</b>
Tomato	149	2.77	40.64	<b>3.67</b>

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

\*For application between rows the treated area has been considered as the 75% as worst case of the application of 1956 g a.s./ha.

**Table 3.5-2: Assessment of the risk for non-target plants due to the use of Pendimethalin 45.5% CS in cereals, maize, garlic, artichoke, brassicas, onion, sunflower, lettuce, potato, tomato, soybean and strawberry**

<b>Intended use</b>		Cereals, maize, garlic, artichoke, brassicas, onion, sunflower, lettuce, potato, tomato, soybean and strawberry		
<b>Active substance/product</b>		Pendimethalin 45.5% CS		
<b>Application rate (g/ha)</b>		1 × 1365 g a.s./ha		
<b>MAF</b>		1		
<b>Test species</b>	<b>ER<sub>50</sub> (g/ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>TER criterion: TER ≥ 5</b>
Tomato	149	2.77	37.81	<b>3.94</b>

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 3.5-3: Assessment of the risk for non-target plants due to the use of Pendimethalin 45.5% CS in pome fruits, stone fruits, citrus, grapevine and ornamentals**

<b>Intended use</b>		Pome fruits, stone fruits, citrus, grapevine and ornamentals		
<b>Active substance/product</b>		Pendimethalin 45.5% CS		
<b>Application rate (g/ha)</b>		1 × 1024 g a.s./ha*		
<b>MAF</b>		1		
<b>Test species</b>	<b>ER<sub>50</sub> (g/ha)</b>	<b>Drift rate</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>TER criterion: TER ≥ 5</b>
Tomato	149	2.77	28.36	5.25

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

\*For application between rows the treated area has been considered as the 75% as worst case of the application of 1365 a.s./ha.

**Table 3.5-4: Assessment of the risk for non-target plants due to the use of Pendimethalin 40% SC in carrot, chickpea, bean, broad bean, field bean, peas**

<b>Intended use</b>		Carrot, chickpea, bean, broad bean, field bean, peas		
<b>Active substance/product</b>		Pendimethalin 45.5% CS		
<b>Application rate (g/ha)</b>		1 x 1137 g a.s./ha		
<b>MAF</b>		1.0		

Test species	ER <sub>50</sub> (g a.s./ha)	Drift rate	PER <sub>off-field</sub> (g/ha)	TER criterion: TER ≥ 5
Tomato	149	2.77	31.49	<b>4.73</b>

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

**Table 3.5-5: Assessment of the risk for non-target plants due to the use of Pendimethalin 45.5% CS in eggplant, pepper**

<b>Intended use</b>	Eggplant, pepper			
<b>Active substance/product</b>	Pendimethalin 45.5% CS			
<b>Application rate (g/ha)</b>	1 x 910 g a.s./ha			
<b>MAF</b>	1.0			
Test species	ER <sub>50</sub> (g a.s./ha)	Drift rate	PER <sub>off-field</sub> (g/ha)	TER criterion: TER ≥ 5
Tomato	149	2.77	25.21	5.91

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

No risk to non-target plants is observed in pome fruits, stone fruits, citrus, grapevine, ornamentals, eggplant and pepper after the application of Pendimethalin 45.5% CS according to the GAP. For the rest of the crops, risk mitigation measures will be needed.

### 3.5.2.1 Higher-tier risk assessment

Not relevant.

### 3.5.2.2 Risk mitigation measures

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

**Table 3.5-6: Risk assessment for non-target terrestrial plants due to the use of Pendimethalin 45.5% CS in cotton considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)**

<b>Intended use</b>	Cotton				
<b>Active substance/product</b>	Pendimethalin 45.5% CS				
<b>Application rate (g/ha)</b>	1 × 1467 g a.s./ha*				
<b>MAF</b>	1				
Buffer strip (m)	Drift rate (%)	PER <sub>off-field</sub> (g/ha)	PER <sub>off-field</sub> 50 % drift red. (g/ha)	PER <sub>off-field</sub> 75 % drift red. (g/ha)	PER <sub>off-field</sub> 90 % drift red. (g/ha)
1/3	2.77	37.81	18.91	-	-
5	0.57	8.36	-	-	-
<b>Toxicity value</b> ER <sub>50</sub> = 149 g/ha	<b>TER</b> criterion: TER ≥ 5				

1/3	<b>3.94</b>	7.88	-	-
5	17.82	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

\*For application between rows the treated area has been considered as the 75% as worst case of the application of 1956 g a.s./ha.

