

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 2600 E

Product name(s): PENSHUI

Chemical active substances:

Pendimethalin, 455 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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Version history

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June 2021	Applicant update
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April 2022	Assessment of the completed DRR

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

This report has been completed and marked by the applicant (January 2021, text highlighted in green; February 2021, text highlighted in blue).

The text highlighted in grey (comments and corrections) is provided by the evaluator.

Storage stability

Pendimethalin and metabolite CL 202347 are stable in commodities with high water, high acid, high protein, high starch and in high lipid commodity for at least a period of 12-43 months.

New storage stability studies were performed (XXX J., 2019a and XXX J., 2019b). Studies are accepted.

The results of these studies showed that Pendimethalin is stable in apple and oilseed rape samples when stored at $\leq -18^{\circ}\text{C}$ for period of up to 24 months.

Sufficient stability has been demonstrated to support the residue data presented in this submission.

No further data are required.

Metabolism in plants and animals

The metabolism in plants and livestock for the active substance was reviewed during the Annex I inclusion and renewal process.

Plant residue definitions for monitoring and risk assessment: Pendimethalin (EFSA, 2016)

Animal residue definitions for monitoring and risk assessment: Pendimethalin (EFSA, 2016)

The data evaluated are sufficient to support the proposed uses.

Additionally high temperature hydrolysis of ^{14}C -pendimethalin under cooking, baking and pasteurization conditions new study have been submitted by the applicant in the framework of this application. Study is accepted.

The study demonstrated that pendimethalin was hydrolytically stable under conditions representative of pasteurization, baking or boiling and sterilization.

Magnitude of residues in plants

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

Proposed uses:

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

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

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

Proposed uses are within the EU GAP.

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

Trials GAP:

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

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

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

Results

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

Barley grain: 7 x <0.01, 0.01

Additionally applicant refers to the unprotected EU studies.

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

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

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

Uses are accepted.

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

Maize

Proposed uses:

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

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

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

Trials GAP:

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

Results

Maize grain: 6 x < 0.01 mg/kg

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

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

Uses are accepted.

Pome fruits (apple, pear)

Proposed use:

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

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

Trials GAP (more critical than proposed):

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

Results:

Apple: 6 x < 0.01 mg/kg

Additionally, applicant refers to the unprotected EU studies.

Pears

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

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

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

Uses are accepted.

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

Proposed use:

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

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

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

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

Trials GAP (more critical than proposed):

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

Results:

Apple: 4 x < 0.01 mg/kg

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

Uses are accepted

Sunflower, Soybean

Proposed use:

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

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

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

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

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

Results:

Soybean: 4 x < 0.01 mg/kg

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

Additionally, applicant refers to the unprotected EU studies.

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

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

Uses are accepted.

Winter oilseed rape

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

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

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

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

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

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

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

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

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

Garlic

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

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

Onion

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

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

Residues: 4x < 0.01 mg/kg

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

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

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

Uses are accepted.

Bean, pea, broad bean, field bean

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

EU GAPs:

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

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

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

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

Beans

Applicant refers to the unprotected EU studies

Residues:

Pods: $9x < 0.05$ mg/kg

Seed: $9x < 0.05$ mg/kg

Peas

Applicant refers to the new studies and unprotected EU studies.

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

Residues (new studies):

Seeds: $9x < 0.01$ mg/kg

Pods: $2x < 0.0025$ (ND)

Seeds with pods: < 0.003 (ND)

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

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

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

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

Lupine

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

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

Carrot, parsley

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

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

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

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

The number of trials is sufficient as to support the use of Pendimethalin in carrot according to the pro-

posed GAP in Central Zone.

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

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

Parsnip

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

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

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

Leeks

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

Applicant refers to the unprotected EU studies.

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

Residues:

6x<0.05 mg/kg

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

6 additional residue trials on leek are required.

Artichokes

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

Applicant refers to the unprotected EU studies.

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

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

Proposed uses on stem vegetables are not accepted.

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

6 additional residue trials on artichokes are required

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

Flowering brassica (broccoli, cauliflower)

Head brassica (brussels sprouts, cabbage)

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

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

Uses are accepted.

Broccoli

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

Cauliflower

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

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

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

Cabbage

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

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

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

According to SANCO 7525/VI/95 Rev. 10.3 extrapolation from 8 trials on head cabbages (0242020) + 8 trials on cauliflower (0241020) to whole subgroups (a) flowering brassica (0241000) and (b) head brassica (0242000) before forming of the edible part is possible.

Strawberry

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

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

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

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

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

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

Proposed uses is accepted only at BBCH: 00

Grapevine

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

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

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

Results: 2x<0.003 (ND)

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

Results; 18x<0.05 mg/kg

Use is accepted.

cane fruits (Raspberries (red and yellow))

other small fruits and berries (currants)

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

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

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

lettuces and salad plants (lettuce, endive)

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

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

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

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

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

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

Potato

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

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

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

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

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

Additionally applicant refers to the unprotected EU studies.

Use is accepted.

Cucurbits with edible peel (cucumber, zucchini, squash)

Cucurbits with inedible peel (melons)

Residue trials are not provided. Uses are not accepted.

Clover, alfalfa

No residue trials available. Uses are not accepted.

Residue data and animal intake are required.

Magnitude of residues in livestock

There is no risk for animal MRLs to be exceeded.

Magnitude of residues in processed commodities

As quantifiable residues of pendimethalin are not expected in the edible parts of most crops under consideration, and as consumer exposure is far below 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing.

Magnitude of residues in representative succeeding crops

EFSA Journal 2016;14(3):4420:

The radioactive residues were characterised as polar fractions further incorporated into the natural compounds of the plant tissues (16% of TRR in wheat straw, up to 81% of TRR in wheat grain). The parent compound was identified at lower proportions (<1% TRR in wheat grain to 19% TRR in immature lettuce) whilst metabolite M455H030 was identified in radish root only (13% TRR-0.011 mg/kg) at 30 d plant back interval.

Field rotational crop study are not required.

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

Estimation of exposure through diet and other means

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

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation SHA 2600 E are presented in Table 7.1-1. They have been selected from the individual GAPs in the CEU. A list of all intended uses within the SHA 2600 E is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLS for pendimethalin as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of pendimethalin residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

- Residue trials for Stone fruits at BBCH 00-09, Winter oilseed rape at BBCH 10-16, asparagus (4 residue trials on asparagus), leek (6 additional residue trials on leek), Clover (residue data and animals intake), alfalfa (residue data and animals intake), Artichoke (6 additional residue trials on artichokes), Fennel (4 residue trials on fennel) , Cucurbits (melon, cucumber, squash, zucchini; 8 residue trials on cucumbers and 8 residue trials on melons)
-

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
1	Winter cereals (wheat, barley, rye, oats, triticale)	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	1	NA		200-400	1.137-1.59		A
2	Winter cereals (wheat, barley, rye, oats, triticale)	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Post emergence BBCH 10-13	1	NA		200-400	1.137-1.59		A
3	Maize	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	1	NA		200-600	1.137-1.59		A
4	Maize	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Post emergence BBCH 10-13	1	NA		200-600	1.137-1.59		A
5	Pome fruits (apple, pear)	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09 applications between rows	1	NA		200-600	1.59		A
6	Stone fruits (peach, apricot, plum, nectarine, cherry)	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09 applications between rows	1	NA		200-600	1.59		A Only post-harvest use is acceptable

7	Sunflower	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	1	NA		200-600	1.183		A
8	Soybean	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	1	NA		200-600	1.183		A
9	Bulb vegetables (onion, garlic, shallot, spring onion)	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	1	NA		200-600	1.137-1.59		A
10	Bulb vegetables (onion, garlic, shallot, spring onion)	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Post emergence BBCH 10-13	1	NA		200-600	1.137-1.59		A
11	Bean, pea, broad bean, field bean	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	1	NA		200-600	1.137-1.59		A
12	Carrot, parsley	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	1	NA		200-600	1.137-1.59		A
13	Lupine	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	1	NA		200-600	1.183		A
14	Winter oilseed rape	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	1	NA		200-400	0.455		A
15	Winter oilseed rape	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Post emergence BBCH 10-16	1	NA		200-400	0.91		A
16	Asparagus	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	1	NA		200-400	1.59		N

17	Brassica vegetables (broccoli, Brussels sprouts, cabbage, cauliflower)	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre-transplanting	I	NA		200-400	1.137-1.59		A
18	Strawberry	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09 applications between rows	I	NA		200-400	1.365		A Only at BBCH: 00
19	Raspberry	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09 applications between rows	I	NA		200-400	1.59 1.365		A Only BBCH: 00 Application rate: max. 1.365
20	Currants	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09 applications between rows	I	NA		200-400	1.59 1.365		A Only BBCH: 00 Application rate: max. 1.365
21	Leek	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	I	NA		200-400	1.59		N
22	Leek	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Post emergence BBCH 10-13	I	NA		200-400	1.59		N
23	Parsnip	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	I	NA		200-400	1.59		A
24	Lettuce, endive	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre-transplanting	I	NA		200-400	1.59		A
25	Potato	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	I	NA		200-400	1.137-1.59		A

26	Grapevine	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09 applications between rows	I	NA		200-400	1.59		A
27	Ornamentals	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	I	NA		200-400	1.0		A
28	Clover, alfalfa	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Post emergence BBCH 13-18	I	NA		200-400	1.59		N
29	Artichoke	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	I	NA		200-400	1.59		N
30	Fennel	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	I	NA		200-400	1.59		N
31	Cucurbits (melon, cucumber, squash, zucchini)	CEU	SHA 2600 E	F	Broadleaved and grass weeds	CS	455 g/L	Spray	Pre emergence BBCH 00-09	I	NA		200-400	1.59		N

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

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

Explanation for Column 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation SHA 2600 E is composed of pendimethalin.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of pendimethalin

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

7.1.2.1 Summary for pendimethalin

Table 7.1-3: Summary for pendimethalin

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1-2	Wheat	Yes	Yes	Yes	Yes	Yes	No	No
1-2	Barley	Yes	Yes	Yes	Yes	Yes		No
1-2	Rye	Yes	Yes	Yes	Yes	Yes		No
1-2	Oats	Yes	Yes	Yes	Yes	Yes		No
1-2	Triticale	Yes	Yes	Yes	Yes	Yes		No
3-4	Maize	Yes	Yes	Yes	Yes	Yes		No
5	Apple	Yes	Yes	Yes	Yes	Yes		No
5	Pear	Yes	Yes	Yes	Yes	Yes		No
6	Peach	Yes	Yes	Yes	Yes	Yes		No
6	Apricot	Yes	Yes	Yes	Yes	Yes		No
6	Plum	Yes	Yes	Yes	Yes	Yes		No
6	Nectarine	Yes	Yes	Yes	Yes	Yes		No
6	Cherry	Yes	Yes	Yes	Yes	Yes		No
7	Sunflower	Yes	Yes	Yes	Yes	Yes		No
8	Soybean	Yes	Yes	Yes	Yes	Yes		No
9-10	Onion	Yes	Yes	Yes	Yes	Yes		No
9-10	Garlic	Yes	Yes	Yes	Yes	Yes		No
9-10	Shallot	Yes	Yes	Yes	Yes	Yes	No	

Use- No.*	Crop	Plant me- tabolism covered?	Sufficient residue trials?	PHI suffi- ciently sup- ported?	Sample storage covered by stabil- ity data?	MRL com- pliance	Chronic risk for consumers identified?	Acute risk for con- sumers identified?
9-10	Spring onion	Yes	Yes	Yes	Yes	Yes		No
11	Bean	Yes	Yes	Yes	Yes	Yes		No
11	Pea	Yes	Yes	Yes	Yes	Yes		No
11	Broad bean	Yes	Yes	Yes	Yes	Yes		No
11	Field bean	Yes	Yes	Yes	Yes	Yes		No
12	Carrot	Yes	Yes	Yes	Yes	Yes		No
12	Parsley	Yes	Yes	Yes	Yes	Yes		No
13	Lupine	Yes	Yes	Yes	Yes	Yes		No
14-15	Winter oilseed rape	Yes	Yes BBCH 00-09	Yes	Yes	Yes		No
16	Asparagus	Yes	Yes-No	Yes-No	Yes-No	Yes-No		No
17	broccoli	Yes	Yes	Yes	Yes	Yes		No
17	Brussels sprouts	Yes	Yes	Yes	Yes	Yes		No
17	cabbage	Yes	Yes	Yes	Yes	Yes		No
17	cauliflower	Yes	Yes	Yes	Yes	Yes		No
18	Strawberry	Yes	Yes	Yes	Yes	Yes		No
19	Raspberry	Yes	Yes	Yes	Yes	Yes		No
20	Currants	Yes	Yes	Yes	Yes	Yes		No
21-22	Leek	Yes	Yes-No	Yes-No	Yes-No	Yes-No		No
23	Parsnip	Yes	Yes	Yes	Yes	Yes		No
24	Lettuce	Yes	Yes	Yes	Yes	Yes		No
24	endive	Yes	Yes	Yes	Yes	Yes		No
25	Potato	Yes	Yes	Yes	Yes	Yes		No
26	Grapevine	Yes	Yes	Yes	Yes	Yes		No
27	Ornamentals	Yes	NR	Yes-NR	Yes-NR	Yes-NR		No
28	Clover	Yes	Yes- No	Yes- No	Yes- No	Yes- No		No
28	alfalfa	Yes	Yes-No	Yes-No	Yes-No	Yes-No		No
29	Artichoke	Yes	Yes-No	Yes-No	Yes-No	Yes-No		No
30	Fennel	Yes	Yes- No	Yes- No	Yes- No	Yes- No		No
31	melon	Yes	Yes-No	Yes-No	Yes-No	Yes-No		No
31	cucumber	Yes	Yes-No	Yes-No	Yes-No	Yes-No		No
31	squash	Yes	Yes-No	Yes- No	Yes-No	Yes-No		No
31	zucchini	Yes	Yes-No	Yes- No	Yes-No	Yes-No		No

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

As residues of pendimethalin do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

7.1.2.2 Summary for SHA 2600 E

Table 7.1-4: Information on SHA 2600 E (KCA 6.8)

Crop	PHI for SHA 2600 E proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for SHA 2600 E proposed by zRMS	zRMS Comments (if different PHI proposed)
		pendimethalin	-	-		
Wheat	NR	NR	-	-		
Barley	NR	NR	-	-		
Rye	NR	NR	-	-		
Oats	NR	NR	-	-		
Triticale	NR	NR	-	-		
Maize	NR	NR	-	-		
Apple	NR	NR	-	-		
Pear	NR	NR	-	-		
Peach	NR	NR	-	-		
Apricot	NR	NR	-	-		
Plum	NR	NR	-	-		
Nectarine	NR	NR	-	-		
Cherry	NR	NR	-	-		
Sunflower	NR	NR	-	-		
Soybean	NR	NR	-	-		
Onion	NR	NR	-	-		
Garlic	NR	NR	-	-		
Shallot	NR	NR	-	-		
Spring onion	NR	NR	-	-		
Bean	NR	NR	-	-		
Pea	NR	NR	-	-		
Broad bean	NR	NR	-	-		
Field bean	NR	NR	-	-		

Crop	PHI for SHA 2600 E proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for SHA 2600 E proposed by zRMS	zRMS Comments (if different PHI proposed)
		pendimethalin	-	-		
Carrot	NR	NR	-	-		
Parsley	NR	NR	-	-		
Lupine	NR	NR	-	-		
Winter oilseed rape	NR	NR				
Asparagus	NR	NR				
broccoli	NR	NR				
Brussels sprouts	NR	NR				
cabbage	NR	NR				
cauliflower	NR	NR				
Strawberry	NR	NR				
Raspberry	NR	NR				
Currants	NR	NR				
Leek	NR	NR				
Parsnip	NR	NR				
Lettuce	NR	NR				
endive	NR	NR				
Potato	NR	NR				
Grapevine	NR	NR				
Ornamentals	NR	NR				
Clover	NR	NR				
alfalfa	NR	NR				
Artichoke	NR	NR				
Fennel	NR	NR				
melon	NR	NR				
cucumber	NR	NR				
squash	NR	NR				
zucchini	NR	NR				

NR: not relevant

* Purpose of withholding period to be specified

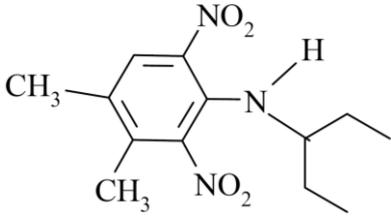
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Pendimethalin

General data on pendimethalin are summarized in the table below (last updated 2019/04/18)

Table 7.2-1: General information on pendimethalin

Active substance (ISO Common Name)	pendimethalin
IUPAC	N-(1-ethylpropyl)-3,4-dimethyl-2,6- dinitrobenzenamine
Chemical structure	
Molecular formula	C ₁₃ H ₁₉ N ₃ O ₄
Molar mass	281.3
Chemical group	Dinitroaniline
Mode of action (if available)	Microtubule assembly inhibition
Systemic	Yes
Company (ies)	ADAMA Agriculture B.V. and BASF SE
Rapporteur Member State (RMS)	Netherlands
Approval status	Approved on 01/09/2017 by Reg. (EU) 2017/1114
Restriction	Not restricted
Review Report	SANTE/11656/2016
Current MRL regulation	Reg. (EU) 2018/687 Reg. (EU) 2019/1791
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes EFSA Journal 2016;14(3):4420
EFSA Journal: conclusion on article 12	Yes, EFSA Journal 2012;10(4):2683 . Confirmatory data on Art. 12: EFSA Journal 2018; 16(10):5426
Current MRL applications on intended uses	EFSA-Q-2009-00054 (EMS) Status: Evaluation ongoing

* Notifier in the EU process to whom the a.s. belong(s)

** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Onions	High water content	24 months	EFSA 2012; Spain 1998, Netherlands, 2017 Tonderau, R., 1988a
Potatoes	High water content	12 months	
Grapes	High acid content	24 months	
Soyabean seed	High lipid content	6 months	
Almond	High lipid content	12 months	
Almond hulls	Dry	24 months	
Wheat straw	Dry	24 months	
Tobacco	Other	12 months	Netherlands, 2017 Schwartz, N.L., Singh, S., 1999
Alfalfa forage	High water content	43 months	Netherlands, 2017 Withonton, S., 1996
Alfalfa hay	High protein content	43 months	
Alfalfa seed	High starch content	43 months	
Orange	High acid content	24 months	Netherlands, 2017 Withonton, S., 1993
Apples	High water content	24 months	KCP 8.1.1
Oilseed rape	High lipid content	24 months	KCP 8.1.2
Soybean seed	High lipid content	24 months	Netherlands, 2017 Afzal, 2006
Corn grain	High starch content	18 months	

Conclusion on stability of residues during storage

Pendimethalin and metabolite CL 202347) are stable in commodities with high water, high acid, high protein, hay starch and in high lipid commodity for at least a period of 12-43 months.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Root and tuber vegetables	Potatoes	4- ¹⁴ C-methyl pendimethalin	Soil treatment	2.20	1	120 DAT		EFSA 2012, Spain 1998 Zulalian, J., 1992
			Soil treatment, G and F	1.10	1	93, 106 DAT		
		U- ¹⁴ C-phenyl pendimethalin	Foliar treatment	1.68	1	0, 109 DAT		Zulalian, J., 1978
	Onions	U- ¹⁴ C-phenyl pendimethalin	Foliar treatment	3.00	2	77 DAT		EFSA 2012, Spain 1998 Afzal, J. 1994
Pulses and oilseeds	Soybean	position unknown	Soil treatment	1.68	1	4, 8, 14 weeks after treatment		EFSA 2012, Spain 1998 Chiu T., 1987 Marei, A.H., 1975
		3,4- ¹⁴ C-dimethyl pendimethalin	Soil treatment	1.65	1	1, 2, 4 months after treatment		
Cereals	Sweet corn	¹⁴ C-ethylpropyl and 4- ¹⁴ C-methyl pendimethalin	Soil treatment, G	1.60	1	30, 60, 80 DAT		EFSA 2012, Spain 1998 Barringer D.F., 1973 Mangels, G., 1981
			3,4- ¹⁴ C-dimethyl pendimethalin	Foliar treatment, G	1.65	1	2, 6, 12 weeks after treatment	
		U- ¹⁴ C-phenyl pendimethalin	Foliar treatment, F	2.24	1	14, 30, 60, 81 DAT		Zulalian, J., 1993
	Wheat	¹⁴ C-ethylpropyl and 4- ¹⁴ C-	Soil treatment, F	1.54-1.65	1	30, 60, 120 days after		EFSA 2012, Spain 1998 Barringer,

		methyl pendimethalin				breaking winter dormancy		D.F., 1975
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Summary of plant metabolism studies reported in the EU

The metabolism of radiolabeled pendimethalin (CL 92,553) has been examined in a variety of crops including sweet corn, soybeans, potatoes, wheat and onions. Studies were conducted outdoors in small contained field plots, or in pots under greenhouse conditions. Application rates of the 14C-CL 92,553 to the test crop plants were in the range 1-2 lb ai/A (~1.1-2.2 kg/ha). Most of the applications were at 1.5 lb ai/A (~1.7 kg/ha) with the exception of the onion study in which the total application rate was 6.0 kg/ha. The early studies utilized 14C-CL 92,553 radiolabeled in one of three positions: the 4-methyl group, the 3,4-dimethyl groups, or the N-1-(ethyl-1-14C-propyl) group. The more recent studies were conducted with 14C-CL 92,553 that was uniformly ring-labeled. Typically, the 14C-CL 92,553 that was uniformly ring-labeled. Typically, the 14C-CL 92,553 was prepared as an emulsifiable concentrate formulation for application to the test system.

No significant differences in plant metabolite profiles have been observed for the differently labeled CL 92,553 tracers utilized in the studies. Total radioactive residues (TRR) present in the harvest crop commodities were low, falling in the range of <0.01 - 0.13 ppm, depending upon the crop and the growing conditions (greenhouse vs outdoors in field). Extraction and analysis (radio-TLC and/or radio-HPLC) showed that only trace amounts of parent CL 92,553, the 4-hydroxymethyl metabolite CL 202,347, and the 4-carboxylic acid metabolite CL 99,900 were detectable in the TRR of crop samples. Of the TRR that was extractable with organic solvents, the vast majority was found to be a mixture of several water-soluble, polar metabolites, each present in trace (<0.01 ppm) amounts. The residue remaining in the tissue marc following extraction with organic solvents was found to be associated with natural, endogenous cell constituents such as protein (soybean), cellulose, hemicellulose, and lignin.

Conclusion on metabolism in primary crops

The residue definition for risk assessment and monitoring purposes is set as pendimethalin.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	3,4- ¹⁴ C-dimethyl pendimethalin	Soil treatment	2.20	30, 90	90, 120, 150		EFSA 2012, Spain 1998 Lee, T.M., 1987
					365	Maturity and half maturity		
Root and tuber	Red beet	4- ¹⁴ C-methyl	Soil	1.68	180	210, 270,		Lee, T.M.,

vegetables		pendimethalin	treatment			330		1989
	Carrot	3,4- ¹⁴ C-dimethyl pendimethalin		2.20	30, 120	140		
					365	Half mature size and maturity		
	Radishes				30, 90	-	Important signs of phyto-toxicity observed	
365			Half mature size and maturity					
Pulses and oilseeds	Cotton	4- ¹⁴ C-methyl pendimethalin	Soil treatment	1.10	± 120	138, 154, 184, 254		
	Soybean							
	Snap bean	3,4- ¹⁴ C-dimethyl pendimethalin	Soil treatment	2.20	30, 90	90, 120, 150		
					365	Half maturity and maturity		
Cereals	Wheat	3,4- ¹⁴ C-dimethyl pendimethalin	Soil treatment	2.20	30, 120	-	Important signs of phyto-toxicity observed	
					365	Maturity and half maturity		

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

The nature of pendimethalin residues in rotational crops was investigated using ¹⁴C-labelled pendimethalin. Four metabolism studies were submitted on cotton seed, soya bean, red beets, lettuce, winter and spring wheat, snap beans, carrots and radishes. These studies were used also for assessing the magnitude of pendimethalin residues in rotational crops (Spain, 1998b).

Total radioactive residues found in the harvested commodities of lettuce, carrots and snap beans planted back at 30-DAT were in the range of 0.07 mg eq./kg (snap bean seeds) to 0.52 mg eq./kg (snap bean plants). The 30-DAT radish and spring wheat crops suffered phytotoxic damage and were not analysed. At the 90-DAT plant back interval, TRR levels at harvest were in the range of 0.02 mg eq./kg (snap bean seeds) to 0.16 mg eq./kg (snap bean plants). Radishes at the 90-DAT plant back interval still showed signs of phytotoxic damage. Beet roots planted about six months after pendimethalin treatment of a corn crop contained TRR levels of 0.04 mg eq./kg. At the plant back interval 365-DAT, the TRR levels in the harvested commodities of lettuce, snap bean seeds, carrot roots, and spring wheat were in the range of 0.02 mg eq./kg (wheat grain) to 0.15 mg eq./kg (wheat straw). Winter wheat and spring wheat planted back at 110-DAT and 270-DAT, respectively, contained total residues of 0.03-0.02 mg eq./kg (grain) and 0.19-0.15 mg eq./kg (straw). The spring wheat planted back at 120-DAT showed signs of phytotoxicity; spring wheat at 365-DAT contained residues in the range of 0.02 mg eq./kg (grain) to 0.15 mg eq./kg (straw).