**Table 3.5-7: Risk assessment for non-target terrestrial plants due to the use of Pendimethalin 45.5% CS in cereals, maize, garlic, artichoke, brassicas, onion, sunflower, lettuce, potato, tomato, soybean and strawberry considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)**

<b>Intended use</b>		Cereals, maize, garlic, artichoke, brassicas, onion, sunflower, lettuce, potato, tomato, soybean, strawberry and ornamentals			
<b>Active substance/product</b>		Pendimethalin 45.5% CS			
<b>Application rate (g/ha)</b>		1 × 1365 g a.s./ha			
<b>MAF</b>		1			
<b>Buffer strip (m)</b>	<b>Drift rate (%)</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>PER<sub>off-field</sub> 50 % drift red. (g/ha)</b>	<b>PER<sub>off-field</sub> 75 % drift red. (g/ha)</b>	<b>PER<sub>off-field</sub> 90 % drift red. (g/ha)</b>
1/3	2.77	37.81	18.91	-	-
5	0.57	7.78	-	-	-
<b>Toxicity value</b>		<b>TER</b>			
ER <sub>50</sub> = 149 g/ha		criterion: TER ≥ 5			
1/3		<b>3.98</b>	7.88	-	-
5		19.15	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

**Table 3.5-8: Risk assessment for non-target terrestrial plants due to the use of Pendimethalin 40% SC in carrot, chickpea, bean, broad bean, field bean, peas considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)**

<b>Intended use</b>		Carrot, chickpea, bean, broad bean, field bean, peas			
<b>Active substance/product</b>		Pendimethalin 45.5% CS			
<b>Application rate (g/ha)</b>		1 × 1137 g a.s./ha			
<b>MAF</b>		1			
<b>Buffer strip (m)</b>	<b>Drift rate (%)</b>	<b>PER<sub>off-field</sub> (g/ha)</b>	<b>PER<sub>off-field</sub> 50 % drift red. (g/ha)</b>	<b>PER<sub>off-field</sub> 75 % drift red. (g/ha)</b>	<b>PER<sub>off-field</sub> 90 % drift red. (g/ha)</b>
1/3	2.77	31.49	15.75	-	-
5	0.57	6.48			
<b>Toxicity value</b>		<b>TER</b>			
ER <sub>50</sub> = 149 g/ha		criterion: TER ≥ 5			
1/3		<b>4.73</b>	9.46	-	-
5		22.99	-	-	-

AF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in

bold breach the relevant trigger.

According to the risk assessment performed above, no risk to non-target plants is expected after the application of Pendimethalin 45.5% CS when the following risk mitigation measures are considered:

Cotton, cereals, maize, garlic, artichoke, brassicas, onion, sunflower, lettuce, potato, tomato, soybean, strawberry, carrot, chickpea, bean, broad bean, field bean and peas: 5 m no spray buffer zone or no spray buffer zone with 50% drift reducing nozzles

### Overall conclusions

No risk to non-target plants located outside the treated area after application of PENSHUI is expected in eggplant and pepper. For the other crops, no risk is expected when risk mitigation measures are considered:

**Cotton, cereals, maize, pome fruit, stone fruits, citrus, garlic, artichoke, brassicas, onion, sunflower, lettuce, potato, tomato, soybean, grapevine, strawberry, ornamentals, carrot, chickpea, bean, broad bean, field bean and peas - SPe3:** To protect non-target plants respect an unsprayed buffer zone of 5 m or no-spray buffer zone with 50% drift reducing nozzles to non-agricultural land

Comments of zRMS:	<p>As every plant protection product – including PENSHUI (product code: SHA 2600 E) should not be used during wind that may cause drift spray solution on adjacent plants. Such recommendation will be contained on the label - instruction of use.</p> <p>Applicant submitted a study to determine the effects of Pendimethalin 40% SC (pendimethalin 400 g/L on the vegetative vigour of terrestrial plants Deslandes, L. 2013. Study code: 34SRFR12C7. SynTech Research France S.A.S. According to the risk assessment performed above, no risk to non-target plants is expected after the application of Pendimethalin 45.5% CS when the following risk mitigation measures are considered: <i>Cotton, cereals, maize, garlic, artichoke, brassicas, onion, sunflower, lettuce, potato, tomato, soy-bean, strawberry, carrot, chickpea, bean, broad bean, field bean and peas: 5 m no spray buffer zone or no spray buffer zone with 50% drift reducing nozzles.</i></p>
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### 3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

From the experimentation carried out with Pendimethalin 45.5% CS in 2019, 2020 and 2021, 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.

### Compatibility with current management practices including IPM

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

Comments of zRMS:	Detailed studies on the possible adverse effects to beneficial organisms are sub-
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mitted and summarised in Part B, Section 9 (Ecotoxicology).

### 3.5.4 Tank cleaning

Relevant information on tank cleaning is included in dRR Part B124. Please refer to this section for complete evaluation.

Comments of zRMS:	<p>Tank cleaning procedure is submitted in dRR B124.</p> <p>ZRMs agree with Applicant that residues of the spray liquid after treatment should be handled in a manner that reduces the risk of surface water and groundwater contamination, in the meaning of the Water Law regulations, and of ground contamination, i.e:</p> <ul style="list-style-type: none"> <li>- after prior dilution, use on the surface on which the treatment was carried out, if possible or</li> <li>- neutralize using technical solutions ensuring biological degradation of active substances of plant protection products, or</li> <li>- neutralise in another way, in accordance with waste regulations.</li> </ul>
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### 3.6 Other/special studies

No other studies were conducted

### 3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified, and the trials were conducted according to GEP guidelines.

**Table 3.7-1: List of test facilities**

Testing facility	Zone	Country	Year and trial type				
			Efficacy trials	Selectivity trials	Efficacy trials	Selectivity trials	
			2019	2019	2020	2020	2021
<b>Maize</b>							
Zemservis ZSD	MAR	Czech Republic	4	2			
ZS Trutnov	MAR	Czech Republic	2				
ZS Rymarov	MAR	Czech Republic	2	2			
ZS Kujavy	MAR	Czech Republic	4				
Fertico	N-E	Poland	6	1			
Institute of Agriculture, RCAF	N-E	Lithuania	2	1			
Sharda Poland	N-E	Poland	4	2			
UKSUP	S-E	Slovakia	2				
ICDPP	S-E	Romania	2				
Argicola 2000	MED	Italy	4	1			
<b>Total, ZEAMX</b>			<b>32</b>	<b>9</b>			
<b>Cereals</b>							
Biotek	MED	Spain	12	6			
Zemservis, zkusebni stanice Domaninek s.r.o.	MAR	Czech Republic	5	4			
Zkusebni stanice Trutnov s.r.o.	MAR	Czech Republic			3		
Zkusebni stanice Rymarov s.r.o.	MAR	Czech Republic			6	4	
ZZS Kujavy s.r.o.	MAR	Czech Republic			4		
Sharda Poland SP. Z o.o.	N-E	Poland			12	4	
Estonia Crop Research Institute	N-E	Estonia	1	2			
LAAMC	N-E	Lithuania			2	2	

Total, HORX, TRAZX				18	12	27	10	
<b>Apple</b>								
PP Trial	MAR	Czech Republic	6					
SGS	N-E	Poland	5					
SynTech	N-E	Poland	1					
ICDPP	S-E	Romania	2					
Argicola 2000	MED	Italy	2					
Biotek	MED	Spain	4					
Fertico	N-E	Poland						4
Plant-Art Research	N-S	Hungary						2
<b>Total, MABSD</b>			<b>20</b>					<b>6</b>
<b>Total, All crops</b>			<b>70</b>	<b>21</b>	<b>27</b>	<b>10</b>	<b>6</b>	

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
KCP 6.0-001		2021	Biological Assessment Dossier: Pendimethalin 45.5% CS (455 g/L pendimethalin CS) – EU Central zone Sharda Cropchem España -, - Unpublished	N	Sharda