In general, studies show that rotational crops, planted back at various intervals after pendimethalin applications up to 2.2 kg a.s./ha contain low TRR levels in the harvested crop commodities. Most of the residue is attributable to incorporation into naturally occurring structural cell components and/or metabolism to water-soluble degradates. Only small percentages of the total residue were identified as pendimethalin (9 – 51 % TRR) and the 4-hydroxymethyl metabolite (1 – 4 % TRR). Pendimethalin is extensively metabolised to a complex mixture of water-soluble components and other minor components, some of which incorporate into macromolecular plant material such as cellulose and lignin (Spain, 1998b).

Conclusion on metabolism in rotational crops

The metabolic pathway of pendimethalin in rotational crops is similar to that in primary crops and no formation of new metabolites was observed. Hence the same residue definition of as for primary crops applies to the rotational crops.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

Table 7.2-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Pendimethalin (102.0 %)	Netherlands, 2017 Singh M, 2002a; Effects of processing— nature of residues study
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Pendimethalin (102.0 %)	
Sterilisation (20 minutes, 120°C, pH 6)	Pendimethalin (94.0 %)	
Pasteurisation (20 minutes, 90°C, pH 4)	Pendimethalin (96.2 %)	Netherlands, 2017 Singh M, 2002a; Effects of processing— nature of residues study
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Pendimethalin (90.9 %)	
Sterilisation (20 minutes, 120°C, pH 6)	Pendimethalin (88.9 %)	
		KCP 8.5.1 XXX , 2018

Conclusion on nature of residues in processed commodities

Pendimethalin is stable under all conditions of high temperature hydrolysis for simulation of food processing.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Root and tuber vegetables (potatoes, onions) Cereals (wheat, sweet corn) Pulses and oilseeds (soybean)
Rotational crops covered	Leafy vegetables (lettuce) Root and tuber vegetables (red beet, carrot, radishes) Cereals (wheat) Pulses and oilseeds (cotton, soybean, snap bean)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Pendimethalin is stable under hydrolysis process.
Residue pattern in processed commodities similar to pattern in raw commodities?	Residue pattern in raw and processed commodities is similar
Plant residue definition for monitoring	Pendimethalin (EFSA, 2016)
Plant residue definition for risk assessment	Pendimethalin (EFSA, 2016)
Conversion factor from enforcement to RA	Not relevant

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg DM)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	U- ¹⁴ C-phenyl pendimethalin	3	2.1 and 6.3	7	Urine and faeces	Daily	EFSA 2012, Spain 1998 Haugwitz, M.I., 1974
						Tissues	At sacrifice	
						Milk	Daily	
	Position unknown	4	0.5, 1.5 and 20	10	Urine and faeces	Daily	Lee, T. M., 1990 Zulalian, J., 1990	
					Tissues	At sacrifice		
					Milk	Daily		
4- ¹⁴ C-methyl	3	6.5	7	Urine and	Daily			

		pendimethalin				faeces		
						Tissues	At sacrifice	
	Goat	¹⁴ C-pendimethalin	1	0.75 mg/kg bw/d	5	Urine and faeces	Daily	Netherlands, 2017
						Tissues	At sacrifice	XXXXX 2002a;
						Milk	Twice daily	
Laying poultry	Hens	U- ¹⁴ C-phenyl pendimethalin	-	0.5 and 10	7	Eggs	Twice daily	EFSA 2012, Spain 1998 Chiu T. Y.1992;
						Excreta	Once daily	
						Tissues	After sacrifice	

Summary of animal metabolism studies reported in the EU

[¹⁴C]-4-methyl or [¹⁴C]-uniformly ring labeled pendimethalin administered orally to lactating goats once daily via capsules for up to ten consecutive days is rapidly excreted, 8-15% in the urine and 54-67% in the feces. Recoveries of administered dose were in the range 68.8-93.7%. Five doses representing dietary feed intake equivalents in the range 0.5-20 ppm in the feed were studied. Liver was the target tissue in which the maximum observed residue was 0.25 ppm (at the 20 ppm feed equivalent). Residues in milk were <0.01 at all doses except at the highest where they were 0.02 ppm.

Normal and reversed phase HPLC analysis of the organo- and aqueous soluble liver residues, respectively, indicated that extensive metabolism of pendimethalin had occurred.

[¹⁴C]-uniformly ring labeled pendimethalin was administered orally to laying hens once daily via capsule for seven consecutive days. The doses represented dietary feed intake equivalents of 0.5 and 10 ppm in the feed. In the low dose group total radioactive residue (TRR) in tissues and whole eggs were less than 0.01 ppm, the validated detection limit of the radioassay. In the high dose group the maximum TRR in whole eggs was 0.035 ppm. Residues in tissues were 0.205 ppm in the liver, 0.035 ppm in skin with adhering fat, <0.01 ppm in muscle and 0.141 ppm in blood. TLC and HPLC analyses of the acetonitrile extractable carbon-14 residues from the eggs collected in the high dose treatment contained a trace amount of pendimethalin (0.002 ppm) and a number of polar components at concentrations of <0.01 ppm. No one fraction from the HPLC analysis contained carbon-14 residues \square 0.01 ppm.

Organic solvents extracted 17.9% (0.041 ppm) of the liver tissue residue; the unextractable residue could be released by enzymatic hydrolysis with protease (27%, 0.062 ppm) or acid hydrolysis (45%, 0.103 ppm). In this manner a total of 90% of the residue was released from the liver tissue. In the extractable residue (63%, 0.021 ppm) from the skin with adhering fat pendimethalin was observed (by HPLC and TLC) to account for 15.7% of the TRR, 0.005 ppm. Analyses of daily composites of excreta from hens in low and high dose treatment groups showed average recoveries of 85.2 and 88.3% of the total administered doses.

Thus, the administration of pendimethalin to laying hens for seven consecutive days at a dietary feed equivalents of 0.5 and 10 ppm in the diet, 5X and 100X the maximum potential exposure in a variety of crops, resulted in no detectable residues (<0.01 ppm) in tissues and eggs at the low dose and residues of 0.205, 0.035 and <0.01 ppm in liver, skin with adhering fat and muscle, respectively, at the high dose. These residues extrapolated to X, the maximum potential exposure, are equivalent to \leq 0.002 ppm.

Netherlands, 2017; XXXXX 2002a;

The results from this goat metabolism study demonstrated that among the edible tissues and milk, only

liver and kidney contained significant residues (>0.01 mg/kg). Of the total radioactive residue, 80.6% in the liver and 90.6% in the kidney were extractable. The residues in the liver and kidney were extensively metabolised. With the exception of Goat metabolite 6 (at 13.5% TRR), each major component accounted for <10% of the total radioactive residues in the liver, while in the kidney the highest component accounted for less than 0.005 mg/kg of the total TRR. Only trace amounts of parent, BAS 455 H, were detected. Goat metabolite 6 is the major fraction in liver and other matrices including urine, bile and faeces. The major phase I biotransformation involved nitro-reduction and cyclization as well as hydroxylation and oxidation of the methyl group. Phase II metabolism, such as glucuronidation, and sulfation was also involved.

Conclusion on metabolism in livestock

The residue definition for risk assessment and monitoring purposes is set as pendimethalin.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	1 day
Animal residue definition for monitoring	Pendimethalin (EFSA, 2016)
Animal residue definition for risk assessment	Pendimethalin (EFSA, 2016)
Conversion factor	Not relevant
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of SHA 2600 E and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance		
Wheat	Spain 1998	N-EU	<p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.5 kg as/ha, pre emergence, PHI 273-280d, outdoor Grain: 2x<0.05 Straw: 2x<0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 2.0 kg as/ha, pre-emergence, PHI 273-357d, outdoor Grain: 9x<0.05 Straw: 9x<0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 2.5 kg as/ha, pre-emergence, PHI 298d, outdoor Grain: <0.05 Straw: <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.75 kg as/ha, post emergence – BBCH 12-13, PHI 105d, outdoor</p>	N/A						

			<p>Grain: <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.00 kg as/ha, pre emergence, PHI 301d, outdoor Grain: <0.05 Straw: <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 2.00 kg as/ha, pre emergence, PHI 301d, outdoor Grain: <0.05 Straw: <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 4.00 kg as/ha, pre emergence, PHI 301d, outdoor Grain: <0.05 Straw: <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.00 kg as/ha, pre emergence, PHI 293-327d, outdoor Grain: 3x<0.05 Straw: 3x<0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.00 kg as/ha, BBCH 10-12, PHI 247-327d, outdoor Grain: 5x<0.05 Straw: 5x<0.05</p>					
	New trials	N-EU	<p>GAP on which assessment is based: 1 x 1.98 1.498 – 1.650 kg as/ha, BBCH 25-30, pre-emergence, outdoor <0.0025 (ND), 4x<0.003 (ND), <0.01, 0.02, 0.03, 0.0318 6 x < 0.01, 0.02, 2 x 0.03</p>					
	Overall supporting data for cGAP	EU	<p><0.0025 (ND), 4x<0.003 (ND), 6 x <0.01, 0.02, 0.03, 0.0318, 24x<0.05</p>	0.05	0.05		0.05	Yes
Barley	Spain 1998	N-EU	<p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.65 kg as/ha, post emergence – BBCH 12, PHI 275d, outdoor</p>	N/A				

			<p>Grain: <0.05 Straw: <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, pre emergence/ post emergence – BBCH 13-25, PHI 227-287d, outdoor Grain: 4x<0.05 Straw: 4x<0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 2.0 kg as/ha, pre emergence, PHI 294-315d, outdoor Grain: 5x<0.05 Straw: 5x<0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1.65 kg as/ha, pre emergence, PHI 89d, outdoor Grain: <0.05 Straw: 0.15</p> <p>GAP on which MRL/EU a.s. assessment is based: 2.0 kg as/ha, pre emergence, PHI 250-268d, outdoor Grain: 2x<0.05 Straw: 2x<0.05</p>					
	New trials	N-EU	<p>GAP on which assessment is based: 1 x 1.98 kg as/ha, pre-emergence, outdoor 1 x 1.510 – 1.752 kg/ha. as/ha, BBCH 25-30, outdoor 5x<0.003 (ND), 2x<0.01, 0.01 7 x <0.01, 0.01</p>					
	Overall supporting data for cGAP	EU	5x<0.003 (ND), 2 7 x<0.01, 0.01, 13x<0.05	0.05	0.05		0.05	Yes
Maize	New trials	N-EU	<p>GAP on which assessment is based: 1 x 1.98 kg as/ha, pre-emergence, outdoor 1 x 1.584 – 2.010 kg as/ha, BBCH 00-16, outdoor 6x<0.003(ND)</p>					

	Overall supporting data for cGAP	EU	6x<0.003(ND)	0.003	0.003		0.05	Yes
Apples → extrapolated to peach, apricot, nectarine, cherry	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 3.20 kg as/ha, outdoor 6x<0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 6.40 kg as/ha, outdoor 6x<0.05	N/A				
	New trials	N-EU	GAP on which assessment is based: 1 x 1.98 kg as/ha, pre-emergence, outdoor 1 x 1.886 – 2.283 kg as/ha, BBCH 61-69, outdoor 3x<0.003 (ND)					
	Overall supporting data for cGAP	EU	3x<0.003 (ND), 12x<0.05	0.05	0.05		0.05	Yes
Pears	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 3.20 kg as/ha, outdoor 2x<0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 6.40 kg as/ha, outdoor 2x<0.05					
	Overall supporting data for cGAP	EU	4x<0.05					
Garlic	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 1.32 kg as/ha, pre-emergence, PHI 164-193d, outdoor 2x<0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 2.64 kg					

			<p>as/ha, pre-emergence, PHI 164-193d, outdoor 2x<0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.32 kg as/ha, pre-emergence, PHI 136d, outdoor <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 2.64 kg as/ha, pre-emergence, PHI 136d, outdoor <0.05</p>					
	Overall supporting data for cGAP	EU	6x<0.05	0.05	0.05		0.05	Yes
Carrot → extrapolated to whole group Root and tuber vegetables	Spain 1998	N-EU	<p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.485 kg as/ha, outdoor 0.07</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, outdoor 0.11</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 2.00 kg as/ha, outdoor <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 0.84 kg as/ha, outdoor <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.68 kg as/ha, outdoor <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.00 kg as/ha, outdoor 0.06</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 2.00 kg as/ha, outdoor <0.05</p>					
	New trials	N-EU	GAP on which assessment is based: 1 x 1.98 kg as/ha, pre-emergence, outdoor					

			1 x 1.282 – 2.085 kg as/ha, BBCH 00 - 14 2x<0.0025 (ND), 4x<0.01, 0.01					
	Overall supporting data for cGAP	EU	2x<0.0025 (ND), 4x<0.01, 0.01, 4x<0.05, 0.06, 0.07, 0.11	0.01	0.11		0.7	Yes
Peas	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 2.0 kg as/ha, pre-emergence, outdoor Pod: 4x<0.05 – PHI 79-98 Seed: 4x<0.05 – PHI 97-137 GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, pre-emergence, outdoor Pod: 3x<0.05 – PHI 68-90 Seed: 5x<0.05 – PHI 76-111					
	New trials	N-EU	GAP on which assessment is based: 1 x 1.98 kg as/ha, pre-emergence, outdoor 1 x 1.317 – 1.980 kg as/ha, pre-emergence, BBCH: 01- 15 Seeds: 2x<0.001 (ND), 4x<0.0025(ND), <0.003(ND), 2x<0.01 Pods: 2x<0.0025(ND) Seeds with pods: <0.003(ND)					
	Overall supporting data for cGAP	EU	Pods: 2x<0.0025 (ND), 7x<0.05 Seeds: 2x<0.001 (ND), 4x<0.0025 (ND), <0.003(ND), 2x<0.01, 9x<0.05	0.03	0.05		0.05	Yes
Onion →	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, post emergence 6-8 cm height, PHI 60-127d, outdoor 4x<0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 1.32-2.64 kg as/ha, pre emergence, PHI 171-195d, outdoor 8x<0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 0.99-1.98 kg as/ha, post emergence, PHI 54-122d, outdoor 2x<0.05					

			<p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, pre-emergence, PHI 58d, outdoor 4x<0.05, 0.07</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, pre-emergence, PHI 65-159d, outdoor 29x<0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 0.99+1.32 kg as/ha, post-emergence, PHI 113d, outdoor <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 0.99 kg as/ha, pre-emergence, PHI 142-145d, outdoor 2x<0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.32 kg as/ha, pre-emergence, PHI 142d, outdoor <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.12 kg as/ha, pre-emergence, PHI 167d, outdoor <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 2.24 kg as/ha, pre-emergence, PHI 167d, outdoor <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.32 kg as/ha, same day as planting out, PHI 1136d, outdoor <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 2.64 kg as/ha, same day as planting out, PHI 1136d, outdoor <0.05</p>	
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	New trials	N-EU	GAP on which assessment is based: 1 x 1.98 1 x 1.318 – 1.650 kg as/ha, , pre-emergence, outdoor 4x<0.0025(ND) 4x < 0.01 (LOQ)					
	Overall supporting data for cGAP	EU	4x<0.0025(ND), 55x<0.05	0.05	0.05		0.05	Yes
Bean	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, pre-emergence, outdoor Pod: 5x<0.05 – PHI 77-97 Rest of plant: 5x<0.05 – PHI 77-97 Seed: 5x<0.05 – PHI 106-144 GAP on which MRL/EU a.s. assessment is based: 1 x 2.0 kg as/ha, pre-emergence, outdoor Pod: 4x<0.05 – PHI 98-112 Rest of plant: 4x<0.05 – PHI 98-112 Seed: 4x<0.05 – PHI 144-168					
	Overall supporting data for cGAP	EU	Pods: 9x<0.05 Seed: 8x<0.05	0.05	0.05		0.05	Yes
Sunflower→ extrapolated to oilseed rape	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 2.0 kg as/ha, PHI 115d, outdoor <0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 1.32 kg as/ha, PHI 146-160d, outdoor 3x<0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 2.64 kg as/ha, PHI 146-169d, outdoor 4x<0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, PHI 152-180d, outdoor 4x<0.05					

			GAP on which MRL/EU a.s. assessment is based: 1 x 2.0 kg as/ha, PHI 147-180d, outdoor 8x<0.05					
	New trials	N-EU	GAP on which assessment is based: 1 x 1.98 kg as/ha, pre-emergence, outdoor 1 x 1.835– 2.143 kg as/ha, BBCH 00-09, outdoor <0.025, 2x<0.003 (ND), <0.01, 0.01					
	Overall supporting data for cGAP	EU	<0.025, 2x<0.003 (ND), <0.01, 0.01, 20x<0.05	0.05	0.05		0.05	Yes
Soybean → extrapolated to oilseed rape	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 1.25 kg as/ha, pre-plant incorporated, PHI 137-182 days, outdoor 2x<0.05					
	New trials	N-EU	GAP on which assessment is based: 1 x 1.98 kg as/ha, pre-emergence, outdoor 1 x 1952 – 2.123 kg as/ha, BBCH 00-09, outdoor <0.0025 (ND), 3x<0.003 (ND)					
	Overall supporting data for cGAP	EU	<0.0025 (ND), 3x<0.003 (ND), 2x<0.05	0.003	0.05		0.05	Yes
Broccoli	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 1.65 kg as/ha, PHI 40d, outdoor <0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 2.00 kg as/ha, transplanting seedling, PHI 132d, outdoor <0.05					
	Overall supporting data for cGAP	EU	2x<0.05	0.05	0.05		0.05	Yes

Cauliflower	Spain 1998	N-EU	<p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.65 kg as/ha, PHI 54d, outdoor <0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.32-2.64 kg as/ha, pre-planting, PHI 83-127d, outdoor 12x<0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, before trasplanting, PHI 65-93d, outdoor 4x<0.05</p>					
	Overall supporting data for cGAP	EU	17x<0.05	0.05	0.05		0.05	Yes
Cabbage	Spain 1998	N-EU	<p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.32-2.64 kg as/ha, pre-planting, PHI 130d, outdoor 2x<0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.485 kg as/ha, 2-3 leaf stage, PHI 130d, outdoor 4x<0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, before trasplanting, PHI 63-91d, outdoor 4x<0.05</p>					
	Overall supporting data for cGAP	N-EU	10x<0.05	0.05	0.05		0.05	Yes
Strawberry → extrapolated to berries and small fruits	Spain 1998	N-EU	<p>GAP on which MRL/EU a.s. assessment is based: 1 x 2.0 kg as/ha, PHI 79-86d, outdoor 2x<0.05</p> <p>GAP on which MRL/EU a.s. assessment is based: 1 x 4.0 kg as/ha, PHI 79-86d, outdoor 2x<0.05</p>					

	New trials	N-EU	GAP on which assessment is based: 1 x 1.98 kg as/ha, pre-emergence, outdoor 1 x 1.822 – 2.014 kg as/ha, pre-emergence, outdoor 2x<0.003, 2x0.01						
	Overall supporting data for cGAP	EU	2x<0.003, 2x0.01, 4x<0.05	0.03	0.05		0.05	Yes	
Grapevine → extrapolated to berries and small fruits	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 3.2 kg as/ha, PHI 161-207d, outdoor 8x<0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 6.4 kg as/ha, PHI 161-207d, outdoor 8x<0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 2.64 kg as/ha, PHI 207d, outdoor <0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 5.28 kg as/ha, PHI 207d, outdoor <0.05						
	New trials	N-EU	GAP on which assessment is based: 1 x 1.98 kg as/ha, pre-emergence, outdoor 1 x 2.022 – 2.025 kg as/ha, BBCH:55, outdoor 2x<0.003 (ND)						
	Overall supporting data for cGAP	EU	2x<0.003 (ND), 18x<0.05	0.05	0.05		0.05	Yes	
Leeks	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 1.32-2.64 kg as/ha, PHI 134, 184d, outdoor 4x<0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 1.32-2.64 kg as/ha, PHI 70d, outdoor 2x<0.05						
	Overall	EU	6x<0.05	0.05	0.05		0.05	Yes	

	supporting data for cGAP							
Potato→ extrapolated to whole group Root and tuber vegetables	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, outdoor 14x<0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 1.65 kg as/ha, outdoor <0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 1.98 kg as/ha, outdoor <0.05					
	New trials	N-EU	GAP on which assessment is based: 1 x 1.98 kg as/ha, pre-emergence, outdoor 1 x 1320 - 1.665 kg as/ha, BBCH:07, outdoor 4x<0.0025 (ND), <0.01					
	Overall supporting data for cGAP	EU	4x<0.0025 (ND), <0.01, 16x<0.05	0.05	0.05		0.05	Yes
Celery→ extrapolated to Fennel	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 1.32-2.64 kg as/ha, PHI 94d, outdoor 4x<0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 1.6 kg as/ha, PHI 63-91d, outdoor 3x<0.02, 0.045					
	Overall supporting data for cGAP	EU	3x<0.02, 0.045, 4x<0.05	0.05	0.05		0.1	Yes
Artichoke	Spain 1998	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 1.32 kg as/ha, pre-emergence, PHI 159d, outdoor					

			2x<0.05 GAP on which MRL/EU a.s. assessment is based: 1 x 2.64 kg as/ha, pre-emergence, PHI 159d d, outdoor 2x<0.05					
	Overall supporting data for cGAP	EU	4x<0.05	0.05	0.05		0.05	Yes
Lettuce→ extrapolated to endive	New trials	N-EU	GAP on which assessment is based: 1 x 1.98 kg as/ha, pre-emergence, outdoor 1 x 1.330 – 1.650 kg as/ha, pre-emergence, outdoor 2x<0.0025 (ND), 2x<0.01					
	Overall supporting data for cGAP	EU	2x<0.0025 (ND), 2x<0.01	0.01	0.01		4	Yes
Plum→ extrapolated to peach, apricot, nectarine, cherry	New trials	N-EU	Trials GAP: 1 x 2000 g as/ha, BBCH 69, PHI 161d, outdoor 4 x <0.003 (<LOD)	N/A				
	Overall supporting data for cGAP	EU	4 x <0.003 (<LOD)	0.003	0.003		0.05	Yes

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on wheat, barley, rye, oat, triticale, maize, pome fruits, stone fruits, stone fruit, sunflower, soybean, bulb vegetables, bean, pea, broad bean, field bean, carrot, parsley and lupine are considered acceptable, for both outdoor uses.

According to appendix D of EU guidelines, extrapolation to:

- rye, oats and triticale is possible with trials on wheat and barley,
- pears is possible with trials on apples,
- whole group of stone fruits with trials on apples,
- garlic with trials on onions,
- whole group legume vegetables with trials on peas
- whole category pulses with trials on peas
- whole subgroups of flowering brassica and head brassica with trials on cauliflower and head cabbage.
- berries and small fruits with trials on strawberries and grapes,
- whole group Root and tuber vegetables with trials on carrot and potato,
- oilseed rape with trials on sunflower and soybean,
- fennel with trials on celery
- endive with trials on lettuce

According to SANTE/2019/12752 of EU guidelines, extrapolation to whole group of stone fruits: peach, apricot, nectarine and cherry is possible with minimum 4 trials on apples and 4 trials on plum.

which is the case here.

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

zRMS conclusion:

See assessment in point 7.1 Summary and zRMS Conclusion

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-10: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS/authorized within the zone/evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: pendimethalin				
Cabbage	0.05	Median residue	0.05	Highest residue
Kale	0.05	Median residue	0.25	Highest residue

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Maize silage	0.05	Median residue	0.05	Highest residue
Apple pomace	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Cereal grain	0.05	Median residue	0.05	Median residue
Brewer's grain, dried	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Distiller's grain dried	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Wheat gluten, meal	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Wheat, milled by-pdts	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Cereal straw	0.07	Median residue	0.14	Highest residue
Bean, pea seed (dry)	0.06	Median residue	0.06	Median residue
Poatoes	0.05	Median residue	0.05	Highest residue
Potato, process waste	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Potato, dried pulp	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Cotton seed	0.05	Median residue	0.05	Median residue
Cotton meal	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Sunflower seed (meal)	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Soya bean seed	0.05	Median residue	0.05	Median residue
Soybean meal	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Soybean hulls	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)
Peanuts (meal)	0.05	Median residue x PF (1.0)	0.05	Median residue x PF (1.0)

Table 7.2-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Pendimethalin					
Cattle (all diets)	0.011	0.021	Kale leaves	0.58	Yes
Cattle (dairy only)	0.011	0.021	Kale leaves	0.55	Yes
Sheep (all diets)	0.010	0.014	Kale leaves	0.42	Yes
Sheep (ewe only)	0.010	0.014	Kale leaves	0.42	Yes
Swine (all diets)	0.006	0.009	Kale leaves	0.39	Yes
Poultry (all diets)	0.007	0.007	Potato culls	0.10	Yes
Poultry (layer only)	0.006	0.006	Cabbage, heads leaves	0.09	Yes

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

No new data were submitted in the framework of this application.

Table 7.2-12: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^(c)	Calculated MRL (mg/kg)	CF for RA ^(d)
	Med. (mg/kg DM)	Max. (mg/kg DM)	Dose Level (mg/kg DM)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (Netherlands, 2015; EFSA, 2016)												
XXXXX 2005a												
Pendimethalin												
Ruminant meat	0.32	0.58	100	5	<0.05	<0.05	<0.05	<0.05	0.01	0.01	0.01	
Ruminant fat	0.32	0.58	100	5	<0.05	<0.05	<0.05	<0.05	0.01	0.01	0.01	
Ruminant liver	0.32	0.58	100	5	<0.05	<0.05	<0.05	<0.05	0.01	0.01	0.01	
Ruminant kidney	0.32	0.58	100	5	<0.05	<0.05	<0.05	<0.05	0.01	0.01	0.01	
Milk	0.28	0.55	100	5	<0.01	<0.01	<0.01	<0.01	0.01	0.01	0.01	

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, and regarding available feeding data, there is **no a clear** risk for animal MRL to be exceeded.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

As quantifiable residues of pendimethalin are not expected in the edible parts of most crops under consideration, and as consumer exposure is far below 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 0), no study dealing with magnitude of residues in succeeding crops is needed.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of SHA 2600 E. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-13: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
pendimethalin				
All commodities	Reg. (EU) 2019/1791			

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-14: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev.3.1	4 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo* rev.3.1	<p>Unprocessed commodities</p> <p>Results for children</p> <p>14.79% Carrots</p> <p>2.31% Pears</p> <p>1.80% Apples</p> <p>1.58% Peaches</p> <p>1.05% Parsley roots/Hamburg roots parsley</p> <p>0.91% Beans</p> <p>0.70% Plums</p> <p>0.58% Apricots</p> <p>0.41% Quinces</p> <p>0.38% Onions</p> <p>0.33% Peas</p> <p>0.24% Wheat</p> <p>0.23% Medlar</p> <p>0.20% Cherries (sweet)</p> <p>0.19% Beans (with pods)</p> <p>Results for adults</p> <p>4.60% Carrots</p> <p>2.40% Parsley roots/Hamburg roots parsley</p> <p>0.51% Pears</p> <p>0.47% Apples</p> <p>0.33% Beans</p> <p>0.31% Peaches</p> <p>0.30% Plums</p> <p>0.25% Quinces</p> <p>0.25% Onions</p> <p>0.18% Apricots</p> <p>0.17% Cherries (sweet)</p> <p>0.17% Peas</p> <p>0.14% Wheat</p> <p>0.13% Beans (with pods)</p> <p>0.11% Medlar</p> <p>Processed commodities</p> <p>Results for children</p> <p>8.4% Carrots / juice</p> <p>0.9% Apples / juice</p> <p>0.5% Pears / juice</p> <p>0.4% Peaches / canned</p> <p>0.4% Maize / oil</p> <p>0.4% Peas / canned</p> <p>0.3% Peaches / juice</p> <p>0.2% Beans (with pods) / boiled</p> <p>0.2% Wheat / milling (flour)</p> <p>0.2% Plums / juice</p> <p>0.1% Peas (without pods) / canned</p> <p>0.1% Wheat / milling (wholemeal)-baking</p> <p>0.1% Soyabeans / soya drink</p> <p>0.1% Rye / boiled</p> <p>0.1% Oat / boiled</p> <p>Results for adults</p> <p>1.9% Carrots / canned</p>

	0.56% Apples / juice 0.36% Beans / canned 0.21% Maize / oil 0.16% Onions / boiled 0.14% Peaches / canned 0.13% Peas / canned 0.12% Barley / beer 0.09% Beans (without pods) / boiled 0.07% Wheat / bread/pizza 0.06% Wheat / pasta 0.06% Wheat / bread (wholemeal) 0.06% Peas (with pods) / boiled 0.05% Peas (without pods) / boiled 0.03% Oat / boiled
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

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

7.3 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

Not relevant. The product contains only one active substance.

7.4 References

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for pendimethalin according to Article 12 of Regulation (EC) No 396/2005

European Commission, 2003a. Review report for the active substance pendimethalin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 13 November 2002 in view of the inclusion of pendimethalin in Annex I of Directive 91/414/EEC. Pendimethalin 7477/VI/98-final, 13 January 2003.

Pendimethalin – monograph, Spain 1998

Conclusion on the peer review of the pesticide risk assessment of the active substance pendimethalin

Pendimethalin – RAR, Netherlands

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.
 MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.1.1	J. XXX	2019	Stability study of pendimethalin residues in apple samples during 2 years of storage Report No. ZBBZ-2017/24/DPL/1 Food Safety Laboratory GLP Unpublished	N	Sharda
KCP 8.1.2	J. XXX	2019	Stability study of pendimethalin residues in oilseed rape samples during 2 years of storage Report No. ZBBZ-2017/24/DPL/1 Food Safety Laboratory GLP Unpublished	N	Sharda
KCP 8.3.1.1	T. XXX	2018	Magnitude of the residue of Pendimethalin in wheat (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – one decline curve trial in Poland -2017. Report No. 17SGS011 SGS Polska Sp. z o.o. GLP Unpublished	N	Sharda
KCP 8.3.1.2	M. XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-289-LABCHI-REV.0. Report No. 18.618093.0002 CHELAB S.R.L.	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 8.3.1.3	S. XXX	2018	Magnitude of residue of Pendimethalin in wheat Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial and 1 refinement decline trial. Report No. BPL17-010 BIOTEK Agriculture España SL GLP Unpublished	N	Sharda
KCP 8.3.1.4	S. XXX	2019	Residue study (Harvest and Decline) in wheat following one post emergence application with Pendimethalin 33% EC in Germany 2018. Report No. CT17-1-46 CropTrials GmbH GLP Unpublished	N	Sharda
KCP 8.3.1.5	M.XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-289-LACHI-REV.0. Report No 18.641074.0001 CHELAB S.R.L. GLP Unpublished	N	Sharda
KCP 8.3.1.6	T. XXX	2018	Residue study (Decline) in wheat following one post emergence application with Pendimethalin 33% EC in Germany 2017. Report No. CT17-1-47 CropTrials GmbH GLP Unpublished	N	Sharda
KCP 8.3.1.7	M.XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-2289-LABCHI-REV.0 Report No 18.618095.0005	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			CHELAB S.R.L. GLP Unpublished		
KCP 8.3.1.8	M. XXX	2018	Determination of residues at harvest and decline of Pendimethalin in Wheat, following one broadcast application of PENDIMETHALIN 330 g/L EC, under open field conditions Central Europe – Season 2017, Report No FRS 001/17 Field Research Support GLP Unpublished	N	Sharda
KCP 8.3.1.9	J. XXX	2017	Determination of the residues of Pendimethalin applied as “Pendimethalin 330 g/L” in wheat at one site in Germany, 2016 Report No. ZBBZ-2016/12/DPL/10 DE Food Safety Laboratory GLP Unpublished	N	Sharda
KCP 8.3.2.1	S. XXX	2018	Magnitude of residue of Pendimethalin in barley Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial Report No. BPL17-009 BIOTEK Agriculture España SL GLP Unpublished	N	Sharda
KCP 8.3.2.2	T. XXX	2018	Residue study (Harvest and decline) in barley following one post emergence application with Pendimethalin 33% EC in Germany 2017 – field part Report No. CT17-1-45 CropTrials GmbH GLP Unpublished	N	Sharda
KCP 8.3.2.3	M.XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in barley by LC-MS according to SOPa-288-LABCHI-Rev. 0 and SOPa-289-LABCHI-Rev. 0	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No. 18.618095.0004 CHELAB S.R.L. GLP Unpublished		
KCP 8.3.2.4	Ch. XXX	2020	Field residue trials to determine levels of Pendimethalin 33% EC on Barley in Northern Europe Report No. 18-00246 SGS United Kingdom Ltd. GLP Unpublished	N	Sharda
KCP 8.3.2.5	M.XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in Barley by LC-MS according to SOPa-288-LABCHI-Rev.0 and SOPa-289-LABCHI-Rev.0 Report No. 19.503381.0001 CHELAB S.R.L. GLP Unpublished	N	Sharda
KCP 8.3.3.1	S. XXX	2018	Magnitude of residue of Pendimethalin in maize whole plants and Raw Agricultural Commodity (grains) after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial – Poland – 2017 Report No. BPL17-017 BIOTEK Agriculture España SL GLP Unpublished	N	Sharda
KCP 8.3.3.2	S. XXX	2018	Residue study (Harvest and Decline) in maize following one pre emergence application with Pendimethalin 33% EC in Germany 2017 – field part Report No. CT17-1-48 CropTrials GmbH GLP Unpublished	N	Sharda
KCP 8.3.3.3	M.XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in maize by LC-MS according to SOPa-288-LABCHI-Rev.0 and SOPa-289-LABCHI-Rev.0	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No. 18.618096.0008 CHELAB S.R.L. GLP Unpublished		
KCP 8.3.3.4	K. XXX	2016	Determination of residues at harvest and decline of Pendimethalin in Maize, following one broadcast application of PENDIMETHALIN 330g/L EC, under open field conditions, Central Europe – Season 2016 Report No. FRS 056/16 Field Research Support GLP Unpublished	N	Sharda
KCP 8.3.3.5	J. XXX	2018	Determination of the residues of pendimethalin applied as “Pendimethalin 330 g/L” in maize at one site in Germany 2016 Report No. ZBBZ-2016/12/DPL/9DE Food Safety Laboratory GLP Unpublished	N	Sharda
KCP 8.3.4.1	T. XXX	2018	Residue study (Harvest) in apple following one application with Pendimethalin 33% EC in Germany 2017 Report No. CT17-1-49 CropTrials GmbH GLP Unpublished	N	Sharda
KCP 8.3.4.2	M.XXX	2018	Determination of pendimethalin (CAS:40487-42-1) in pome fruits by LC-MS according to SOPa-285-LABCHI-Rev.0 Report No. 18.618095.0009 CHELAB S.R.L. GLP Unpublished	N	Sharda
KCP 8.3.4.3	T. XXX	2018	Magnitude of the residue of Pendimethalin in apple (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – one harvest trial in Poland	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No. 17SGS015 SGS Polska Sp. z o.o. GLP Unpublished		
KCP 8.3.4.4	M.XXX	2018	Determination of pendimethalin (CAS:40487-42-1) in pome fruits by LC-MS according to SOPa-285-LABCHI-Rev.0 Report No. 18.618093.0006 CHELAB S.R.L. GLP Unpublished	N	Sharda
KCP 8.3.4.5	Ch. XXX	2020	Field residue trials to determine levels of Pendimethalin 33% EC on Pome Fruits (apples) in Norther Europe Report No. 18-00305 SGS United Kingdom Ltd. GLP Unpublished	N	Sharda
KCP 8.3.4.6	M.XXX	2019	Determination of Pendimethalin (CAS: 40487-42-1) in Pome Fruits by LC-MS according to SOPa-285-LABCHI-Rev.0 Report No. 19.503381.0002 CHELAB S.R.L. GLP Unpublished	N	Sharda
KCP 8.3.5.1	S. XXX	2018	Residue study (harvest) in soybean following one pre emergence application with Pendimethalin 33% EC in Germany 2017 – field part CropTrials GmbH GLP Unpublished	N	Sharda
KCP 8.3.5.2	M. XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in soy bean by LC-MS according to SOPa-284-LABCHI-Rev.0 Report No. 18.618095.0011	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			CHELAB S.R.L. GLP Unpublished		
KCP 8.3.5.3	K. XXX	2019	Magnitude of the residue of Pendimethalin in soybean (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – two harvest trials in Poland – 2017 Report No. 17SGS016 SGS Polska Sp. z o.o. GLP Unpublished	N	Sharda
KCP 8.3.5.4	M. XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in soy bean by LC-MS according to SOPa-284-LABCHI-Rev.0 Report No. 18.618093.0007 CHELAB S.R.L. GLP Unpublished	N	Sharda
KCP 8.3.5.5	Z. XXX	2016	Residue study of pendimethalin/Pendimethalin 33% (harvest) in soybean, Poland (Central Europe) – Season 2016 Report PL-PH/04/2016-1/7-H InHort GLP Unpublished	N	Sharda
KCP 8.3.5.6	J. XXX	2018	Determination of residues of pendimethalin applied as “Pendimethalin 330 g/L EC” in soybean at one site in Poland, 2016 Report No. ZBBZ-2016/12/DPL/8PL Food Safety Laboratory GLP Unpublished	N	Sharda
KCP 8.3.6.1	T. XXX	2018	Residue study (Harvest) in carrot following one post emergence application with Pendimethalin 33% EC in Germany 2017. Report No. CT17-1-32	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			CropTrials GmbH GLP Unpublished		
KCP 8.3.6.2	M. XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in carrot by LC-MS according to SOPa-285-LABCHI-REV.0. Report No. 18.618095.0006 CHELAB S.R.L. GLP Unpublished	N	Sharda
KCP 8.3.6.3	T. XXX	2018	Magnitude of the residue of Pendimethalin in carrot (Taw Agricultural Commodity) after one application of Pendimethalin 33% EC – one decline curve trial and one harvest trial in Poland – 2017. Report No. 17SGS012 SGS Polska Sp. z o.o. GLP Unpublished	N	Sharda
KCP 8.3.6.4	M. XXX	2018	Determination of pendimethalin (CAS: 40487-42-1) in carrot by LC-MS according to SOPa-285-LABCH-REV.0. Report No. 18.618093.0003 CHELAB S.R.L. GLP Unpublished	N	Sharda
KCP 8.3.6.5	K. XXX	2016	Determination of residues at harvest and decline of Pendimethalin in carrot, following one pre-emergence application of PENDIMETHALIN 330g/L EC, under open field conditions, Central Europe – Season 2016. Report No. FRS 051/16 Field Research Support GLP Unpublished	N	Sharda
KCP 8.3.6.6	J. XXX	2017	Determination of residues of pendimethalin applied as ‘PENDIMETHALIN 330 g/L’ in carrot at one site in Germany.	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No. ZBBZ-2016/12/DPL/5DE Food Safety Laboratory GLP Unpublished		
KCP 8.3.6.7	S. XXX	2017	Field phase residue trial Pendimethalin 330 g/L EC – carrots – decline – Belgium – 2016 Report No. OL16 WORES1 PCG GLP Unpublished	N	Sharda
KCP 8.3.6.8	S. XXX	2017	Field phase residue trial Pendimethalin 330 g/L EC – carrots – harvest – Belgium – 2016 Report No. OL16 WORES2 PCG GLP Unpublished	N	Sharda
KCP 8.3.6.9	J. XXX	2017	Determination of residues of Pendimethalin applied as “PENDIMETHALIN 330 g/L” in carrot at one site in Belgium, 2017 Report No. ZBBZ/12/DPL/5BE Food Safety Laboratory GLP Unpublished	N	Sharda
KCP 8.3.7.1	K. XXX	2016	Determination of residues at harvest and decline of Pendimethalin in Peas, following one pre-emergence application of Pendimethalin 330 g/L EC under open field conditions, Central Europe – Season 2016 Report No. FRS 055/16 Field Research Support GLP Unpublished	N	Sharda
KCP 8.3.7.2	P. XXX	2018	Magnitude of the residues of Pendimethalin in pea (plant and seeds), following one application of Pendimethalin 330 g/L EC in two trials (1DCS and 1 HS), Central Europe (Germany) – 2016 Report No. ZBBZ – 2016/121/DPL/1DE Food Safety Laboratory	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 8.3.7.3	S. XXX	2017	Field phase residue trial Pendimethalin 330 g/L EC Peas (Pisum sativum/Pissa) – Decline – Belgium – 2016 Report No. OL16 ERRES2 PCG GLP Unpublished	N	Sharda
KCP 8.3.7.4	S. XXX	2017	Field phase residue trial Pendimethalin 330 g/L EC Peas (Pisum Sativum/Pissa) – Harvest – Belgium – 2016 Report No. OL16 ERRES3b PCG GLP Unpublished	N	Sharda
KCP 8.3.7.5	P. XXX	2018	Magnitude of the residues of Pendimethalin in Pea (Plant, pods and seeds), following one application of Pendimethalin 330 g/L EC in three trials (1DCS and 2 HS), Central Europe (Belgium) – 2016 Report No. ZBBZ-2016/12/DPL/1BE Food Safety Laboratory GLP Unpublished	N	Sharda
KCP 8.3.7.6	Z. XXX	2016	Residue study of pendimethalin / Pendimethalin 33% EC (decline and harvest) in pea, Poland (Central Europe) – Season 2016 InHort GLP Unpublished	N	Sharda
KCP 8.3.7.7	P. XXX	2018	Magnitude of the residues of pendimethalin in pea (plant, pods and seeds), following one application of pendimethalin 330 g/l ec in two trials (1 dcs and 1 hs), Central Europe (Poland) - 2016 Report No. ZBBZ-2016/12/DPL/1PL Food Safety Laboratory GLP	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 8.3.7.8	S. XXX	2018	Residue study (Harvest) in pea following one post emergence application with Pendimethalin 33% EC in Germany 2017 – field part Report No. CT17-1-33 CropTrials GmbH GLP Unpublished	N	Sharda
KCP 8.3.7.9	M. XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in peas by LC-MS according to SOPa-285-LABCHI-Rev.0 Report No. 18.618095.0007 CHELAB S.R.L. GLP Unpublished	N	Sharda
KCP 8.3.7.10	T. XXX	2018	Magnitude of the residue of Pendimethalin in peas (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – decline curve trial and harvest trial in Poland – 2017 Report No. 17SGS014 SGS Polska Sp. z o.o. GLP Unpublished	N	Sharda
KCP 8.3.7.11	M. XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in peas by LC-MS according to SOPa-285-LABCHI-Rev.0 Report No. 18.618093.0005 CHELAB S.R.L. GLP Unpublished	N	Sharda
KCP 8.3.8.1	K. XXX	2016	Determination of residues at harvest and decline of Pendimethalin in Onion, following one pre-emergence application of Pendimethalin 330 g/L EC, under open field conditions, Central Europe – Season 2016 Report No. FRS 052/16 Field Research Support GLP	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 8.3.8.2	J. XXX	2018	Determination of the residues of Pendimethalin applied as “Pendimethalin 330 g/L” in onion at one site in Germany Report No. ZBBZ-2016/12/DPL/3DE Food Safety Laboratory GLP Unpublished	N	Sharda
KCP 8.3.8.3	S. XXX	2018	Field phase residue trial Pendimethalin 330 g/L EC Onions – Decline – Central Zone – Belgium – 2016 Report No. OL16 UIRES1 PCG GLP Unpublished	N	Sharda
KCP 8.3.8.4	S. XXX	2018	Field phase residue trial Pendimethalin 330 g/L EC Onions – Harvest – central zone – Belgium – 2016 Report No. OL16 UIRES2 PCG GLP Unpublished	N	Sharda
KCP 8.3.8.5	J. XXX	2018	Determination of the residues of Pendimethalin applied as “Pendimethalin 330 g/L” in onion at one site in Belgium, 2016 Report No. ZBBZ-2016/12/DPL/3BE Food Safety Laboratory GLP Unpublished	N	Sharda
KCP 8.3.9.1	S. XXX	2018	Residue study (Harvest) in sunflower following one pre emergence application with Pendimethalin 33% EC in Germany 2017 – field part Report No. CT17-1-53 CropTrials GmbH GLP Unpublished	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.9.2	M. XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in sunflower by LC-MS according to SOPa-286-LABCHI-Rev.0 Report No 18.618095.0012 CHELAB S.R.L. GLP Unpublished	N	Sharda
KCP 8.3.9.3	S. XXX	2018	Magnitude of residue of Pendimethalin in sunflower Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial – Poland – 2017 Report No. BPL17-018 BIOTEK Agriculture España SL GLP Unpublished	N	Sharda
KCP 8.3.9.4	Ch. XXX	2020	Field Residue Trials to Determine Levels of Pendimethalin 33% EC on Sunflowers in Northern Europe Report No. 18-00307 SGS United Kingdom Ltd. GLP Unpublished	N	Sharda
KCP 8.3.9.5	M. XXX	2019	Determination of Pendimethalin (CAS: 40487-42-1) in sunflower by LC-MS according to SOPa-284-LABCHI-Rev. 0 Report No. 19.503381.0003 CHELAB S.R.L. GLP Unpublished	N	Sharda
KCP 8.3.9.6	Z. XXX	2016	Residue study of pendimethalin/Pendimethalin 33% EC (harvest) in sunflower, Poland (Central Europe) – Season 2016 Report No. PL-PH/04/2016-1/8-H InHort GLP Unpublished	N	Sharda
KCP	J. XXX	2018	Determination of residues of pendimethalin applied as “Pendimethalin 330 g/L EC” in sunflower at one	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
8.3.9.7			site in Poland, 2016 Report No. ZBBZ-2016/12/DPL/7PL Food Safety Laboratory GLP Unpublished		
KCP 8.3.10.1	S. XXX	2019	Residue study (Harvest) in strawberry following one application during dormancy with Pendimethalin 33% EC in Germany 2017-2018 – field part. Report No. CT17-1-50 (Field phase) GLP Unpublished	N	Sharda
KCP 8.3.10.2	M. XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in strawberry by LC-MS according to SOPa-286-LABCHI-Rev.0. 18.641074.0002 (Analytical phase) GLP Unpublished	N	Sharda
KCP 8.3.10.3	A. XXX	2020	Determination of the residues of Pendimethalin in/on strawberries after one application of Pendimethalin 33% EC in Northern Europe – Hungary in 2019. Report No. 034SRHU19R39 (Field phase) GLP Unpublished	N	Sharda
KCP 8.3.10.4	M. XXX	2020	Determination of residual trials Pendimethalin (CAS: 40487-42-1) in strawberry by LC-MS according to SOPa-286-LABCHI-Rev.0. Report No. 19.528632.0004 (Analytical phase) GLP Unpublished	N	Sharda
KCP 8.3.10.5	T. XXX	2020	Magnitude of the residue of pendimethalin in strawberry (raw agricultural commodity) after one application of pendimethalin 33% EC – one harvest trial in Poland – 2018. Report No. 18SGS04 (Field phase) GLP Unpublished	N	Sharda
KCP 8.3.10.6	M. XXX	2020	Magnitude of the residue of pendimethalin in strawberry (raw agricultural commodity) after one application of pendimethalin 33% EC – one harvest trial in Poland – 2018	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No. 86/2020 (analytical phase) GLP Unpublished		
KCP 8.3.11.1	S. XXX	2018	Residue study (Harvest) in grapevine following one application with Pendimethalin 33% EC in Germany 2017. Report No. CT17-1-51(Field phase) GLP Unpublished	N	Sharda
KCP 8.3.11.2	M. XXX	2018	Determination of Pendimethalin (CAS: 40487-42-1) in grapes by LC-MS according to SOPa-285-LABCHI-Rev. 0. Report No. 18.618095.0010 (Analytical phase) GLP Unpublished	N	Sharda
KCP 8.3.12.1	K. XXX	2020	Determination of residues at harvest and decline of Pendimethalin in Potato, following one broadcast application of Pendimethalin 330 g/L EC, under open field conditions, Central Europe – Season 2016. Report No. FRS 050/16 (Field phase) GLP Unpublished	N	Sharda
KCP 8.3.12.2	J. XXX	2017	Determination of residues of Pendimethalin applied as “Pendimethalin 330 g/L” in potato at one site in Germany, 2016. Report No. ZBBZ-2016/12/DPL/4DE (Analytical phase) GLP Unpublished	N	Sharda
KCP 8.3.12.3	M. XXX	2017	Field phase residue trial – pre-emergence application of pendimethalin 330 g/L EC in potatoes (Solanum tuberosum) – decline – Central zone – Belgium 2016 Report No. GPE16KR (Field phase) GLP Unpublished	N	Sharda
KCP	M. XXX	2017	Field phase residue trial – pre-emergence application of pendimethalin 330 g/L EC in potatoes (Solanum	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
8.3.12.4			tuberosum) – harvest – central zone – Belgium 2016 Report No. GPE16LO (Field phase) GLP Unpublished		
KCP 8.3.12.5	J. XXX	2017	Determination of residues of pendimethalin applied as “Pendimethalin 330 g/L” in potato at one site in Belgium, 2016 Report No. ZBBZ-2016/DPL/4BE (Analytical phase) GLP Unpublished	N	Sharda
KCP 8.3.12.6	Z. XXX	2016	Residue study of pendimethalin/Pendimethalin 33% EC (harvest) in potato, Poland (Central Europe) – Season 2016 Report PL-PH/04/2016-1/1-H/1 (Field phase) GLP Unpublished	N	Sharda
KCP 8.3.12.7	J. XXX	2018	Determination of the residues of pendimethalin applied as “Pendimethalin 330 g/L” in potato at one site in Poland, 2016 Report No. ZBBZ-2016/12/DPL/4PL (Analytical phase) GLP Unpublished	N	Sharda
KCP 8.3.13.1	K. XXX	2016	Determination of residues at harvest and decline of Pendimethalin in Lettuce, following one broadcast application of PENDIMETHALIN 330 g/L EC, under open field conditions, Central Europe – Season 2016 Report No. FRS 054/16(Field phase) GLP Unpublished	N	Sharda
KCP 8.3.13.2	J. XXX	2018	Determination of the residues of pendimethalin applied as “Pendimethalin 330 g/L” in lettuce at one site in Germany, 2016 Report No. ZBBZ-2016/12/DPL/2DE (Analytical phase) GLP Unpublished	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.13.3	S. XXX	2017	Field phase residue trial Pendimethalin 330 g/L EC lettuce (Lactuca sativa var capitata) – Harvest – Central Zone – Belgium – 2016 Report No. OL16 SLRES1 (Field phase) GLP Unpublished	N	Sharda
KCP 8.3.13.4	S. XXX	2017	Field phase residue trial Pendimethalin 330 g/L EC lettuce (Lactuca sativa var capitata) – Decline – Central Zone – Belgium – 2016 Report No. OL16 SLRES2 (Field phase) GLP Unpublished	N	Sharda
KCP 8.3.13.5	J. XXX	2018	Determination of the residues of Pendimethalin applied as “Pendimethalin 330 g/L” in lettuce at one site in Belgium, 2016, Report No. ZBBZ-2016/12/DPL/2BE (Analytical phase) GLP Unpublished	N	Sharda
KCP 8.5.1	XXX	2018	High temperature hydrolysis of ¹⁴ C-pendimethalin under cooking, baking and pasteurization conditions. Study No. G16100. GLP Unpublished	N	Sharda
KCP 8.3.14.1	G. XXX	2021	Determination of the residues of Pendimethalin in/on plum after one application of Pendimethalin 33% EC in Northern Europe - Hungary in 2021 Report No.: 065CPRHU21R55 CPR Europe Kft. GLP Unpublished	N	Sharda
KCP 8.3.14.2	Z. XXX	2021	Determination of the residues of Pendimethalin in/on plum after one applications of Pendimethalin 33% EC in Northern Europe – Hungary in 2021 Report No.: 74/2021 Łukasiewicz Research Network - Institute of Heavy Organic Synthesis „Blachownia” GLP	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 8.3.14.3	T. XXX	2018	Magnitude of the residue of Pendimethalin in stone fruits (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – two harvest trials in Poland – 2018 Report No.: 18SGS03 SGS Polska Sp. z o.o. GLP Unpublished	N	Sharda

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

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

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Pendimethalin

A 2.1.1 Stability of residues

A 2.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.1.1
Report	Stability study of pendimethalin residues in apple samples during 2 years of storage. Joanna XXX, 2019. Report No. ZBBZ-2017/24/DPL/1.
Guideline(s):	Yes EU Directive 96/46/EC Amending Directive 91/414/EEC, Annex II, section 4 of Part A EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1 OECD Test Guidance No. 506
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

This storage stability study was designed to evaluate the stability of Pendimethalin in Apple when stored under frozen conditions up to 24 months. Apple samples were fortified with Pendimethalin at 0.1 mg/kg, and were stored in a freezer at $\leq -18^{\circ}\text{C}$.

Samples were analyzed after frozen storage intervals: 0 day, 3 months, 6 months, 12 months, 18 months and 24 months.

The analytical method used was previously validated in study No. ZBBZ-2016/69/DPL/2ES.

Preparation of stability samples

The Apples (2000 g) without Pendimethalin residues used for the storage stability study was obtained from the organic orchard of the Research Institute of Horticulture on September 25, 2017. This sample was assigned unique identification number: ZBBZ-2017/24/DPL/1 and stored at $\leq -18^{\circ}\text{C}$ prior to use. On September 28, 2017, the sample was thoroughly homogenized in a knife mill with dry ice and was divided into two parts:

a) ZBBZ-2017/24/DPL/1/1 – untreated for calibration and recovery study - the 1500 g homogenized Apple sample was divided on 40 sub-samples and stored at $\leq -18^{\circ}\text{C}$ in polyethylene bags until analyses;

b) ZBBZ-2017/24/DPL/1/2 – treated of Pendimethalin (Reference Item) for stability study - the 500 g homogenized Apple sample was spiked with Pendimethalin at 0.1 mg/kg (0.5 mL of 100 $\mu\text{g}/\text{mL}$ Pendime-

thalin was added), well mixed, divided on 25 sub-samples and stored at $\leq -18^{\circ}\text{C}$ in polyethylene bags until analyses.

At time “0” one control sub-sample, three sub-samples spiked with Pendimethalin and three sub-samples fortified with Pendimethalin were analysed. At each time point subsequent to time “0”, the analysis consisted of one control sub-sample, three sub-samples spiked with Pendimethalin at 0.1 mg/kg prior the storage and three sub-samples fortified with Pendimethalin at 0.1 mg/kg prior the analysis.

Results and discussions

Table A 1: Stability of pendimethalin residues in apples following storage at -18°C

Matrix	Spike level (mg/kg)	Storage interval (months)	Individual recovered residues (mg/kg)	Individual recoveries (%)
pendimethalin				
Apple	0.1	0	0.101	101
			0.080	80
			0.081	81
	0.1	3	0.098	98
			0.095	95
			0.091	91
	0.1	6	0.092	92
			0.090	90
			0.088	88
	0.1	12	0.096	96
			0.091	91
			0.100	100
	0.1	18	0.081	81
			0.080	80
			0.076	76
	0.1	24	0.079	79
			0.082	82
			0.096	96

Conclusion

The results of this study showed that Pendimethalin is stable in Apple when stored at $\leq -18^{\circ}\text{C}$ for period of up to 24 months.

A 2.1.1.1.2 Study 2

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.1.2
Report	Stability study of pendimethalin residues in oilseed rape samples during 2 years of storage. Joanna XXX, 2019. Report No. ZBBZ-2017/24/DPL/1.
Guideline(s):	Yes EU Directive 96/46/EC Amending Directive 91/414/EEC, Annex II, section 4 of Part A EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1 OECD Test Guidance No. 506
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

This storage stability study was designed to evaluate the stability of Pendimethalin in oilseed rape when stored under frozen conditions up to 24 months. Apple samples were fortified with Pendimethalin at 0.1 mg/kg, and were stored in a freezer at $\leq -18^{\circ}\text{C}$. Samples were analyzed after frozen storage intervals: 0 day, 3 months, 6 months, 12 months, 18 months and 24 months. The general principles of the analytical procedure were based on the Final Report N. 16.566423.0002

Preparation of stability samples

The 2000 g Oilseed rape (seeds) without Pendimethalin residues used for the storage stability study was supplied on September 25, 2017 by the Test Facility in local market. This sample was assigned unique identification number: ZBBZ-2017/24/DPL/2 and stored at $\leq -18^{\circ}\text{C}$ prior to use. On September 27, 2017, the sample was thoroughly homogenized in a knife mill with dry ice and was divided into two parts:

a) ZBBZ-2017/24/DPL/2/1 – untreated for calibration and recovery study - the 1500 g homogenized Oilseed rape sample was divided on 40 sub-samples and stored at $\leq -18^{\circ}\text{C}$ in polyethylene bags until analyses;

b) ZBBZ-2017/24/DPL/2/2 – treated of Pendimethalin (Reference Item) for stability study - the 500 g homogenized Oilseed rape sample was spiked with Pendimethalin at 0.1 mg/kg (0.5 mL of 100 $\mu\text{g}/\text{mL}$ Pendimethalin was added), well mixed, divided on 25 sub-samples and stored at $\leq -18^{\circ}\text{C}$ in polyethylene bags until analyses.

At time “0” one control sub-sample, three sub-samples spiked with Pendimethalin and three sub-samples fortified with Pendimethalin were analysed. At each time point subsequent to time “0”, the analysis consisted of one control sub-sample, three sub-samples spiked with Pendimethalin at 0.1 mg/kg prior the storage and three sub-samples fortified with Pendimethalin at 0.1 mg/kg prior the analysis.

Results and discussions

Table A 1: Stability of pendimethalin residues in apples following storage at -18°C

Matrix	Spike level (mg/kg)	Storage interval (months)	Individual recovered residues (mg/kg)	Individual recoveries (%)
pendimethalin				
Oilseed rape	0.1	0	0.086	86
			0.096	96

Matrix	Spike level (mg/kg)	Storage interval (months)	Individual recovered residues (mg/kg)	Individual recoveries (%)
	0.1	3	0.096	96
			0.085	85
			0.097	97
	0.1	6	0.094	94
			0.084	84
			0.087	87
	0.1	12	0.100	100
			0.094	94
			0.090	90
	0.1	18	0.097	97
			0.094	94
			0.092	92
	0.1	24	0.097	97
			0.082	82
			0.082	82
			0.099	99

Conclusion

The results of this study showed that Pendimethalin is stable in oilseed rape when stored at $\leq -18^{\circ}\text{C}$ for period of up to 24 months.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

No new data were submitted in the framework of this application.

A 2.1.2.1.1 Nature of residues in processed commodities

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.5.1
Report	High temperature hydrolysis of ^{14}C -pendimethalin under cooking, baking and pasteurization conditions. Study No. G16100. XXX, 2018.
Guideline(s):	Yes (OECD 507)
Deviations:	No
GLP:	Yes

Acceptability: Yes

Materials and methods

The hydrolytic stability of ¹⁴C-pendimethalin was investigated in sterile buffer solutions at pH 4, 5 and 6 which were incubated at 90°C for 20 min (pH 4), 100°C for 60 min (pH 5) and 120°C under pressure 15 psi for 20 min (pH 6) to represent pasteurization, baking, brewing or boiling and sterilization, respectively. This study was conducted to investigate the nature of potential residues in processed commodities under these conditions.

Solutions of radiolabeled test item were prepared in 0.01 M citrate buffer (pH 4, 5 and 6) at a nominal test concentration of 0.03 µg/mL, which was not more than one-half of the solubility of pendimethalin in buffer solutions of pH 4, 5 and 6.

At the end of the incubation period, an aliquot of each sample was analyzed by LSC to determine the quantity of radioactivity present in each sample.

Results and discussion

Table A 1: Identification of compounds from high temperature hydrolysis study

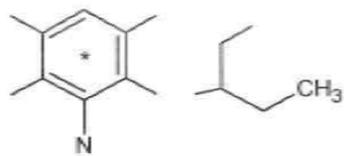
Common name/code ID No.	Chemical name	Chemical structure
pendimethalin	N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine	

Table A 2: Standard hydrolysis study of pendimethalin

Process represented	T° (°C)	Time (min)	pH	Parent Initial conc. (µ/mL)	% of TRR
					Parent
pasteurization	90±5	20	4	0.014	96.2
Baking, brewing and boiling	100±5	60	5	0.014	90.9
sterelisation	120±5	20	6	0.013	88.9

Conclusions

The study demonstrated that pendimethalin was hydrolytically stable under conditions representative of pasteurization, baking or boiling and sterilization.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Wheat

A 2.1.3.1.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.1.1
Report	Magnitude of the residue of Pendimethalin in wheat (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – one decline curve trial in Poland -2017. T. XXX, 2018. Report No. 17SGS011 (Field phase)
Guideline(s):	Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: wheat

Crop parts(s) or processed commodity: whole plant, grain straw

STUDY DESIGN AND METHODS

The application equipment consisted of boom sprayer. The foliar application closely simulated commercial-type treatments. On treated plot, one application on wheat was made according study plan. Calibrations of the spray equipment at the trial site were accomplished by using the volume/time method for liquid applications. Before application, the spray equipment and the sprayer speed were calibrated to deliver an average volume of spray mixture per time unit at a given opening position resulting in the desired spray volume per hectare.

Pendimethalin 33% EC was only mixed with water. No adjuvant was added to the spray mixture. The target dose rate of the test item for the study was 5 L/ha of formulated product per application, equivalent to 328 g as/L. Application was made at a target water volume of 500 litres per hectare of mixture according sprays in Good Agricultural Practice.

The application was carried out within one hour of mixing the spray solution and performed under conditions typical for the crop with either no wind or a light wind of less than 3m/s. The environmental conditions at the time of application were recorded in the Field Notebook.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.1.2
Report	Determination of pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-289-LABCHI-REV.0. M.XXX, 2018, Report No. 18.618093.0002 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Wheat

Crop parts(s) or processed commodity: grain, straw, whole plant

STUDY DESIGN AND METHODS

The analytical phase of the study 18.618093.0002 was conducted to determine the residual level of Pendimethalin in wheat by LC-MS according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 and SOPa-289-LABCHI-REV.0 as described in study No 16.566423.0005 validated on the matrix wheat grain and as described in study No 16.566423.0006 validated on the matrix wheat straw.

Storage in laboratory: field samples were stored frozen at about $T < -18^{\circ}\text{C}$ from reception time to extraction date. Before the analysis, the specimens were grinded and stored the extracts in a freezer about -20°C date.

The determination of Pendimethalin in wheat by LC-MS.

SAMPLE EXTRACTION

For whole plants and grain samples

About 5.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture B were added to the sample. After vortexing for about 1 min, about 6 g (± 0.01 g) of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. The tube was centrifuged at 4750 rpm for 5 min and kept at about 20°C for about 2 hours. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of suspernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

For straw samples

About 3.00 g of sample grinded were introduced into a 50 ml plastic tube. 12.5 ml of milliQ water and 15 ml of extraction mixture A were added to the sample. After vortexing for about 1 min, about 6 g (± 0.01 g) of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1min. The tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and crntrifuged at 4750 rpm for 5 min.

The supernatant of purified sample were recovered and transferred into an HPLC vial and injected.

LIMIT OF QUANTIFICATION AND LIMIT OF DETECTION

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in wheat matrices.

The LOD was set at < 30 % of the LOQ (0.003 mg/kg for wheat). The chromatographic peaks at the LOD were more than three times the background noise.

ACCURACY

Accuracy evaluation was performed on sample aliquots spiked with Pendimethalin at LOQ (about 0.01 mg/kg) 3 replicate analyses were performed for each spiking level.

Mean recovery was 98.2% with RSD = 9.0% for first mass transition and 100.2% with RSD = 9.0% for the second mass transition in grain.

Mean recovery was 104.4% with RSD = 4.0% for first mass transition and 102.6% with RSD = 5.0% for the second mass transition in whole plant.

Mean recovery was 83.6% with RSD = 9.0% for first mass transition and 90.4% with RSD = 4.0% for the second mass transition in straw.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
17SGS011 PL01/Poland/N- EU/2017	Wheat/Tybalt	11/04/2017 13-28/06/2017 14-15/08/2017	1523	472	323	29/05/2017	BBCH 27	Whole plants Whole plants Straw Grain Straw	2.90 0.12 0.03 n.d. 0.04	0 44 77 77 77	12 months Analytical report: 18.618093.0002

Table A 3: Summary of the study 1 trials

A 2.1.3.1.2 Study 2

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.1.3
Report	Magnitude of residue of Pendimethalin in wheat Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial and 1 refinement decline trial. S. XXX, 2018, Report No. BPL17-010. (Field phase)
Guideline(s):	Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: wheat

Crop parts(s) or processed commodity: whole plant, grain straw

STUDY DESIGN AND METHODS

Three field trials were conducted in Poland (Northern Europe). The trials were on representative varieties of wheat.

Each trial was comprised of one untreated control plot and one plot treated with Pendimethalin 33% EC (*Pendimethalin* 330 g/l).

One application was performed at crop growth stage BBCH 25-30 and at a dose rate between 4.51 and 4.74 l/ha of test item; corresponding to a total dose of active ingredient between 1497.6 and 1573.9 g/ha.

One trial was performed to gain grain specimens of wheat (raw agricultural commodities) at harvest.

The other two trials were conducted to study the decline curve of the active ingredient in wheat whole plants, grain and straw. In the decline trial specimens were generated at ±0 DAA, 30-50 DAA and at maturity (harvest at BBCH 89). In the refinement decline trial specimens were generated at ±0 DAA, 1DAA, 2 DAA, 3 DAA, 4 DAA, 5 DAA; 6 DAA, 7 DAA, 8 DAA, 9 DAA, 10 (+/-1) DAA, 12 (+/-1) DAA, 14 (+/-1) DAA and at maturity (harvest at BBCH 89).

ANALYTICAL PHASE

STUDY DESIGN AND METHODS

The analytical phase was conducted according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 “Analytical Procedure for the Determination of Pendimethalin (CAS: 40487-42-1), in wheat grains by Liquid Chromatography” (applied for specimens of whole plants without roots and grain) and SOPa-289-LABCHI-Rev.0 “Analytical Procedure for the Determination of Pendimethalin (CAS: 40487-42-1), in wheat straw by Liquid Chromatography” applied for specimens of straw).

Residues of pendimethalin were extracted from grinded, homogenized wheat (whole plants and grain) with acetonitrile, acetic acid and water. After vortexing, magnesium sulphate anhydrous and sodium acetate were added and vortexed again. The tube was centrifuged and kept at about -20°C for about 2 hours, following a further centrifugation to purify the supernatant. Then a part was transferred to a mixture of magnesium sulphate anhydrous and PSA resin. It was vortexed and centrifuged again. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

The residues of pendimethalin of grinded, homogenized wheat straw were extracted with acetonitrile, glacial acetic acid and water. After vortexing, magnesium sulphate anhydrous and sodium acetate were added and vortexed again. The tube was centrifuged and the supernatant was purified. Then a part was transferred to a mixture of magnesium sulphate anhydrous and PSA resin. It was vortexed and centrifuged again. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

The quantification as *pendimethalin* was performed by LC-MS (liquid chromatography with mass spectrometry detection).

For *pendimethalin* the limit of quantification (LOQ) was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
BPL17-010-01/Poland/N-EU/2017	Spring wheat/Arabella	29/03/17 19-28/06/17 3-4/08/18	1574	306	510	18/05/17	BBCH 25-30	Grain	n.d.	78	
BPL17-010-02/Poland/N-EU/2017	Spring wheat/Harenda	14/03/17 12-28/06/17 07/08/17	1510	294	510	08/05/17	BBCH 25-30	Whole plant Whole plant Grain Straw	6.23 0.13 <0.01 0.04	0 30 91 91	
BPL17-010-03/Poland/N-EU/2017	Spring wheat/Rospuda	30/03/17 19-26/06/17 07/08/17	1498	291	510	16/05/17	BBCH 25-30	Whole plant Whole plant Whole plant Whole plant Whole plant	6.79 2.80 3.19 2.68 1.19	+0 1 2 3 4	

								Whole plant	1.16	5	
								Whole plant	1.15	6	
								Whole plant	1.22	7	
								Whole plant	1.34	8	
								Whole plant	1.49	9	
								Whole plant	1.46	10	
								Whole plant	0.68	13	
								Whole plant	0.78	14	
								Grain	n.d.	83	
								Straw	0.04	83	

A 2.1.3.1.3 Study 3

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.1.4

Report Residue study (Harvest and Decline) in wheat following one post emergence application with Pendimethalin 33% EC in Germany 2018. S. XXX, 2019, Report No. CT17-1-46 (Field phase)

Guideline(s): OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009)
 - EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials
 - The Principles of Good Laboratory Practice, ChemG 25.07.1994, § 19, Annex 1 (BGBL 21, I, 2001, p. 843-855)
 - OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999) 20, Paris 2002
 - The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002
 - The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9
 - Rückstandsversuche, Teil 1 Prüfungen an Pflanzen, A: Allgemeiner Teil, B: Spezieller Teil, IVA-Guideline, Industrieverband Agrar e. V. 1992

Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: wheat

Crop parts(s) or processed commodity: whole plant, grain straw

STUDY DESIGN AND METHODS

The purpose of the study was to generate specimens for the determination of residues after one post emergence application with Pendimethalin 33% EC in wheat in Germany 2018. The specimens to be analysed were the raw agricultural commodity whole plant without roots, grain and straw.

One harvest trial CT17-1-46DE1 and one decline trial CT17-1-46DE2 were carried out in North Germany. For each trial, two plots were measured out on open field in wheat: one untreated control plot (= U / plot 1) and one treated plot (= T / plot 2). Plot 2 was treated once with the test item Pendimethalin 33% EC with the rate of 5.0 L/ha. The applications were performed at the crop stage BBCH 27-30. The used water volume was 200 L/ha.

Specimens of the raw agricultural commodity whole plant without roots were taken at the day of the application and 41 days after the application (decline trial). Specimens of the raw agricultural commodities grain (harvest and decline trials) and straw (decline trial) were collected at the time of commercial harvest / at crop stage BBCH 89. At all sampling dates, specimens were taken from the untreated and treated plots. The specimens were stored frozen (targeting -18°C) at the test facility in Burgwedel / Germany.

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.1.5
Report: Determination of Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-289-LACHI-REV.0. M. XXX, 2018, Report No 18.641074.0001 (Analytical phase)
Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC

Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
EU Guidance Document SANCO/3029/99 rev. 4
EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Wheat

Crop part(s) or processed commodity: grain, straw, whole plant

STUDY DESIGN AND METHODS

The analytical phase of the study 18.641074.0001 was conducted to determine the residual level of Pendimethalin in wheat by LC-MS according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 and SOPa-LABCHI-Rev.0 and as described in study No 16.566423.0005 and No 16.566423.0006 validated on the matrix wheat grains and wheat straw.

Storage in laboratory: field samples were stored frozen at about $T < -18^{\circ}\text{C}$ from reception time to extraction date. Before the analysis, the specimens were grinded and stored the extracts in a freezer about -20°C date.

The determination of Pendimethalin in wheat by LC-MS.

SAMPLE EXTRACTION

For whole plants and grain samples

About 5.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture B were added to the sample. After vortexing for about 1 min, about 6 g (± 0.01 g) of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for

about 1 min. The tube was centrifuged at 4750 rpm for 5 min and kept at about 20°C for about 2 hours. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of suspernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

For straw samples

About 3.00 g of sample grinded were introduced into a 50 ml plastic tube. 12.5 ml of milliQ water and 15 ml of extraction mixture A were added to the sample. After vortexing for about 1 min, about 6 g (± 0.01 g) of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1min. The tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and cntrifuged at 4750 rpm for 5 min.

The supernatant of purified sample were recovered and transferred into an HPLC vial and injected.

LIMIT OF QUANTIFICATION AND LIMIT OF DETECTION

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in wheat matrices.

The LOD was set at < 30 % of the LOQ (0.003 mg/kg for wheat). The chromatographic peaks at the LOD were more than three times the background noise.

ACCURACY

Accuracy evaluation was performed on sample aliquots spkied with Pendimethalin at LOQ (about 0.01 mg/kg) 3 replicate analyses were performed for each spiking level.

Mean recovery was 102.0% with RSD = 2.0% for first mass transition and 100.0% with RSD = 6.0% for the second mass transition in whole plant.

Mean recovery was 97.0% with RSD = 3.0% for first mass transition and 94.0% with RSD = 2.0% for the second mass transition in grain.

Mean recovery was 96.0% with RSD = 2.0% for first mass transition and 94.0% with RSD = 4.0% for the second mass transition in straw.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
(a)	(b)	(c)						(d)	(e)		
CT17-1-46DE1/Germany/N- EU/2018	Winter wheat/Rgt Reform	03/10/2017 -	1604	300	535	11/04/2018	BBCH 27	Grain	0.02	107	12 months

		15/07/2018									Analytical report: 18.618093.0002
CT17-1-46DE2/Germany/N-EU/2018	Winter wheat/Tobak	15/10/2017 - 20/07/2018	1590	200	795	27/04/2018	BBCH 30	Whole plant Whole plant Grain Straw	68/95 0.06 0.03 0.13	0 41 87 87	

A 2.1.3.1.4 Study 4

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.1.6

Report Residue study (Decline) in wheat following one post emergence application with Pendimethalin 33% EC in Germany 2017. T. XXX (Field phase). Report No. CT17-1-47

Guideline(s): OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009)
 - EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials
 - The Principles of Good Laboratory Practice, ChemG 25.07.1994, § 19, Annex 1 (BGBL 21, I, 2001, p. 843-855)
 - OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999) 20, Paris 2002

- The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002
- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9
- Rückstandsversuche, Teil 1 Prüfungen an Pflanzen, A: Allgemeiner Teil, B: Spezieller Teil, IVA-Guideline, Industrieverband Agrar e. V. 1992

Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: wheat

Crop part(s) or processed commodity: whole plant, grain straw

STUDY DESIGN AND METHODS

The trial CT17-1-47DE1 was carried out in open field on the crop spring wheat. The study director assured before start of the trial, that no Pendimethalin containing products would be used on the trial site during the current season (2017). One untreated control plot (U = plot 1) and one treated plot (T = plot 2) were laid out and labelled for each trial. The plot size (8 subplots of 24 m² = 192 m²) was chosen large enough to provide representative specimens for sampling.

Drift of spray solution during the application was avoided by choosing an adequate distance between the untreated and treated plot (10 m).

The application was conducted with a knapsack sprayer with boom. The spraying equipment was cleaned with water before and after use. The output of the nozzles was checked for uniformity before start of application. The speed of walk was adapted to the output of the sprayer and test runs were performed before start of application. The application rate of the test item Pendimethalin 33% EC was 5.0 L/ha. The water volume was 300 L/ha. The application was performed post emergence at crop stage BBCH 30.

The specimens from the untreated plot were always taken prior to the specimens of the treated plot. Ship and retain specimens were taken at each sampling date. The specimens were taken from all subplots at each sampling date. Specimens of the raw agricultural commodity whole plant without roots were taken from the untreated and treated plot at the day of the application and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 12 and 14 days after the application (DALA). Each of these specimen

consisted of ≥ 1.0 kg plant material. At the time of commercial harvest (crop stage BBCH 89, 73 DALA) specimens of the raw agricultural commodities grain (≥ 1.0 kg) and straw (≥ 0.5 kg) were collected from the untreated and treated plot by using a research size combine harvester.

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.1.7

Report Determination of Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-2289-LABCHI-REV.0, M. XXX, 2018, Report No 18.618095.0005 (Analytical phase)

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC
Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
EU Guidance Document SANCO/3029/99 rev. 4
EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No

GLP: Yes

Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Wheat

Crop parts(s) or processed commodity: grain, straw, whole plant

STUDY DESIGN AND METHODS

The analytical phase of the study 18.618095.0005 was conducted to determine the residual level of Pendimethalin in wheat by LC-MS according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 and SOPa-LABCHI-Rev.0 and as described in study No 16.566423.0005 and No 16.566423.0006 validated on the matrix wheat grains and wheat straw.

Storage in laboratory: field samples were stored frozen at about $T < -18^{\circ}\text{C}$ from reception time to extraction date. Before the analysis, the specimens were grinded and stored the extracts in a freezer about -20°C date.

The determination of Pendimethalin in wheat by LC-MS.

SAMPLE EXTRACTION

For whole plants and grain samples

About 5.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture B were added to the sample. After vortexing for about 1 min, about 6 g (± 0.01 g) of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. The tube was centrifuged at 4750 rpm for 5 min and kept at about 20°C for about 2 hours. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of suspernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

For straw samples

About 3.00 g of sample grinded were introduced into a 50 ml plastic tube. 12.5 ml of milliQ water and 15 ml of extraction mixture A were added to the sample. After vortexing for about 1 min, about 6 g (± 0.01 g) of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1min. The tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and crntrifuged at 4750 rpm for 5 min.

The supernatant of purified sample were recovered and transferred into an HPLC vial and injected.

LIMIT OF QUANTIFICATION AND LIMIT OF DETECTION

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in wheat matrices.

The LOD was set at $< 30\%$ of the LOQ (0.003 mg/kg for wheat). The chromatographic peaks at the LOD were more than three times the background noise.

ACCURACY

Accuracy evaluation was performed on sample aliquots spkied with Pendimethalin at LOQ (about 0.01 mg/kg) 3 replicate analyses were performed for each spiking level.

Mean recovery was 101.3% with RSD = 9.0% for first mass transition and 90.3% with RSD = 11.0% for the second mass transition in whole plant.
 Mean recovery was 103.0% with RSD = 4.0% for first mass transition and 101.4% with RSD = 6.0% for the second mass transition in grain.
 Mean recovery was 80.6% with RSD = 13.0% for first mass transition and 92.7% with RSD = 14.0% for the second mass transition in straw.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin			
CT17-1-47DE1/Germany/N- EU/2018	Spring wheat/Dino	25/03/2017	1498.6	300	500	26/05/2017	BBCH 30	Whole plant	5.81	0	12 months Analytical report: 18.618095.0005	
		-						Whole plant	3.69	1		
		-						Whole plant	3.42	2		
								Whole plant	1.39	3		
								Whole plant	1.19	4		
								Whole plant	1.21	5		
								Whole plant	0.31	6		
								Whole plant	0.34	7		
								Whole plant	0.21	8		
								Whole plant	0.03	9		
								Whole plant	0.19	10		
								Whole plant	0.07	12		
								Whole plant	0.12	14		
								Grain	n.d.	73		
	Straw	0.01	73									

A 2.1.3.1.5 Study 5

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.1.8
 Report Determination of residues at harvest and decline of Pendimethalin in Wheat, following one broadcast application of

PENDIMETHALIN 330 g/L EC, under open field conditions Central Europe – Season 2017, K. XXX, Report No FRS 001/17 (Field phase)

Guideline(s): Directive 91/414/EEC
Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: wheat

Crop parts(s) or processed commodity: whole plant, grain straw

STUDY DESIGN AND METHODS

The object of this study was to determine the magnitude and decline of residues of PENDIMETHALIN in wheat resulting from one foliar application at the maximum anticipated labelled rate of PENDIMETHALIN 330 g/L EC. Raw agricultural commodity specimens have been generated from wheat plants harvested from treated and untreated plots 0 and 35(±2) days after last application (DALA) and at commercial harvest for the decline trial and at commercial harvest for the harvest trial. The specimens were harvested from the central part of each plot (discarding 0.5 m at both ends of the plots and borders). No diseased, injured or abnormal samples were taken. Duplicate samples were taken at each plot. Grains and straw were obtained by mechanical threshing of the plots. The study was conducted under field conditions in Central Europe.

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.1.9
Report: Determination of the residues of Pendimethalin applied as “Pendimethalin 330 g/L” in wheat at one site in Germany, 2016. J. XXX, 2017, Report No. ZBBZ-2016/12/DPL/10 DE (Analytical phase)
Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing

of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC
Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing
Regulation (EC) 1107/2009
EU Guidance Document SANCO/3029/99 rev. 4
EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Wheat

Crop parts(s) or processed commodity: grain, straw, whole plant

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues of Pendimethalin in Wheat samples taken from the field trial, after applications of Pendimethalin 330 g/L, under open field conditions. To achieve the objective appropriate analytical method for determination of Pendimethalin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2016/69/DPL/1ES. The validated limit of quantification is 0.01 mg/kg. Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity.

Mean recovery was 84.0% with RSD = 6.7% for first mass transition and 92.0% with RSD = 11.1% for the second mass transition in whole plant.

Mean recovery was 74.0% with RSD = 4.3% for first mass transition and 76.0% with RSD = 4.4% for the second mass transition in grain.

Mean recovery was 96.0% with RSD = 6.0% for first mass transition and 97.0% with RSD = 2.5% for the second mass transition in straw.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin			
FRS0001/17- V1/Germany/N-EU/2017	Winter wheat/RGT Reform	13/11/2016 06/2017 10/08/2017	1650	200	825	31/03/17	BBCH 27	Grain Straw	0.0318 0.0116	130 130	3 months Analytical report: ZBBZ- 2016/12/DPL/10DE	
FRS0001/17- V2/Germany/N-EU/2017	Winter wheat/Ritmo	21/10/2016 06/2017 24/08/2017	1650	200	825	13/04/17	BBCH 30	Plant Plant Grain Straw	167 1.92 n.d. 0.0112	0 35 131 131	3 months Analytical report: ZBBZ- 2016/12/DPL/10DE	

A 2.1.3.2 Barley

A 2.1.3.2.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.2.1
Report	Magnitude of residue of Pendimethalin in barley Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial, S. XXX, 2018, Report No. BPL17-009 (Field and analytical phase)
Guideline(s):	The EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997). OECD/OCDE 509 Adopted: 7 September 2009, OECD guidelines for the testing of chemicals, Crop Field Trial. Relevant standard operating procedures (SOPs) of the Test Facility/Test Site Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, rev. 4 of 11/07/00 of the European Commission. OECD (2007). Guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: barley

Crop parts(s) or processed commodity: whole plant, grain straw

Two field trials were conducted in Poland (Northern Europe). The trials were on representative varieties of barley.

Each trial was comprised of one untreated control plot and one plot treated with Pendimethalin 33% EC (*Pendimethalin* 330 g/l).

One application was performed at crop growth stage BBCH 26-30 and at a dose rate between 4.547 and 4.765 l/ha of test item; corresponding to a total dose of active ingredient between 1509.6 and 1581.9 g/ha.

One trial was performed to gain grain specimens (raw agricultural commodities) at harvest of barley.

Another trial was conducted to study the decline curve of the active ingredient in barley whole plants, grain and straw generated at ± 0 DAA, 30-50 (± 3) DAA and at maturity (harvest at BBCH 89).

The analytical phase was conducted according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 “Analytical Procedure for the Determination of Pendimethalin (CAS: 40487-42-1), in wheat grains by Liquid Chromatography” (applied for specimens of whole plants without roots and grain) and SOPa-289-LABCHI-Rev.0 “Analytical Procedure for the Determination of Pendimethalin (CAS:40487-42-1), in wheat straw by Liquid Chromatography” applied for specimens of straw).

Residues of pendimethalin were extracted from grinded, homogenized barley (whole plants and grain) with acetonitrile, acetic acid and water. After vortexing, magnesium sulphate anhydrous and sodium acetate were added and vortexed again. The tube was centrifuged and kept at about -20°C for about 2 hours, following a further centrifugation to purify the supernatant. Then a part was transferred to a mixture of magnesium sulphate anhydrous and PSA resin. It was vortexed and centrifuged again. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

The residues of pendimethalin of grinded, homogenized barley straw were extracted with acetonitrile, glacial acetic acid and water. After vortexing, magnesium sulphate anhydrous and sodium acetate were added and vortexed again. The tube was centrifuged and the supernatant was purified. Then a part was transferred to a mixture of magnesium sulphate anhydrous and PSA resin. It was vortexed and centrifuged again. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

The quantification as *pendimethalin* was performed by LC-MS (liquid chromatography with mass spectrometry detection).

For *pendimethalin* the limit of quantification (LOQ) was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
BPL17-009-01/Poland/N-EU/2017	Spring barley/Propino	13/03/17 14-30/06/17 31/07/17	1510	294	510	11/05/17	BBCH 25-27	Grain	<0.01	81	207-368 days

BPL17-009-02/Poland/N-EU/2017	Spring barley/Propino	16/03/17	1582	308	514	08/05/17	BBCH 26-30	Whole plants	3.94	+0	207-368 days
		10-19/06/17						Whole plants	0.35	30	
		10/08/17						Grain	n.d.	94	
								Straw	<0.01	94	

A 2.1.3.2.2 Study 2

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.2.2

Report: Residue study (Harvest and decline) in barley following one post emergence application with Pendimethalin 33% EC in Germany 2017 – field part, T. XXX, 2018, Report No. CT17-1-45 (Field phase)

Guideline(s): Directive 91/414/EEC

Deviations: No

GLP: Yes

Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: barley

Crop parts(s) or processed commodity: whole plant, grain straw

STUDY DESIGN AND METHODS

The purpose of the study was to generate specimens for the determination of residues after one post emergence application with Pendimethalin 33% EC in barley in Germany 2017. The specimens to be analysed were the raw agricultural commodity whole plant without roots, grain and straw. Two harvest trials CT17-1-45DE1 and CT17-1-45DE2 were carried out in North and South Germany and one decline trial CT17-1-45DE3 was carried

out in North Germany. For each trial, two plots were measured out on open field in barley: one untreated control plot (= U / plot 1) and one treated plot (= T / plot 2). Plot 2 was treated once with the test item Pendimethalin 33% EC with the rate of 5.0 L/ha. The applications were performed at the crop stage BBCH 25-30. The used water volume was 300 L/ha. Specimens of the raw agricultural commodity whole plant without roots were taken at the day of the application and 40 days after the application (decline trial). Specimens of the raw agricultural commodities grain (harvest and decline trials) and straw (decline trial) were collected at the time of commercial harvest / crop stage BBCH 89. At all sampling dates, specimens were taken from the untreated and treated plots. The specimens were stored frozen (targeting -18°C) at the test facility in Burgwedel / Germany, at the test site in Neidenstein / Germany and at an external storage area in Wunstorf / Germany.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.2.3
Report	Determination of pendimethalin (CAS: 40487-42-1) in barley by LC-MS according to SOPa-288-LABCHI-Rev. 0 and SOPa-289-LABCHI-Rev. 0, M.XXX, 2018, Report No. 18.618095.0004 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: barley

Crop parts(s) or processed commodity: grain, straw, whole plant

STUDY DESIGN AND METHODS

The analytical phase of the study 18/618095.0004 was conducted to determine the residua level of Pendimethalin in barley by LC-MS according to the in-house validated methods codified as SOPa-288-LABCHI-Rev. 0 and SOPa-289-LABCHI-Rev. 0 and as described in the study No 16.566423.0005 and No 16.566423.0006 validated on the matrix wheat grains and wheat straw.

– Sample extraction for whole plants and grain samples

About 5.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixtureB were added to the sample. After vortexing for about 1min, about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1min. The tube was centrifuged at 4750 rpm for 5min and kept at about -20°C for about 2 hours. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

– Sample extraction for whole plants and grain samples

About 3.00 g of sample grinded were introduced into a 50 ml plastic tube; 12.5 mL of milliQ water and 15 ml of extraction mixture were added to the sample and vortexed again for about 1 min. The tube was centrifuged at 4750 rpm for 5 min and it was proceed ro purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatants of purified sample were recovered and transferred into an HPLC vial and injected.

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in barley matrices.

The LOD was set at < 30 % of the LOQ (0.003 mg/kg for barley).

Mean recovery was 91.6% with RSD = 3.0% for first mass transition and 105.2% with RSD = 2.0% for the second mass transition in whole plant.

Mean recovery was 88.7% with RSD = 0.2% for first mass transition and 88.2% with RSD =0.04% for the second mass transition in grain.

Mean recovery was 86.0% with RSD = 3.0% for first mass transition and 82.7% with RSD = 1.0% for the second mass transition in straw.

Trial No./	Commodity/ Variety	Date of 1.Sowing or plant-	Application rate per treat- ment	Dates of treat- ment or no. of	Growth stage at last treatment	Portion ana- lyzed	Residues (mg/kg)	PHI (days)	Details on trial
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Location/ EU zone/ Year	(a)	ing 2. Flowering 3. Harvest	g a.s./ ha	Water (l/ha)	g a.s./hl	treatments and last date	or date		Pendimethalin	(d)	(e)
CT17-1-45- DE1/Germany/N-EU/2017	Spring barley/Quench	25/03/2017 01/04/2017 06/08/2017	1723	-	-	26/05/2017	BBCH 30	Grain	0.01	73	3 months Analytical report: 18.618095.0004
CT17-1-45- DE2/Germany/N-EU/2017	Spring barley/Avalon	16/03/2017 01/04/2017 02/08/2017	1752	-	-	10/05/2017	BBCH 25-28	Grain	n.d.	83	3 months Analytical report: 18.618095.0004
CT17-1-45- DE3/Germany/N-EU/2017	Spring barley/Avalon	13/03/2017 28/03/2017 13/07/2017	1623	-	-	26/05/2017	BBCH 30	Whole plant Whole plant Grain Straw	5.66 0.08 n.d. 0.10	0 40 54 54	3 months Analytical report: 18.618095.0004

A 2.1.3.2.3 Study 3

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.2.4

Report: Field residue trials to determine levels of Pendimethalin 33% EC on Barley in Northern Europe, Ch. XXX, Report No. 18-00246 (Field phase)

Guideline(s): Directive 91/414/EEC

Deviations: No

GLP: Yes

Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: barley

Crop parts(s) or processed commodity: whole plant, grain straw

STUDY DESIGN AND METHODS

A study on the residue level of Pendimethalin 33% EC following 1 application on Barley in Northern Europe. The field phase of this study comprised 1 location in the United Kingdom which was representative for this test crop. One harvest trial and two decline trials were conducted consisting of two plots each: 1 untreated plot (plot U) and 1 plot treated with Pendimethalin 33% EC (plot T). The application made at BBCH 30 was carried out using a boom sprayer to reproduce a normal agricultural application technique on a small-scale size. For the harvest trial 4 samples, were collected at harvest, 2 from Plot U and 2 from Plot T. For the decline trials there were 3 sampling occasions; on the day of application and 30-50 days after application. At these timings 2 whole plant samples from Plot U and 2 whole plant samples from T were collected. At harvest 4 samples from Plot U and 4 samples from Plot T were collected.

During storage at the field Test Sites the samples were kept deep frozen at a target temperature of -18°C, any increases were within an acceptable range. For the shipment, the specimens were packed into boxes within a freezer lorry and sent to the analytical laboratory, where they arrived deep-frozen.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.2.5
Report	Determination of Pendimethalin (CAS: 40487-42-1) in Barley by LC-MS according to SOPa-288-LABCHI-Rev.0 and SOPa-289-LABCHI-Rev.0, M. XXX, Report No. 19.503381.0001 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes

Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: barley

Crop parts(s) or processed commodity: grain, straw, whole plant

STUDY DESIGN AND METHODS

The analytical phase of the study 19.503381.0001 was conducted to determine the residua level of Pendimethalin in barley by LC-MS according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 and SOPa-289-LABCHI-Rev.0 and as described in study No. 16.566423.0005 and No. 16.566423.0006 validated on the matrix wheat grains and wheat straw.

SAMPLE EXTRACTION

– Sample extraction for whole plants and grain samples

About 5.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixtureB were added to the sample. After vortexing for about 1min, about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1min. The tube was centrifuged at 4750 rpm for 5min and kept at about -20°C for about 2 hours. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

– Sample extraction for whole plants and grain samples

About 3.00 g of sample grinded were introduced into a 50 ml plastic tube; 12.5 mL of milliQ water and 15 ml of extraction mixture were added to the sample and vortexed again for about 1 min. The tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatants of purified sample were recovered and transferred into an HPLC vial and injected.

LIMIT OF QUANTIFICATION AND LIMIT OF DETECTION

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in barley matrices.

The LOD was set at < 30 % of the LOQ (0.003 mg/kg for barley). The chromatographic peaks at the LOD were more than three times the background noise.

ACCURACY

Accuracy evaluation was performed on sample aliquots spiked with Pendimethalin at LOQ (about 0.01 mg/kg) 3 replicate analyses were performed for each spiking level.

Mean recovery was 98.0% with RSD = 2.0% for first mass transition and 90.0% with RSD = 5.0% for the second mass transition in whole plant.

Mean recovery was 95.0% with RSD = 1.0% for first mass transition and 99.0% with RSD = 3.0% for the second mass transition in grain.

Mean recovery was 98.0% with RSD = 2.0% for first mass transition and 102.0% with RSD = 4.0% for the second mass transition in straw.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
18-00246-01/N- EU/UK/2018	Barley/Planet	22/03/18 02-27/06/2018 21/08/2018	1555	229	679	24/05/2018	BBCH 30	Grain Straw	<0.01 0.05	89 89	7 months Analytical report: 19.503381.0001
18-00246-02/N- EU/UK/2018	Barley/Planet	22/03/18 02-27/06/2018 21/08/2018	1593	234	681	24/05/2018	BBCH 30	Whole plant Whole plant Grain Straw	397.02 0.21 n.d. 0.04	0 50 89 89	7 months Analytical report: 19.503381.0001
18-00246-03/N- EU/UK/2018	Barley/Planet	22/03/18 02-27/06/2018 21/08/2018	1667	245	680	24/05/2018	BBCH 30	Whole plant Whole plant Grain Straw	342.07 0.07 n.d. 0.05	0 50 89 89	7 months Analytical report: 19.503381.0001

A 2.1.3.3 Maize

A 2.1.3.3.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.3.1
Report	Magnitude of residue of Pendimethalin in maize whole plants and Raw Agricultural Commodity (grains) after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial – Poland – 2017, S. XXX, Report No. BPL17-017 (Field and analytical phase)
Guideline(s):	The EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997). OECD/OCDE 509 Adopted: 7 September 2009, OECD guidelines for the testing of chemicals, Crop Field Trial. Relevant standard operating procedures (SOPs) of the Test Facility/Test Site Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, rev. 4 of 11/07/00 of the European Commission. OECD (2007). Guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: maize

Crop parts(s) or processed commodity: whole plant, grain straw

Two field trials were conducted in Poland (Northern Europe). The trials were on representative varieties of maize.

Each trial was comprised of one untreated control plot and one plot treated with Pendimethalin 33% EC (*Pendimethalin* 330 g/l). One soil directed application was performed at crop pre-emergence and at a dose rate between 5.35 and 5.44 l/ha of test item; corresponding to a total dose of active ingredient between 1776,7 and 1806.1 g/ha.

One trial was performed to gain specimens at harvest (raw agricultural commodities) of maize grain. Another trial was conducted to study the decline curve of the active ingredient in maize whole plants, grain and straw generated at 30 (±3) DAA, 45 (±4) DAA, 60 (±5) DAA and at maturity (harvest at BBCH 89).

The analytical phase was conducted according to the in-house validated methods codified as SOPa- 288-LABCHI-Rev.0 “Analytical Procedure for the Determination of Pendimethalin (CAS: 40487-42-1), in wheat grains by Liquid Chromatography” (applied for specimens of whole plants without roots and grain) and SOPa-289-LABCHI-Rev.0 “Analytical Procedure for the Determination of Pendimethalin (CAS: 40487-42-1), in wheat straw by Liquid Chromatography” (applied for specimens of straw). Residues of pendimethalin were extracted from grinded, homogenized maize (whole plants and grain) with acetonitrile, acetic acid and water. After vortexing, magnesium sulphate anhydrous and sodium acetate were added and vortexed again. The tube was centrifuged and kept at around -20°C for about 2 hours, following a further centrifugation to purify the supernatant. Then, a part was transferred to a mixture of magnesium sulphate anhydrous and PSA resin. It was vortexed and centrifuged again. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

The residues of pendimethalin of grinded, homogenized maize straw were extracted with acetonitrile, glacial acetic acid and water. After vortexing, magnesium sulphate anhydrous and sodium acetate were added and vortexed again. The tube was centrifuged and the supernatant was purified. Then, a part was transferred to a mixture of magnesium sulphate anhydrous and PSA resin. It was vortexed and centrifuged again. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

The quantification as *pendimethalin* was performed by LC-MS (liquid chromatography with massspectrometry detection). For *pendimethalin* the limit of quantification (LOQ) was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg. During analysis of maize specimens (whole plants without roots, straw and grain), recovery determinations with fortifications at the levels of 0.01 mg/kg were performed for Pendimethalin in a single extraction with single determination. Percent recoveries obtained were in the range of 70-110 % with RSDs ≤ 20 %, which validates the analyses.

Analysis (extraction) of the specimens took place:

- 148 days after sample collection for grain and straw specimens.
- 239-266 days after sample collection for whole plants specimens.

All untreated specimens were below LOD (30% of LOQ that corresponds to 0.003 mg/kg). In the treated whole plant without root specimens, residues of *Pendimethalin* ranged from below 0.003 to 0.06 mg/kg.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		

BPL17-017-01/Poland/N-EU/2017	Maize/NK Falkone	10/05/17 16/07-02/08/17 09/10/2017	1777	288	617	17/05/17	BBCH 05-06	Grain	n.d.	145	
BPL17-017-02/Poland/N-EU/2017	Maize/P8816	04/05/17 18/07-08/08/17 09/10/17	1806	293	620	11/05/17	BBCH 05 – 07	Whole plant Whole plant Whole plant Grain Straw	0.06 n.d. n.d. n.d. n.d.	33 46 60 151 151	

A 2.1.3.3.2 Study 2

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.3.2

Report Residue study (Harvest and Decline) in maize following one pre emergence application with Pendimethalin 33% EC in Germany 2017 – field part, S. XXX, Report No. CT17-1-48 (Field phase)

Guideline(s): The EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997).
 OECD/OCDE 509 Adopted: 7 September 2009, OECD guidelines for the testing of chemicals, Crop Field Trial.
 Relevant standard operating procedures (SOPs) of the Test Facility/Test Site
 Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414.
 Document SANCO 3029/99, rev. 4 of 11/07/00 of the European Commission.
 OECD (2007). Guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17.

Deviations: No

GLP: Yes

Acceptability: Yes

MATERIAL AND METHODS A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: maize

Crop parts(s) or processed commodity: whole plant, grain straw

The purpose of the study is to generate specimens for the determination of residues after one pre emergence application with Pendimethalin 33% EC in maize in Germany 2017. Specimens will be taken at commercial harvest (Harvest and Decline) and at 30, 45 and 60 days after the application (Decline). The study was carried out according to the study plan CT17-1-48 (accompanied by two study plan amendments), the guideline document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999 and the guidelines mentioned in the “Statement of Compliance”. One harvest trial CT17-1-48DE1 and one decline trial CT17-1-48DE2 were carried out in South Germany. For each trial, two plots were measured out on open field: one untreated control plot (= U / plot 1) and one treated plot (= T / plot 2). Plot 2 was treated once with the test item Pendimethalin 33% EC with the rate of 6.0 L/ha. The applications were performed pre emergence of the crop maize. The used water volume was 300 L/ha. Specimens of the raw agricultural commodity whole plant without roots were taken 30, 45 and 60 days after the application for the decline trial. Specimens of the raw agricultural commodities grain (harvest and decline trials) and straw (decline trial) were collected at the time of commercial harvest. At all sampling dates, specimens were taken from the untreated and treated plots. The specimens were stored frozen (targeting -18°C) at the test site in Neidenstein / Germany and at external storage areas in Heppenheim / Germany and in Wunstorf / Germany.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.3.3
Report	Determination of pendimethalin (CAS: 40487-42-1) in maize by LC-MS according to SOPa-288-LABCHI-Rev.0 and SOPa-289-LABCHI-Rev.0, M. XXX, Report No. 18.618096.0008 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/V1/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Maize

Crop parts(s) or processed commodity: grain, straw, whole plant

STUDY DESIGN AND METHODS

The analytical phase of the study 18.618095.0008 was conducted to determine the residua level of Pendimethalin in maize by LC-MS according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 and SOPa-289-LABCHI-Rev.0 and as described in study No. 16.566423.0005 and No. 16.566423.0006 validated on the matrix wheat grains and wheat straw.

SAMPLE EXTRACTION

For whole plant without roots and grain

About 5.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture B were added to the sample. After vortexing for about 1 min about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 2 hours. Then the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

For straw

About 3.00 g of sample grinded were introduced into a 50 ml plastic tube, 12.5 ml of milliQ water and 15 ml of extraction mixture A were added to the sample. After vortexing for about 1 min, about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1min. The tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of

supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample were recovered and transferred into an HPLC vial and injected.

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in maize matrices.

The LOD was set at < 30 % of the LOQ (0.003 mg/kg for maize). The chromatographic peaks at the LOD were more than three times the background noise.

Mean recovery was 100.2% with RSD = 5.0% for first mass transition and 101.4% with RSD = 5.0% for the second mass transition in grain.

Mean recovery was 109.5% with RSD = 1.0% for first mass transition and 108.3.0% with RSD = 3.0% for the second mass transition in whole plant.

Mean recovery was 83.3% with RSD = 7.0% for first mass transition and 83.3% with RSD = 6.0% for the second mass transition in straw.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
CT17-1-38-DE1/N- EU/Germany/2017	Maize/KWS Figaro	22/04/2017 08/05/2017 14/09/2017	1801	400	450	28/04/2017	BBCH 05-07	Grain	n.d.	157	6 months Analytical report: 18.618095.0008
CT17-1-48DE2/N- EU/Germany/2017	Maize/KWS Stabil	22/04/2017 17/05/2017 13/10/2017	2010	300	670	10/05/2017	BBCH 00-05	Whole plant Whole plant Whole plant Grain Straw	<0.01 n.d. n.d. n.d. n.d.	30 45 60 153 153	6 months Analytical report: 18.618095.0008

A 2.1.3.3.3 Study 3

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.3.4
Report	Determination of residues at harvest and decline of Pendimethalin in Maize, following one broadcast application of PENDIMETHALIN 330g/L EC, under open field conditions, Central Europe – Season 2016, K. XXX, Report No. FRS 056/16 (Field phase)
Guideline(s):	The EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997). OECD/OCDE 509 Adopted: 7 September 2009, OECD guidelines for the testing of chemicals, Crop Field Trial. Relevant standard operating procedures (SOPs) of the Test Facility/Test Site Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, rev. 4 of 11/07/00 of the European Commission. OECD (2007). Guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: maize

Crop parts(s) or processed commodity: whole plant, grain straw

The object of this study is to determine the magnitude and decline of residues of PENDIMETHALIN in Maize resulting from one broadcast foliar application at the maximum anticipated labelled rate of PENDIMETHALIN 330 g/L EC.

Raw agricultural commodity specimens have been generated from plants harvested from treated and untreated plots 20(±2), 10(±2) days before harvest (DBH) and at commercial harvest for the decline trial and at commercial harvest for the harvest trial.

The study was conducted under field conditions in Central Europe.

Plants and cobs were harvested from the central part of each plot (discarding 0.5 m at both ends of the plots and borders) by manual harvest. No diseased, injured or abnormal samples should be taken. Duplicate samples were taken at each plot.

12 stalks of Maize were divided in three equal parts. Upper parts from stalks 1-4, middle parts from stalks 5-8 and lower parts from stalks 9-12 were assembled to one sample. 12 cobs of maize for ship and retain were taken. The leaves of the cobs were removed.

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.3.5

Report: Determination of the residues of pendimethalin applied as “Pendimethalin 330 g/L” in maize at one site in Germany 2016, J. XXX, Report No. ZBBZ-2016/12/DPL/9DE (Analytical phase)

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC
Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
EU Guidance Document SANCO/3029/99 rev. 4
EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No

GLP: Yes

Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Maize

Crop part(s) or processed commodity: grain, straw, whole plant

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues of Pendimethalin in Maize samples taken from the field trial, after applications of Pendimethalin 330 g/L, under open field conditions. To achieve the objective, appropriate analytical method for determination of Pendimethalin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2016/69/DPL/1ES. The validated limit of quantification is 0.01 mg/kg. The general principles of the analytical procedure were based on the Final Report N. 16.566423.005 and Final Report N. 16.566423.006. In brief, samples of Maize were extracted with acidified acetonitrile. After addition of a buffer-salt mixture containing magnesium sulfate and sodium acetate the extract was shaken. After centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulfate addition. Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
FRS056/16-V1/N-EU/Germany/2017	Maize/Fernandez	16/04/16 07-08/16 26/09/16	1584	200	792	08/06/16	BBCH 15-16	Rest of plant Grain	n.d. n.d.	110	19 months Analytical report: ZBBZ- 2016/12/DPL/9DE
FRS056/16-V2/N-EU/Germany/2017	Maize/Palmer	21/05/16 07-08/16 26/09/16	1684	200	792	08/06/16	BBCH 14-15	Whole plant Whole plant Rest of plant Grain	n.d. n.d. n.d. n.d.	90 100 110 110	19 months Analytical report: ZBBZ- 2016/12/DPL/9DE

A 2.1.3.4 Apples

A 2.1.3.4.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.4.1
Report	Residue study (Harvest) in apple following one application with Pendimethalin 33% EC in Germany 2017, T. XXX, Report No. CT17-1-49 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Apple

Crop parts(s) or processed commodity: fruits

STUDY DESIGN AND METHODS

The purpose of the study was to generate specimens for the determination of residues after one application with Pendimethalin 33% EC in apple in Germany 2017. The test item was applied onto the ground between the trees. Specimens were generated at the time of commercial harvest.

Two harvest trials CT17-1-49DE1 and CT17-1-49DE2 were carried out in North and South Germany. For each trial, two plots were measured out in an orchard in apple: one untreated control plot (= U / plot 1) and one treated plot (= T / plot 2). Plot 2 was treated once with the test item Pendimethalin 33% EC with the rate of 6.0 L/ha. The applications were performed before fruit setting at the crop stage BBCH 61 - 62. The used water volume was 400 -500 L/ha.

Specimens of the raw agricultural commodity fruit were taken at the time of commercial harvest / at crop stage BBCH 89. Specimens were taken from the untreated and treated plots. The specimens were stored frozen (targeting -18°C) at the test facility in Burgwedel / Germany, at the test site in Neidenstein / Germany and at an external storage area in Wunstorf / Germany.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.4.2
Report	Determination of pendimethalin (CAS:40487-42-1) in pome fruits by LC-MS according to SOPa-285-LABCHI-Rev.0, M. XXX, Report No. 18.618095.0009 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Apple

Crop parts(s) or processed commodity: fruits

The analytical phase of the study 18.618095.0009 was conducted to determine the residual level of Pendimethalin in pome fruits (apple) by LC-MS according to the in-house validated methods codified as SOPa-285-LABCHI-Rev.0 and as described in study No. 16.566423.0002 validated on the matrix potato.

SAMPLE EXTRACTION

- About 5.00 g of grinded sample were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5min.
 The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

Mean recovery was 104.4% with RSD = 1.0% for first mass transition and 103.2% with RSD = 5.0% for the second mass transition in pepper fruits.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treat- ment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
(a)	(a)	(b)				(c)			(d)	(e)	
CT17-1-49DE1/N- EU/Geramny/2017	Apple/Elstar	1998 24/04/2017 01/10/2017	2283	400	571	25/04/2017	BBCH 62	Fruits	n.d.	127	7 months Analytical report: 18.618095.0009
CT17-1-49DE2/N- EU/Geramny/2017	Apple/Gala	2000 14/04-17/05/2017 31/08/2017	2220	500	440	21/04/2017	BBCH 61	Fruits	n.d.	116	7 months Analytical report: 18.618095.0009

A 2.1.3.4.2 Study 2

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.4.3
Report	Magnitude of the residue of Pendimethalin in apple (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – one harvest trial in Poland, T. XXX, Report No. 17SGS015 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Apple

Crop parts(s) or processed commodity: fruits

STUDY DESIGN AND METHODS

The objective of the study was to generate specimens of apple Raw Agricultural Commodity (RAC) following one application of Pendimethalin 33% EC to quantify residues of Pendimethalin under cultural practice typical for apple production.

One harvest trial was established on apple in central Poland. The site was representative of apple grown in a way typical of the producing region in the test country. Trial consisted one untreated plot U and one treated plot T. Plots were of sufficient size to generate the desired specimen quantities. For untreated and treated plots, they consisted of minimum 6 trees. Around the treated and untreated plots, a buffer zone of at least 10 m was set up. The application equipment consisted of Boom sprayer. The ground spray application of the plot area closely simulated commercial-type treatments.

Pendimethalin 33% EC was only mixed with water. No adjuvant was added to the spray mixture.

The target dose rate of the test item for the study was 6 L/ha of formulated product per application equivalent to 333.33 g as/L. Applications were made at a target volume of 500 litres per hectare of mixture according sprays in GAP.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.4.4
Report	Determination of pendimethalin (CAS:40487-42-1) in pome fruits by LC-MS according to SOPa-285-LABCHI-Rev.0, M. XXX, Report No. 18.618093.0006 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Apple

Crop parts(s) or processed commodity: fruits

The analytical phase of the study 18.618093 was conducted to determine the residual level of Pendimethalin in pome fruits (apple) by LC-MS according to the in-

house validated methods codified as SOPa-285-LABCHI-Rev.0 and as described in study No. 16.566423.0002 validated on the matrix potato.

SAMPLE EXTRACTION

- About 5.00 g of grinded sample were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5min.
 The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

Mean recovery was 103.8% with RSD = 1.0% for first mass transition and 105.5% with RSD = 2.0% for the second mass transition in pepper fruits.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
17SGS015 PL01/N-EU/Poland	Apple/Gloster	02/03/2014 05-25/05/2017 06-15/10/2017	2119	535	396	17/05/2017	BBCH 65	Fruits	n.d.	147	7 months Analytical report: 18.618093.0006

A 2.1.3.4.3 Study 3

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.4.5
Report	Field residue trials to determine levels of Pendimethalin 33% EC on Pome Fruits (apples) in Northern Europe, Ch. XXX, Report No. 18-00305 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Apple

Crop parts(s) or processed commodity: fruits

STUDY DESIGN AND METHODS

A study on the magnitude of the residues of Pendimethalin 33% EC on apples Raw Agricultural Commodity (RAC) was conducted in northern Europe following a single bare ground application of Pendimethalin 33% EC. The field phase of this study comprised one location in northern Europe which was representative for this test crop. One harvest trial was conducted, which consisted of two plots: one untreated plot (plot 1) and one plot treated with Pendimethalin 33% EC (plot 2). The application was carried out using a boom sprayer in order to reproduce a normal agricultural application technique on a small-scale size. One application was applied to plot 2 133 days before normal commercial harvest (NCH). The water volume applied was 190.5 L/ha for Pendimethalin 33% EC bare ground applications. Specimens of fruits were taken at 133 days after application.

During storage at the field Test Sites the samples from trial 18-00305-01 were kept deep frozen at no more than ≤ -13.4 °C. For the shipment, the specimens were packed into boxes and sent to the analytical laboratory, where they arrived deep-frozen.

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.4.6

Report	Determination of Pendimethalin (CAS: 40487-42-1) in Pome Fruits by LC-MS according to SOPa-285-LABCHI-Rev.0, M. XXX, Report No. 19.503381.0002 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Apple

Crop parts(s) or processed commodity: fruits

The analytical phase of the study 19.503381.0002 was conducted to determine the residual level of Pendimethalin in pome fruits (apple) by LC-MS according to the in-house validated methods codified as SOPa-285-LABCHI-Rev.0 and as described in study No. 16.566423.0002 validated on the matrix potato.

SAMPLE EXTRACTION

- About 5.00 g of grinded sample were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of superna-

tant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

Mean recovery was 84.0% with RSD = 3.0% for first mass transition and 87.0% with RSD = 1.0% for the second mass transition in pepper fruits.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
18-00305-01/N- EU/UK/2018	Apple/Braeburn	1998 20/04-13/05/2018 23-30/09/2018	1886	190	992	13/05/2018	BBCH 69	Fruits	n.d.	133	6 months Analytical report: 19.503381.0002

A 2.1.3.5 Soybean

A 2.1.3.5.1 Study 1

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.5.1
 Report Residue study (harvest) in soybean following one pre emergence application with Pendimethalin 33% EC in Germany 2017 – field part, S. XXX, Report No. CT17-1-52 (Field phase)
 Guideline(s): Directive 91/414/EEC

Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Soybeans

Crop parts(s) or processed commodity: grain

STUDY DESIGN AND METHODS

The trial CT17-1-52DE1 was carried out on open field on the crop soybean. The study director assured before start of the trial, that no Pendimethalin containing products would be used on the trial site during the current season (2017).

One untreated control plot (U = plot 1) and one treated plot (T = plot 2) were laid out and labelled. The plot size (30 m²) was chosen large enough to provide representative specimens for the sampling date. Drift of spray solution during the applications was avoided by choosing an adequate distance between the untreated and treated plot (12 m). A buffer zone of 10 m was set up around the plots of the trial.

The application of the test item was performed three days after sowing / pre emergence of the crop. The application was conducted with a knapsack sprayer with boom. The spraying equipment was cleaned with water before and after use. The output of the nozzles of the spraying boom was checked for uniformity before start of application. The speed of walk was adapted to the output of the spraying boom and test runs were performed before start of application. The application rate of the test item Pendimethalin 33% EC was 6.0 L/ha. The used water volume was 400 L/ha. At time of commercial harvest 5 kg plants per plot were collected from at least 12 different places distributed over the central area of the plots. The specimens from the untreated plot were taken prior to the specimens of the treated plot.

Each specimen was placed in a plastic bag labelled with the specimen identification number. The plastic bag was placed in a second bag. The specimens were frozen within 3 hours after collection. 29 days after freezing, the seeds were separated from straw with a combine harvester. After separation, each specimen consisted of 1.0 kg dry seeds. The straw was discarded. Each specimen was placed in a new plastic bag labelled with the specimen identification number. The plastic bag was placed in a second bag. Ship and retain specimens were taken. No thawing occurred during the procedure of specimen preparation.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.5.2
Report	Determination of pendimethalin (CAS: 40487-42-1) in soy bean by LC-MS according to SOPa-284-LABCHI-Rev.0, M. XXX, Report No. 18.618095.0011 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Soybeans

Crop parts(s) or processed commodity: grain

The analytical phase of the study 18.618095.0011 was conducted to determine the residual level of Pendimethalin in soybean grains by LC-MS according to the in-house validated methods codified as SOPa-284-LABCHI-Rev.0 and as described in study No. 16.566423.0011 validated on the matrix soybeans.

SAMPLE EXTRACTION

About 3.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. Then the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min. The supernatant of pruiified sample was recovered and transferred into an HPLC vial and injected.

Mean recovery was 90.7% with RSD = 3.0% for first mass transition and 93.7% with RSD = 3.0% for the second mass transition in soybean grain.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
CT17-1-52DE1/N- EU/Germany/2017	Soybean/Sultana	17/04/2017 02/07/2017 23/07/2017	1952	400	488	20/04/2017	BBCH 05	Grain	n.d.	153	8 months Analytical report: 18.618095.0011

A 2.1.3.5.2 Study 2

Comments of zRMS:	Study is accepted
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Reference:

KCP 8.3.5.3

Report	Magnitude of the residue of Pendimethalin in soybean (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – two harvest trials in Poland – 2017, K. XXX, Report No. 17SGS016 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Soybeans

Crop parts(s) or processed commodity: grain

STUDY DESIGN AND METHODS

Two harvest trials were established on soybean in Poland. The sites were representative of soybean grown in a way typical of the producing region in the test country. Each trial consisted one untreated plot U and one treated plot T. Plots were of sufficient size to generate the desired specimen quantities. Each harvest trial contained untreated and treated plots, their area was 30 m² per plot. Around the treated and untreated plots, a buffer zone of at least 10 m was set up. The untreated plot was separated by a buffer zone of at least 10 m from the treated plot.

The application equipment consisted of boom sprayers. The foliar application closely simulated commercial-type treatments.

PENDIMETHALIN 33% EC was only mixed with water. No adjuvant was added to the spray mixture. The target dose rate of the test item for the study was 6 L/ha of formulated product per application, equivalent to 333.33 g as/L. Applications were made at a target water volume of 500 litres per hectare of mixture according sprays in GAP. The application was carried out within one hour of mixing the spray solution and performed under conditions typical for the crop with either no wind or a light wind of less than 3m/s.

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.5.4

Report	Determination of pendimethalin (CAS: 40487-42-1) in soy bean by LC-MS according to SOPa-284-LABCHI-Rev.0, M. XXX, Report No. 18.618093.0007 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Soybeans

Crop parts(s) or processed commodity: seeds

The analytical phase of the study 18.618093.0007 was conducted to determine the residual level of Pendimethalin in soybean grains by LC-MS according to the in-house validated methods codified as SOPa-284-LABCHI-Rev.0 and as described in study No. 16.566423.0011 validated on the matrix soybeans.

SAMPLE EXTRACTION

About 3.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. Then the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It

was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min. The supernatant of pruned sample was recovered and transferred into an HPLC vial and injected.

Mean recovery was 82.9% with RSD = 2.0% for first mass transition and 83.9% with RSD = 2.0% for the second mass transition in soybean grain.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
17SGS016 PL01/N- EU/Poland/2017	Soybean/Merlin	12/05/2017 30/06-20/07/2017 13/10/2017	2123	539	394	18/05/2017	BBCH 00	Seeds	n.d.	148	5 months Analytical report: 18.618093.0007
17SGS016 PL02/N- EU/Poland/2017	Soybean/Merlin	02/06/2017 05-26/07/2017 12/10/2017	2016	512	394	02/06/2017	BBCH 01	Seeds	n.d.	132	5 months Analytical report: 18.618093.0007

A 2.1.3.5.3 Study 3

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.5.5
Report	Residue study of pendimethalin/Pendimethalin 33% (harvest) in soybean, Poland (Central Europe) – Season 2016, Z. XXX, Report PL-PH/04/2016-1/7-H (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Soybeans

Crop parts(s) or processed commodity: grain

STUDY DESIGN AND METHODS

The object of this study was to determine the magnitude and decline of residues of Pendimethalin 33% EC in soybean resulting from one soil applications at the maximum anticipated labelled rate Pendimethalin 33% EC. The study was conducted under field conditions in Poland (Central Europe). Raw soybean specimens have been generated during the harvest of soybean, variety: Aldana, from the plots treated with Pendimethalin 33% EC and untreated. The samples were collected at correct time. From each plot one sample was taken. Soybeans seeds was picked by hand. During sampling the disposable clothing was worn and gloves were changed between each plot. Sampling equipment was cleaned from the soil between each plot. Soybean in the samples was healthy, at normal heights, with typical colour with no diseases, no injuries or abnormal symptoms. Specimens were placed into dry paper bags and labeled. After collecting samples from experiment, all bags with fresh material was delivered to analytical laboratory within one hour.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.5.6
Report	Determination of residues of pendimethalin applied as “Pendimethalin 330 g/L EC” in soybean at one site in Poland, 2016, J. XXX, Report No. ZBBZ-2016/12/DPL/8PL (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Soybeans

Crop parts(s) or processed commodity: seeds

The objective of this study was to determine the residues of Pendimethalin in Soybean samples taken from the field trial, after applications of Pendimethalin 330 g/L EC, under open field conditions. To achieve the objective, appropriate analytical method for determination of Pendimethalin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the Final Report N. 16555423.0002. In brief, samples of Soybean were extracted with acidified acetonitrile. After addition of a buffer-salt mixture containing magnesium sulfate and sodium acetate the extract was shaken.

Mean recovery was 74.0% with RSD = 8.6% for first mass transition and 72.0% with RSD = 8.9% for the second mass transition in soybean grain.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
PL-PH/04/2016-1/7-H/N- EU/Poland/2016	Soybean/Aldana	30/05/2016 - 16/09/2016	1980	230	861	31/05/2016	BBCH 00-09	Seeds	n.d.	108	14 months Analytical report: ZBBZ- 2016/12/DPL/8PL

A 2.1.3.6 Carrot

A 2.1.3.6.1 Study 1

Comments of zRMS:	Study is accepted
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- Reference: KCP 8.3.6.1
- Report Residue study (Harvest) in carrot following one post emergence application with Pendimethalin 33% EC in Germany 2017. T. XXX, 2018. Report No. CT17-1-32 (Field phase)
- Guideline(s):
- OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009)
 - EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials
 - The Principles of Good Laboratory Practice, ChemG 25.07.1994, § 19, Annex 1 (BGBL 21, I, 2001, p. 843-855)

- OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999) 20, Paris 2002
- The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002
- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9
- Rückstandsversuche, Teil 1 Prüfungen an Pflanzen, A: Allgemeiner Teil, B: Spezieller Teil, IVA-Guideline, Industrieverband Agrar e. V. 1992

Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Carrot

Crop parts(s) or processed commodity: roots

STUDY DESIGN AND METHODS

The purpose of the study was to generate specimens for the determination of residues after one post emergence application with Pendimethalin 33% EC in carrot in Germany 2017. The specimens to be analysed were the raw agricultural commodity roots.

One trial CT17-1-32DE1 was carried out on open field as a harvest trial in Lower Saxony / North Germany. Two plots were measured out in carrot: one untreated control plot (= U / plot 1) and one treated plot (= T / plot 2). Plot 2 was treated once with the test item Pendimethalin 33% EC with the rate of 6.0 L/ha. The application on the trial was performed at the crop stage BBCH 12-14.

The used water volume was 300 L/ha.

Specimens from the untreated and treated plot were taken 70 days after the application at crop stage BBCH 49. The specimens from the untreated plots were taken prior to the specimens of the treated plots.

The specimens were stored frozen (targeting -18°C) at the test facility in Burgwedel / Germany and at an external storage area in Wunstorf / Germany. The test item was applied using a salt/pepper dispenser in order to achieve homogenous application.

To prevent cross contamination, the untreated plot was always sampled first, followed by the treated plot. In each sampling event clean sampling equipment was used. Plant specimens were sampled by hand.

All specimens were stored at a temperature $\leq -18^{\circ}\text{C}$ in freezers. No temperature deviations occurred during storage of specimens from sampling until shipment. The temperature logs of freezers are retained in AgriScience. Temperatures of the freezers were monitored using data loggers.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.6.2
Report	Determination of pendimethalin (CAS: 40487-42-1) in carrot by LC-MS according to SOPa-285-LABCHI-REV.0. M. XXX, 2018, Report No. 18.618095.0006 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Carrot

Crop parts(s) or processed commodity: roots

STUDY DESIGN AND METHODS

The analytical phase of the study 18.618095.0006 was conducted to determine the residual level of Pendimethalin in carrot by LC-MS according to the in-house validated methods codified as SOPa-285-LABCHI-Rev.0 and as described in study No 16.566423.0002 validated on the matrix potato.

Specimen is constituted by carrot treated with Pendimethalin.

Storage in laboratory: field samples were stored frozen at about T<-18°C from reception time to extraction date. Before the analysis, the specimens were grinded and stored the extracts in a freezer about -20°C date.

The determination of Pendimethalin in carrot by LC-MS.

About 5.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6 g (± 0.01 g) of magnesium sulphate anhydrous and about 1.5 g sodium acetate were added to the sample and vortexed again for about 1 min. Then, the tube was centrifuged at 4750 rpm for 5min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in carrot root matrices.

The LOD was set at < 30 % of the LOQ (0.003 mg/kg for carrot root). The chromatographic peaks at the LOD were more than three times the background noise.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
CT17-1-32/Germany/N-EU/2016	Carrot	25/04/2017	1965	300	655	13/06/17	BBCH 12-14	Root	0.01	70	9 months Analytical report: 18.618095.0006

Table A 4: Summary of the study 1 trials

A 2.1.3.6.2 Study 2

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.6.3
Report	Magnitude of the residue of Pendimethalin in carrot (Taw Agricultural Commodity) after one application of Pendimethalin 33% EC – one decline curve trial and one harvest trial in Poland – 2017. T. XXX, 2018, Report No. 17SGS012. (Field phase)
Guideline(s):	Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC

2. Test Commodity:

Crop: Carrot

Crop parts(s) or processed commodity: roots, whole plants, tops

STUDY DESIGN AND METHODS

The objective of the study was to generate specimens of carrot Raw Agricultural Commodity (RAC) following one application of Pendimethalin 33% EC to quantify residues of pendimethalin under cultural practice typical for carrot production. After the end of field phase, the specimens were transferred to the laboratory (Analytical phase)

One harvest and one decline curve trial was established on carrot in Poland. The sites were representative of carrot grown in a way typical of the producing region in the test country.

Each trial consisted one untreated plot U and one treated plot T. Plots were of sufficient size to generate the desired specimen quantities.

In case of harvest trial untreated and treated plots, the area was 30m² per plot.

In case of decline trial untreated and treated plots, the area was 45m² per plot.

Around the treated and untreated plots, a buffer zone (where no forbidden products were applied) of at least 10 m was set up.

The untreated plot was separated by a buffer zone of at least 10 m from the treated plot.

Pendimethalin 33% EC was only mixed with water. No adjuvant was added to the spray mixture. The target dose rate of the test item for the study was 6 L/ha of formulated product per application, equivalent to 333.33 g as/L

The application was carried out within one hour of mixing the spray solution and performed under conditions typical for the crop with either no wind or a light wind of less than 3 m/s.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.6.4
Report	Determination of pendimethalin (CAS: 40487-42-1) in carrot by LC-MS according to SOPa-285-LABCH-REV.0. M. XXX, 2018 Report No. 18.618093.0003 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC

2. Test Commodity:

Crop: Carrot

Crop parts(s) or processed commodity: roots, whole plants, tops

STUDY DESIGN AND METHODS

The analytical phase of the study 18.618093.0003 was conducted to determine the residual level of Pendimethalin in carrot by LC-MS according to the in-house validated methods codified as SOPa-285-LABCHI-Rev.0 and as described in study No 16.566423.0002 validated on the matrix potato.

Specimen is constituted by carrot treated with Pendimethalin.

Storage in laboratory: field samples were stored frozen at about $T < -18^{\circ}\text{C}$ from reception time to extraction date. Before the analysis, the specimens were grinded and stored the extracts in a freezer about -20°C date.

The determination of Pendimethalin in carrot by LC-MS.

About 5.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6 g (± 0.01 g) of magnesium sulphate anhydrous and about 1.5 g sodium acetate were added to the sample and vortexed again for about 1 min. Then, the tube was centrifuged at 4750 rpm for 5min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in carrot root matrices.

The LOD was set at < 30 % of the LOQ (0.003 mg/kg for carrot root). The chromatographic peaks at the LOD were more than three times the background noise.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
17SGS012PL01/Poland/N- EU/2018	Carrot	-	2085	400	500	27/06/17	BBCH 12-14	Roots	<0.01	69	6 months Analytical report: 18.618093.0003
17SGS012PL02/Poland/N- EU/2018	Carrot	-	2073	400	500	22/06/17	BBCH 12-14	Whole plants Roots Tops Roots Tops	7.49 0.04 0.68 <0.01 0.30	0 40 40 70 70	8months Analytical report: 18.618093.0003

A 2.1.3.6.3 Study 3

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.6.5

Report: Determination of residues at harvest and decline of Pendimethalin in carrot, following one pre-emergence application of PENDIMETHALIN 330g/L EC, under open field conditions, Central Europe – Season 2016. K. XXX, Report No. FRS 051/16 (Field phase)

Guideline(s): Directive 91/414/EEC

Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC

2. Test Commodity:

Crop: Carrot

Crop parts(s) or processed commodity: roots, whole plants, tops

STUDY DESIGN AND METHODS

The object of this study is to determine the magnitude and decline of residues of Pendimethalin in carrot resulting from one pre-emergence application at the maximum anticipated labelled rate of Pendimethalin 330 g/L EC.

Raw agricultural commodity specimens have been generated from roots harvested from treated and untreated plots 20(\pm 2), 10(\pm 2) days before harvest (DBH) and at commercial harvest (70 \pm 2 days after last application (DALA)) for the decline trial and at commercial harvest (70 \pm 2 DALA) for the harvest trial.)

The study was conducted under field conditions in Central Europe.

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.6.6

Report Determination of residues of pendimethalin applied as 'PENDIMETHALIN 330 g/L' in carrot at one site in Germany. J. XXX, 2017, Report No. ZBBZ-2016/12/DPL/5DE (Analytical phase)

Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC

2. Test Commodity:

Crop: Carrot

Crop parts(s) or processed commodity: roots

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues of Pendimethalin in Carrot samples taken from the field trial, after applications of Pendimethalin 330 g/L, under open field conditions. To achieve the objective appropriate analytical method for determination of Pendimethalin was validated in accordance to the guidance document SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2016/12/DPL/4DE [3]. The validated limit of quantification is 0.01 mg/kg.

Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity.

Trial No./	Commodity/ Variety	Date of	Application rate per treatment	Dates of treat-	Growth stage at	Portion ana-	Residues (mg/kg)	PHI	Details on trial
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Location/ EU zone/ Year	(a)	1.Sowing or planting 2.Flowering 3. Harvest (b)	g a.s./ ha	Water (l/ha)	g a.s./hl	ment or no. of treatments and last date (c)	last treatment or date	lyzed	Pendimethalin	(days) (d)	(e)
FRS051/16-V1/Germany/N-EU/2016	Carrot/Nan/Jubila	10 June 16 - 22 August 16	1667	200	833.5	13 June 16	BBCH 00	Roots	0.0059 (<LOQ)	70	12 months Analytical report: ZBBZ- 2016/12/DPL/5DE
FRS051/16-V2/Germany/N-EU/2016	Carrot	06 May 16 - 19 July 16	1667	200	833.5	10 May 16	BBCH 00	Roots Roots Roots	0.173 0.0157 0.0064 (<LOQ)	50 60 70	14 months Analytical report: ZBBZ- 2016/12/DPL/5DE

A 2.1.3.6.4 Study 4

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.6.7
 Report Field phase residue trial Pendimethalin 330 g/L EC – carrots – decline – Belgium – 2016, S. XXX, 2017, Report No.

	OL16 WORES1 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC

2. Test Commodity:

Crop: Carrot

Crop parts(s) or processed commodity: roots

STUDY DESIGN AND METHODS

The objective of the study was to determine the residue level of pendimethalin 330 g/l EC after 1 application with the formulated product shortly after sowing and before emergence in carrots.

This study consisted of two phases, a field phase and an analytical phase. This report covers the field phase. The trial was set up at 1 site in Belgium (a research field in Kruishoutem, Belgium). The plot area was 45 m² and the variety sown was Nerac (Bejo). In this trial one plot was treated once with 4l formulated product per ha (1320 g a.s./ha). The trial treatment was performed by a backpack sprayer with a spray volume of 400 l/ha. The application was applied 4 days after sowing, shortly before emergence of the crop.

Sampling procedure: take at harvest 2 times 12 roots (without leaves) per plot. One sample (=12 roots) will be shipped for residue analysis and one sample will be retained at the trial site. Earth should be brushed from the roots. If the roots are still too dirty, rinse with cold water. The samples can be taken at random, or in an X or S pattern. Samples will not be taken in the border rows. First the control samples are taken, then the treated samples. Clean sampling tools are used. Between the samples, gloves are changed and hands are washed. Also the tools are rinsed. Samples are put in translucent plastic bags, closed with a cable tie and put again in a plastic bag with label. The bags are labeled with indelible ink. The samples will be transported immediately to the freezer (-20 C°).

Specimens were collected at 5 different timings: 20 days before normal commercial harvest, 10 days before normal harvest, 5 days before harvest, 1 day before harvest, day of normal commercial harvest (161 days after application).

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.6.8
Report	Field phase residue trial Pendimethalin 330 g/L EC – carrots – harvest – Belgium – 2016, S. XXX, 2017, Report No. OL16 WORES2 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC

2. Test Commodity:

Crop: Carrot

Crop parts(s) or processed commodity: roots

STUDY DESIGN AND METHODS

The objective of the study was to determine the residue level of pendimethalin 330 g/l EC after 1 application with the formulated product shortly after sowing and before emergence in carrots. This study consisted of two phases, a field phase and an analytical phase. This report covers the field phase. The trial was set up at 1 site in Belgium (a research field in Kruishoutem, Belgium). The plot area was 45 m² and the variety sown was Nerac (Bejo). In this trial one plot was treated once with 4l formulated product per ha (1320 g a.s./ha). The trial treatment was performed by a backpack sprayer with a spray volume of 400 l/ha. The application was applied 4 days after sowing, shortly before emergence of the crop. Specimens were collected at normal harvest timing (143 days after application).

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.6.9
Report	Determination of residues of Pendimethalin applied as “PENDIMETHALIN 330 g/L” in carrot at one site in Belgium, 2017, Report No. ZBBZ/12/DPL/5BE (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC

2. Test Commodity:

Crop: Carrot

Crop parts(s) or processed commodity: roots

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues of Pendimethalin in Carrot samples taken from the field trial, after applications of Pendimethalin 330 g/L, under open field conditions. To achieve the objective appropriate analytical method for determination of Pendimethalin was validated in accordance to the guidance document SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The method validation was performed on Potato, as a representative matrix and all validation data were presented in the Final Report No. ZBBZ-2016/12/DPL/4DE .

The validated limit of quantification is 0.01 mg/kg.

Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity.

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in carrot root matrices.

The LOD was set at < 30 % of the LOQ (0.0025 mg/kg for carrot root). The chromatographic peaks at the LOD were more than three times the background noise.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
RAP_OL16/Belgium/N-EU	Carrot/Nerac	09/05/2016	1282	400	320	13/05/2016	BBCH 01	Roots Roots Roots Roots Roots	0.0025 (<LOQ) 0.0042 (<LOQ) n.d. 0.0029 (<LOQ) n.d.	141 151 156 160 161	10 months Analytical report: ZBBZ- 2016/12/DPL/5BE
OL16 WROES2/Belgium/N-EU/2016	Carrot/Nerac	09/05/2016	1314	400	328	13/05/2016	BBCH 01	Roots	n.d.	143	10 months Analytical report: ZBBZ- 2016/12/DPL/5BE

A 2.1.3.7 Peas

A 2.1.3.7.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.7.1
Report	Determination of residues at harvest and decline of Pendimethalin in Peas, following one pre-emergence application of Pendimethalin 330 g/L EC under open field conditions, Central Europe – Season 2016, K. XXX, Report No. FRS 055/16 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Peas

Crop parts(s) or processed commodity: plants, seeds

STUDY DESIGN AND METHODS

The object of this study is to determine the magnitude and decline of residues of PENDIMETHALIN in Peas resulting from one pre-emergence application at the maximum anticipated labelled rate of PENDIMETHALIN 330 g/L EC.

Raw agricultural commodity specimens have been generated from Plants harvested from treated and untreated plots 20(±2), 10(±2) days before harvest (DBH) and at commercial harvest for the decline trial and at commercial harvest for the harvest trials

The study will be conducted under field conditions in Central Europe.

The peas were harvested from the central part of each plot (discarding 0.5 m at both ends of the plots and borders). No diseased, injured or abnormal samples were taken. Duplicate samples were taken at each plot.

The peas at commercial harvest have been obtained by mechanical threshing of the plots.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.7.2
Report	Magnitude of the residues of Pendimethalin in pea (plant and seeds), following one application of Pendimethalin 330 g/L EC in two trials (1DCS and 1 HS), Central Europe (Germany) – 2016, P. XXX, Report No. ZBBZ – 2016/121/DPL/1DE (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Peas

Crop parts(s) or processed commodity: Plant, seeds

The objective of this study was to determine the magnitude of the residues of Pendimethalin in raw agricultural commodity of pea (plant and seeds) following one application of Pendimethalin 330 g/L EC in two trials (1 DCS and 1 HS). To achieve the objective appropriate analytical method for determination of Pendimethalin in target matrices was validated in accordance to the guidance document SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the Final Report N. 16.566423.000 for pea plant matrix and on the Final Report N. 16.566423.0005 for pea seeds matrix. In brief, samples were extracted with acidified acetonitrile after addition of water. After addition of a buffer-salt mixture

containing magnesium sulfate and sodium acetate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA), and dehydrated by magnesium sulfate addition.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
FRS055/16-V1/N-EU/Germany/2016	Pea/Santana	06/05/16 06-07/16 11/08/16	1650	200	825	10/05/16	Pre-emergence	Seeds	n.d.	93	15 months Analytical report: ZBBZ- 2016/12/DPL/1DE
FRS055/16-V2/N-EU/Germany/2016	Pea/Alvesta	06/05/16 06-07/16 16/08/16	1650	200	825	10/05/16	Pre-emergence	Plant Plant Seeds	0.030 (<LOQ) 0.0033 (<LOQ) n.d.	79 88 99	15 months Analytical report: ZBBZ- 2016/12/DPL/1DE

A 2.1.3.7.2 Study 2

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.7.3
 Report Field phase residue trial Pendimethalin 330 g/L EC Peas (Pisum sativum/Pissa) – Decline – Belgium – 2016, S. XXX, Report No. OL16 ERRES2 (Field phase)
 Guideline(s): Directive 91/414/EEC
 Deviations: No
 GLP: Yes

Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Peas

Crop part(s) or processed commodity: plants, seeds

STUDY DESIGN AND METHODS

The objective of the study is to determine the residue level of pendimethalin 330 g/l EC after 1 application with the formulated product Pendimethalin 330 g/l EC in peas. One application of the formulated product of Pendimethalin 330 g/l EC will be applied at a rate of 4 l/ha shortly before emergence of the crop.

Specimens will be collected at 5 different timings: 20 days before normal commercial harvest, 10 days before normal harvest, 5 days before harvest, 1 day before harvest, day of normal commercial harvest (80 days after application). The field trial will be performed at 1 site in Belgium.

Sampling procedure: take at harvest 2 times 1 kg peas (12 plants, without roots) per plot. One sample (= 1 kg peas) will be shipped for residue analysis and one sample will be retained at the trial site. The samples can be taken at random, or in an X or S pattern. Samples will not be taken in the border rows. First the control samples are taken, then the treated samples. Clean sampling tools are used. Between the samples, gloves are changed and hands are washed. Also, the tools are rinsed. Samples are put in translucent plastic bags, closed with a cable tie and put again in a plastic bag with label. The bags are labelled with indelible ink. The samples will be transported immediately to the freezer (-20 C°).

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.7.4

Report: Field phase residue trial Pendimethalin 330 g/L EC Peas (Pisum Sativum/Pissa) – Harvest – Belgium – 2016, S. XXX, Report No. OL16 ERRES3b(Field phase)

Guideline(s): Directive 91/414/EEC

Deviations: No

GLP: Yes

Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Peas

Crop parts(s) or processed commodity: plants, seeds

STUDY DESIGN AND METHODS

The objective of the study was to determine the residue level of pendimethalin 330 g/l EC after 1 application with the formulated product shortly after sowing, when the peas reach around 10 cm (BBCH 14). This study consisted of two phases, a field phase and an analytical phase. This report covers the field phase. The trial was set up at 1 site in Belgium (a research field in Kruishoutem, Belgium). The plot area was 30 m² and the variety sown was Festivert (Syngenta). In this trial one plot was treated once with 4l formulated product per ha (1320 g a.s./ha). The trial treatment was performed by a backpack sprayer with a spray volume of 400 l/ha. The application was applied 26 days after sowing, after emergence of the peas, when the peas reach around 10 cm (BBCH 14). Specimens were collected at normal harvest timing (45 days after application) (BBCH 79).

Sampling procedure: take at harvest 2 times 1 kg pea plants (without roots) per plot. One sample (= 1 kg) will be shipped for residue analysis and one sample will be retained at the trial site. The samples can be taken at random, or in an X or S pattern. Samples will not be taken in the border rows. First the control samples are taken, then the treated samples. Clean sampling tools are used. Between the samples, gloves are changed and hands are washed. Also, the tools are rinsed. Samples are put in translucent plastic bags, closed with a cable tie and put again in a plastic bag with label. The bags are labeled with indelible ink. The samples will be transported immediately to the freezer (-20 C°).

Comments of zRMS:	Study is accepted
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Reference:

KCP 8.3.7.5

Report

Magnitude of the residues of Pendimethalin in Pea (Plant, pods and seeds), following one application of Pendimethalin 330 g/L EC in three trials (1DCS and 2 HS), Central Europe (Belgium) – 2016, P. XXX, Report No. ZBBZ-2016/12/DPL/1BE (Analytical phase)

Guideline(s):

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC

Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
 EU Guidance Document SANCO/3029/99 rev. 4
 EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No
 GLP: Yes
 Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:
 Crop: Peas

Crop parts(s) or processed commodity: Plant, seeds, pods

The objective of this study was to determine the magnitude of the residues of Pendimethalin in raw agricultural commodity of pea (plant, pods and seeds) following one application of Pendimethalin 330 g/L EC in three trials (1 DCS and 2 HS). To achieve the objective appropriate analytical method for determination of Pendimethalin in pea pods and seeds was validated in accordance to the guidance document SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. For the pea plant matrix validation data were presented in the Final Report No. ZBBZ-2016/12/DPL/1DE. The analytical method is quantitative for Pendimethalin at the stated limit of quantification (LOQ) of 0.01 mg/kg.

The general principles of the analytical procedure were based on the Final Report N.16.566423.0002. In brief, samples were extracted with acidified acetonitrile after addition of water. After addition of a buffer-salt mixture containing magnesium sulfate and sodium acetate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA), and dehydrated by magnesium sulfate addition.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		

	(a)	(b)				(c)				(d)	(e)
RAP_OL16 ERRES2/N-EU/Belgium/2016	Pea/Festivert	04/05/2016 - 25/07/2016	1317	500	263	06/05/16	BBCH 01	Plant Plant Pods Plant Pods Plant Pods Seeds Plant Pods Seeds	n.d. <0.01 n.d. <0.01 n.d. <0.01 n.d. n.d. <0.01 n.d. n.d.	60 70 70 75 75 79 79 80 80 80	16 months Analytical report: ZBBZ- 2016/12/DPL/1BE
RAP_OL16 ERRES3b/N-EU/Belgium/2016	Pea/Festivert	06/07/16 - 15/09/16	1320	400	330	01/08/16	BBCH 14	Plant Pods Seeds	0.091 n.d. n.d.	45 45 45	16 months Analytical report: ZBBZ- 2016/12/DPL/1BE

A 2.1.3.7.3 Study 4

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.7.6
 Report Residue study of pendimethalin / Pendimethalin 33% EC (decline and harvest) in pea, Poland (Central Europe) – Season 2016, Z. XXX (Field phase)
 Guideline(s): Directive 91/414/EEC
 Deviations: No
 GLP: Yes
 Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Peas

Crop parts(s) or processed commodity: plants, seeds, pods

STUDY DESIGN AND METHODS

The object of this study was to determine the magnitude and decline of residues of Pendimethalin 33% EC (a.i. pendimethalin) in pea (*Pisum sativum* L.) resulting from one soil applications, at the maximum anticipated labelled rate Pendimethalin 33% EC. The study was conducted under field conditions in Poland (Central Europe).

Raw pea specimens have been generated during vegetation period and during the harvest of pea, variety Biznes, from the plots treated with Pendimethalin 33% EC and untreated at 0; 39; 45 days after last application (DALA) and at plant harvest for the decline trial.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.7.7
Report	Magnitude of the residues of pendimethalin in pea (plant, pods and seeds), following one application of pendimethalin 330 g/l ec in two trials (1 dcs and 1 hs), Central Europe (Poland) - 2016, P. XXX, Report No. ZBBZ-2016/12/DPL/1PL (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Peas

Crop parts(s) or processed commodity: Plant, seeds, pods

The objective of this study was to determine the magnitude of the residues of Pendimethalin in raw agricultural commodity of pea (plant, pods and seeds) following one application of Pendimethalin 330 g/L EC in two trials (1 DCS and 1 HS). To achieve the objective appropriate analytical method for determination of Pendimethalin in pea pods, seeds and plant was validated in accordance to the guidance document SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. For the pea plant matrix validation data were presented in the Final Report No. ZBBZ-2016/12/DPL/1DE. For the pea seeds and pods matrices validation data were presented in the Final Report No. ZBBZ-2016/12/DPL/1BE . The analytical method is quantitative for Pendimethalin at the stated limit of quantification (LOQ) of 0.01 mg/kg.

The general principles of the analytical procedure were based on the Final Report N.16.566423.0002. In brief, samples were extracted with acidified acetonitrile after addition of water. After addition of a buffer-salt mixture containing magnesium sulfate and sodium acetate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA), and dehydrated by magnesium sulfate addition.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
PL-PH/04/2016-1/6-D/N- EU/Poland/2016	Pea/Biznes	19/04/16 - 08/07/16	1980	230	861	25/05/16	BBCH 13-15	Plant Plant Pods Seeds Plant Pods Seeds	49.2 0.218 n.d. n.d. 0.033 n.d. n.d.	0 38 44	16 months Analytical report: ZBBZ- 2016/12/DPL/1PL

PL-PH/04/2016-1/6-D/N-EU/Poland/2016	Pea/Biznes	19/04/16 - 08/07/16	1980	230	861	25/05/16	BBCH 13-15	Seeds	n.d.	44	16 months Analytical report: ZBBZ- 2016/12/DPL/1PL
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A 2.1.3.7.4 Study 5

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.7.8
 Report Residue study (Harvest) in pea following one post emergence application with Pendimethalin 33% EC in Germany 2017 – field part, S. XXX, Report No. CT17-1-33 (Field phase)
 Guideline(s): Directive 91/414/EEC
 Deviations: No
 GLP: Yes
 Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Peas

Crop parts(s) or processed commodity: plants, seeds, pods

STUDY DESIGN AND METHODS

The purpose of the study was to generate specimens for the determination of residues after one post emergence application with Pendimethalin 33% EC in pea in Germany 2017. The specimens to be analysed were the raw agricultural commodity green seeds. The study was carried out according to the study plan CT17-1-33 (accompanied by 1 Amendment), the guideline document 7029/VI/95 rev. 5, 1997, Appendix B working document 1607/VI/97, rev. 2, 1999 and the guidelines mentioned in the “Statement of Compliance”.

One trial CT17-1-33DE1 was carried out on open field as a harvest trial in Baden- Württemberg / South Germany. Two plots were measured out in pea: one untreated control plot (= U / plot 1) and one treated plot (= T / plot 2). Plot 2 was treated once with the test item Pendimethalin 33% EC with the rate of 6.0 L/ha. The application on the trial was performed at the crop stage BBCH 13. The used water volume was 400 L/ha.

Specimens from the untreated and treated plot were taken 64 days after the application at crop stage BBCH 73. The specimens from the untreated plots were taken prior to the specimens of the treated plots. The specimens were stored frozen (targeting -18°C) at the test site in Neidenstein / Germany and at an external storage area in Wunstorf / Germany.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.7.9
Report	Determination of Pendimethalin (CAS: 40487-42-1) in peas by LC-MS according to SOPa-285-LABCHI-Rev.0, 2018, M. XXX, Report No. 18.618095.0007 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Peas

Crop parts(s) or processed commodity: Plant, seeds, pods

The analytical phase of the study 18.618095.0007 was conducted to determine the residual level of Pendimethalin in peas by LC-MS according to the in-house validated method codified as SOPa-285-LABCHI-Rev.0 and as described in study No. 16.566423.0002 validated on the matrix potato.

SAMPLE EXTRACTION

About 5.00 g of sample were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. The tube was centrifuged at 4750 rpm for 5 min and it was proceeded to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min. The supernatant of purified sample was recovered, filtered and transferred into an HPLC vial and injected.

Mean recovery was 98.8% with RSD = 0.4% for first mass transition and 88.1% with RSD = 3.0% for the second mass transition in green seeds.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
CT17-1-33DE1/N-EU/Germany/2017	Pea/Astronauta	06/04/2017 14-31/05/2017 23/07/2017	1975	400	494	21/04/2017	BBCH 13	Green seeds	<0.01	64	8 months Analytical report: 18.618095.0007

A 2.1.3.7.5 Study 6

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.7.10
Report	Magnitude of the residue of Pendimethalin in peas (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – decline curve trial and harvest trial in Poland – 2017, T. XXX, Report No. 17SGS014 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Peas

Crop parts(s) or processed commodity: plants, seeds, pods

STUDY DESIGN AND METHODS

The objective of the study was to generate specimens of peas Raw Agricultural Commodity (RAC) following one application of Pendimethalin 33% EC to quantify residues of pendimethalin under cultural practice typical for peas production.

One harvest and one decline curve trial was established on peas in Poland. The sites were representative of peas grown in a way typical of the producing region in the test country.

Each trial consisted one untreated plot U and one treated plot T. Plots were of sufficient size to generate the desired specimen quantities.

In case of harvest trial untreated and treated plots their area was 30 m² per plot.

In case of decline trial untreated and treated plots, their area was 60 m² per plot.

Around the treated and untreated plots, a buffer zone (where no forbidden products were applied) of at least 10 m was set up. The application equipment consisted of Boom sprayer. The foliar application closely simulated commercial-type treatments. Pendimethalin 33% EC was only mixed with water. No adjuvant was added to the spray mixture. The target dose rate of the test item for the study was 6 L/ha of formulated product per application, equivalent to 333.33 g as/L. Application were made at a target water volume of 500 litres per hectare of mixture according sprays in GAP.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.7.11
Report	Determination of Pendimethalin (CAS: 40487-42-1) in peas by LC-MS according to SOPa-285-LABCHI-Rev.0), M. XXX, 2018, Report No. 18.618093.0005 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Peas

Crop parts(s) or processed commodity: Plant, seeds, pods

The analytical phase of the study 18.618093.0005 was conducted to determine the residua level of Pendimethalin in peas by LC-MS according to the in-house validated method codified as SOPa-285-LABCHI-Rev.0 and as described in study No. 16.566423.0002 validated on the matrix potato.

SAMPLE EXTRACTION

About 5.00 g of sample were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. The tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min. The supernatant of purified sample was recovered, filtered and transferred into an HPLC vial and injected.

Mean recovery was 94.5% with RSD = 1.0% for first mass transition and 90.4% with RSD = 5.0% for the second mass transition in seeds.

Mean recovery was 89.5% with RSD = 1.0% for first mass transition and 89.5% with RSD = 1.0% for the second mass transition in whole plant.

Mean recovery was 100.8% with RSD = 4.0% for first mass transition and 92.7% with RSD = 4.0% for the second mass transition in green seeds.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
(a)	(a)	(b)				(c)			(d)	(e)	
17SGS014PL01/N-EU/Poland/2017	Pea/Milwa	31/03/2017 21/06-13/07-2017 27/07-01/08/2017	1964	500	393	05/05/2017	BBCH 15	Seeds	<0.01	83	7 months Analytical report: 18.618093.0005
17SGS014PL02/N-EU/Poland/2017	Pea/Milwa	24/05/2017 05-28/07/2017 21/08/2017	1907	484	394	19/06/2017	BBCH 15	Whole plants Green seeds Seeds with pods Rest of plant Green seeds Seeds with	3.69 <0.01 n.d. n.d. n.d. n.d.	0 50 50 50 63 63	7 months Analytical report: 18.618093.0005

								pods Rest of plant	<0.01	63	
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A 2.1.3.8 Onion

A 2.1.3.8.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.8.1
Report	Determination of residues at harvest and decline of Pendimethalin in Onion, following one pre-emergence application of Pendimethalin 330 g/L EC, under open field conditions, Central Europe – Season 2016, K. XXX, Report No. FRS 052/16 (Field phase)
Guideline(s):	<ul style="list-style-type: none"> - OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009) - EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials - The Principles of Good Laboratory Practice, ChemG 25.07.1994, § 19, Annex 1 (BGBL 21, I, 2001, p. 843-855) - OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999) 20, Paris 2002 - The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002 - The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9 - Rückstandsversuche, Teil 1 Prüfungen an Pflanzen, A: Allgemeiner Teil, B: Spezieller Teil, IVA-Guideline, Industrieverband Agrar e. V. 1992
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Onion

Crop parts(s) or processed commodity: bulbs

STUDY DESIGN AND METHODS

The object of this study is to determine the magnitude and decline of residues of PENDIMETHALIN in onion resulting from one pre-emergence application at the maximum anticipated labelled rate of PENDIMETHALIN 330 g/L EC.

Raw agricultural commodity specimens have been generated from bulbs harvested from treated and untreated plots 20(±2), 10(±2) days before harvest (DBH) and at commercial harvest for the decline trial and at commercial harvest for the harvest trials.

The study was conducted under field conditions in Central Europe.

The bulbs were harvested from the central part of each plot (discarding 0.5 m at both ends of the plots and borders). No diseased, injured or abnormal samples were taken. Duplicate samples were taken at each plot.

Gloves and disposable clothes were worn and changed between each plot. Sampling equipment was cleaned between each plot where necessary. Specimens were placed into dry plastic bags and subsequently double bagged and labelled.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.8.2
Report	Determination of the residues of Pendimethalin applied as “Pendimethalin 330 g/L” in onion at one site in Germany, 2016, J. XXX, Report No. ZBBZ-2016/12/DPL/3DE (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4

EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No
 GLP: Yes
 Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Carrot

Crop parts(s) or processed commodity: bulbs

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues of Pendimethalin in Onion samples taken from the field trial, after applications of Pendimethalin 330 g/L, under open field conditions. To achieve the objective appropriate analytical method for determination of Pendimethalin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2016/69/DPL/2ES. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the Final Report N. 16555423.002. In brief, samples of Onion were extracted with acidified acetonitrile. After addition of a buffer-salt mixture containing magnesium sulfate and sodium acetate the extract was shaken. After centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulfate addition.

Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity.

Trial No./	Commodity/ Variety	Date of	Application rate per treatment	Dates of treat-	Growth stage at	Portion ana-	Residues (mg/kg)	PHI	Details on trial
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Location/ EU zone/ Year	(a)	1.Sowing or planting 2.Flowering 3. Harvest (b)	g a.s./ ha	Water (l/ha)	g a.s./hl	ment or no. of treatments and last date (c)	last treatment or date	lyzed	Pendimethalin	(days) (d)	(e)
FRS052/16-V1/N-EU/Germany/2016	Onion/Zittauer Gelbe	10/06/16 - 06/10/16	1650	200	825	13/06/16	Pre-emergence	Bulbs	n.d.	115	15 months Analytical report: ZBBZ- 2016/12/DPL/3DE
FRS052/16-V2/N-EU/Germany/2016	Onion/Stuttgart Rieser	06/05/16 - 26/09/16	1650	200	825	10/05/16	Pre-emergence	Bulbs Bulbs Bulbs	n.d. n.d. n.d.	118 128 138	Analytical report: ZBBZ- 2016/12/DPL/3DE

A 2.1.3.8.2 Study 2

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.8.3

Report: Field phase residue trial Pendimethalin 330 g/L EC Onions – Decline – Central Zone – Belgium – 2016, S. XXX, Report No. OL16 UIRES1 (Field phase)

Guideline(s):

- OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009)
- EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials
- The Principles of Good Laboratory Practice, ChemG 25.07.1994, § 19, Annex 1 (BGBL 21, I, 2001, p. 843-855)
- OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999) 20, Paris 2002
- The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002

- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9
- Rückstandsversuche, Teil 1 Prüfungen an Pflanzen, A: Allgemeiner Teil, B: Spezieller Teil, IVA-Guideline, Industrieverband Agrar e. V. 1992

Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Onion

Crop parts(s) or processed commodity: bulbs

STUDY DESIGN AND METHODS

The objective of the study was to determine the residue level of pendimethalin 330 g/l EC after 1 application with the formulated product shortly after sowing and before emergence of the onions. This study consisted of two phases, a field phase and an analytical phase. This report covers the field phase. The trial was set up at 1 site in Belgium (a research field in Kruishoutem, Belgium). The plot area was 30 m² and the variety sown was Hytech (Bejo). In this trial one plot was treated once with 4l formulated product per ha (1320 g a.s./ha). The trial treatment was performed by a backpack sprayer with a spray volume of 500 l/ha. The application was applied 11 days after sowing, shortly before emergence of the crop (BBCH 005). Specimens were collected at 5 different timings: 20 days before normal commercial harvest, 10 days before normal harvest, 5 days before harvest, 1 day before harvest, day of normal commercial harvest (135 days after application). Samples of the test item required for the application were weighed by PCG. For each sample, the amount needed was calculated from the plot surface (m²), the test item rate (l/ha) and a security margin. Sampling procedure: take at harvest 2 times 12 onion plants (without roots) per plot.

One sample (=12 onions) will be shipped for residue analysis and one sample will be retained at the trial site. Earth should be brushed from the onions. If the roots are still too dirty, rinse with cold water. The samples can be taken at random, or in an X or S pattern. Samples will not be taken in the border rows. First the control samples are taken, then the treated samples. Clean sampling tools are used. Between the samples, gloves are changed and hands are washed. Also, the tools are rinsed. Samples are put in translucent plastic bags, closed with a cable tie and put again in a plastic bag with label. The bags are labelled with indelible ink. The samples will be transported immediately to the freezer (-20 C°).

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.8.4
Report	Field phase residue trial Pendimethalin 330 g/L EC Onions – Harvest – central zone – Belgium – 2016, S. XXX, Report No. OL16 UIRES2 (Field phase)
Guideline(s):	<ul style="list-style-type: none">- OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009)- EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials- The Principles of Good Laboratory Practice, ChemG 25.07.1994, § 19, Annex 1 (BGBL 21, I, 2001, p. 843-855)- OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999) 20, Paris 2002- The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9- Rückstandsversuche, Teil 1 Prüfungen an Pflanzen, A: Allgemeiner Teil, B: Spezieller Teil, IVA-Guideline, Industrieverband Agrar e. V. 1992
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Onion

Crop parts(s) or processed commodity: bulbs

STUDY DESIGN AND METHODS

The objective of the study was to determine the residue level of pendimethalin 330 g/l EC after 1 application with the formulated product shortly after sowing and before

emergence of the onions. This study consisted of two phases, a field phase and an analytical phase. This report covers the field phase. The trial was set up at 1 site in Belgium (a research field in Kruishoutem, Belgium). The plot area was 30 m² and the variety sown was Centro (Hazera). In this trial one plot was treated once with 4l formulated product per ha (1320 g a.s./ha). The trial treatment was performed by a backpack sprayer with a spray volume of 400 l/ha. The application was applied 1 day after sowing, before emergence of the crop (BBCH 000). Specimens were collected at normal harvest timing (137 days after application). Samples of the test item required for the application were weighed by PCG. For each sample, the amount needed was calculated from the plot surface (m²), the test item rate (l/ha) and a security margin. Sampling procedure: take at harvest 2 times 12 onion plants (without roots) per plot.

One sample (=12 onions) will be shipped for residue analysis and one sample will be retained at the trial site. Earth should be brushed from the onions. If the roots are still too dirty, rinse with cold water. The samples can be taken at random, or in an X or S pattern. Samples will not be taken in the border rows. First the control samples are taken, then the treated samples. Clean sampling tools are used. Between the samples, gloves are changed and hands are washed. Also, the tools are rinsed. Samples are put in translucent plastic bags, closed with a cable tie and put again in a plastic bag with label. The bags are labelled with indelible ink. The samples will be transported immediately to the freezer (-20 C°).

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.8.5
Report	Determination of the residues of Pendimethalin applied as “Pendimethalin 330 g/L” in onion at one site in Belgium, 2016, J. XXX, Report No. ZBBZ-2016/12/DPL/3BE (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Onion

Crop parts(s) or processed commodity: bulbs

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues of Pendimethalin in Onion samples taken from the field trial, after applications of Pendimethalin 330 g/L, under open field conditions. To achieve the objective appropriate analytical method for determination of Pendimethalin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2016/69/DPL/2ES. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the Final Report N. 16555423.002. In brief, samples of Onion were extracted with acidified acetonitrile. After addition of a buffer-salt mixture containing magnesium sulfate and sodium acetate the extract was shaken. After centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulfate addition.

Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
OL 16 UIRES1/N-EU/Belgium/2016	Onion/Hytek	21/04/2016 - 14/09/2016	1333	500	267	02/05/16	BBCH 05	Bulbs Bulbs Bulbs Bulbs Bulbs	n.d. n.d. n.d. n.d. n.d.	115 125 130 134 135	16 months Analytical report: ZBBZ- 2016/12/DPL/3BE
OL 16 UIRES2/N-EU/Belgium/2016	Onion/Centro	12/05/2016 - 27/09/2016	1318	398	331	13/05/16	Pre-emergence	Bulbs	n.d.	137	16 months Analytical report: ZBBZ- 2016/12/DPL/3BE

A 2.1.3.9 Sunflower

A 2.1.3.9.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.9.1
Report	Residue study (Harvest) in sunflower following one pre emergence application with Pendimethalin 33% EC in Germany 2017 – field part, S. XXX, Report No. CT17-1-53 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Sunflower

Crop parts(s) or processed commodity: grain

STUDY DESIGN AND METHODS

The trials were carried out on open field on the crop sunflower. The study director / principal investigator assured before start of the trials, that no Pendimethalin containing products would be used on the trial sites during the current season (2017).

One untreated control plot (U = plot 1) and one treated plot (T = plot 2) were laid out and labelled for each trial. The plot size (30 m²) was chosen large enough to provide representative specimens for the sampling date. Drift of spray solution during the applications was avoided by choosing an adequate distance between the untreated and treated plot (12 m).

The application was performed after sowing before emergence of the crop sunflower. The application was conducted with a knapsack sprayer with boom. The spraying equipment was cleaned with water before and after use. The output of the nozzles of the spraying boom was checked for uniformity before start of application. The speed of walk was adapted to the output of the spraying boom and test runs were performed before start of application. The application rate of the test item Pendimethalin 33% EC was 6.0 L/ha. The used water volume was 300 L/ha. The specimens which were taken at the time of commercial harvest were the raw agricultural commodity grain. The specimens from the untreated plots were generated prior to the specimens of the treated plots.

Each specimen consisted of a minimum of 1.0 kg grain. The heads of plants were collected from at least 12 plants equally distributed over the entire plots. A 0.5 m wide strip round the edge of the plots remained unharvested. After collecting the heads, the grain was separated from the heads by hand. Each specimen was placed in a plastic bag labelled with the specimen identification number. The plastic bag was placed in a second bag. Ship and retain specimens were taken. Specimens were frozen within a maximum of 5:30 hours after collection.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.9.2
Report	Determination of Pendimethalin (CAS: 40487-42-1) in sunflower by LC-MS according to SOPa-286-LABCHI-Rev.0, M. XXX, 18.618095.0012 (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: sunflower

Crop parts(s) or processed commodity: grain

The analytical phase of the study 18.618095.0012 was conducted to determine the residual level of Pendimethalin in sunflower seeds by LC-MS according to the in-house validated methods codified as SOPa-284-LABCHI-Rev.0 and as described in study No. 16.566423.0001

SAMPLE EXTRACTION

About 3.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5min. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

Mean recovery was 88.5% with RSD = 2.0% for first mass transition and 86.9% with RSD = 1.0% for the second mass transition in sunflower grain.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treat- ment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
	(a)	(b)				(c)			(d)	(e)	
CT17-1-53DE1/N- EU/Germany/2017	Sunflower/MAS 83.R	10/06/2017 10/08/2017	1970	300	657	10/06/2017	BBCH 00	Grain	n.d.	101	6 months

		26/08/2017									Analytical report: 18.618095.0012
CT17-1-53DE2/N- EU/Germany/2017	Sunflower/mix	09/05/2017 - 11/09/2017	2143	300	714	09/05/2017	BBCH 01	Grain	n.d.	125	6 months Analytical report: 18.618095.0012

A 2.1.3.9.2 Study 2

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.9.3
Report	Magnitude of residue of Pendimethalin in sunflower Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial – Poland – 2017, S. XXX, Report No. BPL17-018 (Field and analytical phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Sunflower

Crop parts(s) or processed commodity: grain

STUDY DESIGN AND METHODS

One field trial was conducted in Poland (Northern Europe). The trial was on representative variety of sunflower.

The trial was comprised of one untreated control plot and one plot treated with Pendimethalin 33% EC (*Pendimethalin* 330 g/l). One soil directed application was performed at crop pre-emergence and at a dose rate of 5.53 l/ha of test item; corresponding to a total dose of active ingredient 1835.4 g/ha. The trial was performed to gain specimens at harvest (raw agricultural commodities) of sunflower Seeds

The objective of the analytical phase was to determine the magnitude of residue of *pendimethalin* in sunflower.

The analytical phase was conducted according to the in-house validated methods codified as SOPa- 284-LABCHI-Rev.0 “Analytical Procedure for the Determination of Pendimethalin (CAS:40487-42-1), in soybeans by Liquid Chromatography” and as described in study n° 16.566423.0001 (“Validation of the analytical procedure for Pendimethalin (CAS: 40487-42-1) in soybeans by liquid chromatography”) validated on the matrix soybeans. Residues of pendimethalin were extracted from grinded, homogenized sunflower (seeds) with acetonitrile, formic acid and water. After vortexing, magnesium sulphate anhydrous and sodium acetate were added and vortexed again. The tube was centrifuged to purify the supernatant. Then, a part was transferred to a mixture of magnesium sulphate anhydrous and PSA resin. It was vortexed and centrifuged again. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected. The quantification as *pendimethalin* was performed by LC-MS (liquid chromatography with mass spectrometry detection). For *pendimethalin* the limit of quantification (LOQ) was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg. During analysis of sunflower specimens (seeds), recovery determinations with fortifications at the levels of 0.01 mg/kg were performed for Pendimethalin in a single extraction with single determination. Percent recoveries obtained were in the range of 70-110 % with RSDs ≤ 20 %, which validates the analyses. Analysis (extraction) of the specimens took place:

- 173 days after sample collection for seed specimens.

The untreated specimen was below LOD (30% of LOQ that corresponds to 0.003 mg/kg). In the treated seed specimen, residues of *Pendimethalin* detected were 0.01 mg/kg.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
BPL17-018-01/N-EU/Poland/2017	Sunflower/Regata	12/05/17 11-15/08/2017 19/09/2017	1835	298	620	17/05/2017	BBCH 05-06	Seed	0.01	119	173 days Analytical report: 18.011087.0008

A 2.1.3.9.3 Study 3

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.9.4
Report	Field Residue Trials to Determine Levels of Pendimethalin 33% EC on Sunflowers in Northern Europe. Ch. XXX, Report No. 18-00307 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Sunflower

Crop parts(s) or processed commodity: grain

STUDY DESIGN AND METHODS

This study located in Northern Europe (United Kingdom) was conducted to determine the residue levels of Pendimethalin 33% EC resulting from one application on Sunflowers.

A study on the magnitude of the residue of Pendimethalin 33% EC on sunflowers Raw Agricultural Commodity (RAC) was conducted in northern Europe following a single bare ground application of Pendimethalin 33% EC. The field phase of this study comprised one location in northern Europe which was representative for this test crop. One harvest trial was conducted, and each trial consisted of two plots: one untreated plot (plot 1) and one plot treated with Pendimethalin 33% EC (plot 2).

Applications were carried out using a boom sprayer in order to reproduce a normal agricultural application technique on a small scale size. One application was applied to plot 2 pre-emergence of the crop, 158 days before normal commercial harvest (NCH). The applied water volume was 297 L/ha for Pendimethalin 33% EC bare ground applications. Specimens of seeds were taken at NCH, 158 days after application.

During storage at the field Test Sites the samples were kept deep frozen at no more than $\leq -17^{\circ}\text{C}$. For the shipment, the specimens were packed into boxes and sent to the analytical laboratory, where they arrived deep-frozen.

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.9.5

Report Determination of Pendimethalin (CAS: 40487-42-1) in sunflower by LC-MS according to SOPa-284-LABCHI-Rev. 0, M. XXX, Report No. 19.503381.0003 (Analytical phase)

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC
Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
EU Guidance Document SANCO/3029/99 rev. 4
EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No

GLP: Yes

Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: sunflower

Crop parts(s) or processed commodity: grain

The analytical phase of the study 19.503381.0003 was conducted to determine the residual level of Pendimethalin in sunflower (seeds) by LC-MS according to the in-house validated methods codified as SOPa-284-LABCHI-Rev. 0 and as described in study No. 16.566423.0001 validated on the matrix soy beans.

SAMPLE EXTRACTION

About 3.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5min. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

Mean recovery was 101.0% with RSD = 2.0% for first mass transition and 108.0% with RSD = 2.0% for the second mass transition in sunflower grain.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treat- ment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
(a)	(a)	(b)				(c)			(d)	(e)	
18-00307-01/N- EU/UK/2018	Sunflower/SSN-008	09/05/2018 09/08-06/09/2018 25/09-23/10/2018	1980	292	678	15/05/2018	BBCH 00	Grain	<0.01	158	5 months Analytical report: 19.503381.0003

A 2.1.3.9.4 Study 4

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.9.6
 Report Residue study of pendimethalin/Pendimethalin 33% EC (harvest) in sunflower, Poland (Central Europe) – Season

2016, Z. XXX, Report No. PL-PH/04/2016-1/8-H (Field phase)

Guideline(s): Directive 91/414/EEC

Deviations: No

GLP: Yes

Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Sunflower

Crop parts(s) or processed commodity: grain

STUDY DESIGN AND METHODS

The object of this study was to determine the magnitude and decline of residues of Pendimethalin 33% EC in sunflower resulting from one soil applications at the maximum anticipated labelled rate Pendimethalin 33% EC. The study was conducted under field conditions in Poland (Central Europe). Raw sunflower specimens have been generated during the harvest of sunflower, from the plots treated with Pendimethalin 33% EC and untreated at plant harvest for the decline trial. The samples were collected at correct time, according to the plan of experiment. From each plot one sample was taken. Sunflower seeds were picked by hand. During sampling the disposable clothing was worn and gloves were changed between each plot. Sampling equipment was cleaned from the soil between each plot. Sunflower in the samples was healthy, at normal heights, with typical colour, with no diseases, no injuries or abnormal symptoms. Specimens were placed into dry paper bags and labeled. After collecting samples from experiment, all bags with fresh material were delivered to analytical laboratory within one hour.

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.9.7

Report: Determination of residues of pendimethalin applied as “Pendimethalin 330 g/L EC” in sunflower at one site in Poland, 2016, J. XXX, Report No. ZBBZ-2016/12/DPL/7PL (Analytical phase)

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing

of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC
 Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing
 Regulation (EC) 1107/2009
 EU Guidance Document SANCO/3029/99 rev. 4
 EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No
 GLP: Yes
 Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: sunflower

Crop parts(s) or processed commodity: grain

The objective of this study was to determine the residues of Pendimethalin in Sunflower samples taken from the field trial, after application of Pendimethalin 330 g/L EC, under open field conditions. To achieve the objective, appropriate analytical method for determination of Pendimethalin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the normalized method EN 15662:2008. In brief, samples of Sunflower were extracted with acetonitrile. After addition of a buffer-salt mixture containing magnesium sulphate, sodium chloride and sodium citrate the extract was shaken. Following centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulphate addition.

Mean recovery was 81.0% with RSD = 5.4% for first mass transition and 80.0% with RSD = 6.3% for the second mass transition in sunflower grain.

Trial No./ Location/	Commodity/ Variety	Date of 1.Sowing or plant-	Application rate per treat- ment	Dates of treat- ment or no. of	Growth stage at last treatment	Portion ana- lyzed	Residues (mg/kg)	PHI (days)	Details on trial
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	(a)	(b)	g a.s./ha	Water (l/ha)	g a.s./hl	(c)			Pendimethalin	(d)	(e)
PL-PH/04/2016-1/8-H/N-EU/Poland/2016	Sunflower	30/05/2016 - 16/09/2016	1980	225	880	31/05/2016	BBCH 00-09	Grain	n.d.	108	26 months Analytical report: ZBBZ- 2016/12/DPL/7PL

A 2.1.3.1 Strawberry

Data already evaluated

Strawberry	UK (N) 1979	STOMP 300 g/l EC	2.0 (1) 4.0 (1)	Pre flowering	Fruit Fruit	79-86 79-86	<0.05 (2) <0.05 (2)	1118
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A 2.1.3.1.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:

KCP 8.3.10.1

Report

Residue study (Harvest) in strawberry following one application during dormancy with Pendimethalin 33% EC in Germany 2017-2018 – field part, S. XXX, Report No. CT17-1-50 (Field phase)

Guideline(s):

Directive 91/414/EEC

Deviations:

No

GLP:

Yes

Acceptability:

Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Strawberry

Crop parts(s) or processed commodity: fruit

STUDY DESIGN AND METHODS

The trials CT17-1-50DE1 and CT17-1-50DE2 were carried out in open field on the crop strawberry. The study director / principal investigator assured before start of the trial, that no Pendimethalin containing products were used and would be used on the trial site during the current season (2017 / 2018). One untreated control plot (U = plot 1) and one treated plot (T = plot 2) were laid out per trial and labelled. The plot size (30 m²) was chosen large enough to provide representative specimens for sampling. Drift of spray solution during the application was avoided by choosing an adequate distance between the untreated and treated plot (10 m). A buffer zone of 5 m - 10 m around the plots of the trials was set up.

The applications were conducted with a knapsack sprayer with boom. The spraying equipment was cleaned with water before and after use. The output of the nozzles was checked for uniformity before start of application. The speed of walk was adapted to the output of the sprayer and test runs were performed before start of application.

The application rate of the test item Pendimethalin 33% EC was 6.0 L/ha. The water volume was 300 L/ha. The plots were sprayed once.

The applications were performed during crop dormancy before weed emergence in winter 2017/2018.

The sampling was performed at the time of commercial harvest in June 2018. The specimens were the raw agricultural commodity fruits.

The specimens from the untreated plots were taken prior to the specimens of the treated plots. Each specimen consisted of ripe fruits collected from ≥12 plants per plot and of a minimum of 1.0 kg. The fruits were picked by hand. Each specimen was placed in a plastic bag labelled with the specimen identification number. The plastic bag was placed in a second bag. Ship and retain specimens were collected. Specimens were frozen within 1:30 hours after start of collection.

Comments of zRMS:

Study is accepted

Reference:

KCP 8.3.10.2

Report

Determination of Pendimethalin (CAS: 40487-42-1) in strawberry by LC-MS according to SOPa-286-LABCHI-Rev.0, M. XXX, 18.641074.0002 (Analytical phase)

Guideline(s):

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing

of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EEC
Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing
Regulation (EC) 1107/2009
EU Guidance Document SANCO/3029/99 rev. 4
EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Strawberry

Crop parts(s) or processed commodity: fruit

The analytical phase of the study 18.641074.0002 was conducted to determine the residual level of Pendimethalin in strawberry by LC-MS according to the in-house validated methods codified as SOPa-286-LABCHI-Rev.0 and as described in study No. 16.544423.0003 validated on the matrix orange.

SAMPLE EXTRACTION

About 5.00 g of grinded sample were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6.00 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

Mean recovery was 96.0% with RSD = 2.0% for first mass transition and 93.0% with RSD = 2.0% for the second mass transition in strawberry fruit.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
CT17-1-50DE1/N- EU/Germany/2018	Strawberry/Malwina	15/08/2017 17/05/2018 19/06/2018	2014	300	671	13/12/2017	BBCH 00	Fruit	n.d.	188	5 months Analytical report: 18.641074.0002
CT17-1-50DE2/N- EU/Germany/2018	Strawberry/Malwina	10/06/2017 20/04/2018 20/05-06/2018	1904	300	635	08/01/2018	BBCH 00	Fruit	0.01	168	5 months Analytical report: 18.641074.0002

A 2.1.3.1.2 Study 2

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.10.3
Report	Determination of the residues of Pendimethalin in/on strawberries after one application of Pendimethalin 33% EC in Northern Europe – Hungary in 2019, A. XXX, Report No. 034SRHU19R39 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Strawberry

Crop parts(s) or processed commodity: fruit

STUDY DESIGN AND METHODS

The objective of the study was to provide results from the magnitude of residues of pendimethalin in/on strawberries, grown in open field conditions, in order to support the registration of the plant protection product applied according Good Laboratory Practice (GLP).

One trial was conducted in Hungary in 2019. The field phase was performed in Sé.

One application of the formulated product Pendimethalin 33% EC was applied at a target rate of 6.0 L / ha to strawberries, using conventional sprayer equipment, under open field condition before weed emergence.

Specimens (berries) was collected at harvest day, frozen and shipped deep frozen to analytical facility of Rag. Soc. Chelab S.r.l. for residue analysis.

There was no unusual event that affected this phase of the study.

Samples were collected randomly from minimum 12 places, except the edges (approx. 0.5 m) or any areas of potential spray overlap. Fruits were collected from all parts, top and bottom, exposed and covered by the foliage and both sides of the rows, leaving the end of the rows unharvested. Both large and small and fruits were sampled and only fruits of marketable quality. Calyx and stem were removed in fresh condition.

Untreated plot was sampled first. All samples were double bagged, weighed and labelled in the field.

Comments of zRMS:

Study is accepted

Reference:

KCP 8.3.10.4

Report

Determination of residual trials Pendimethalin (CAS: 40487-42-1) in strawberry by LC-MS according to SOPa-286-LABCHI-Rev.0, M. XXX, Report No. 19.528632.0004 (Analytical phase)

Guideline(s):

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC
Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
EU Guidance Document SANCO/3029/99 rev. 4

EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Strawberry

Crop part(s) or processed commodity: fruit

The analytical phase of the study 19.528632.0004 was conducted to determine the residual level of Pendimethalin in strawberry by LC-MS according to the in-house validated methods codified as SOPa-286-LABCHI-Rev. 0 and as described in study No. 16.566423.0003 validated on the matrix oranges.

SAMPLE EXTRACTION

About 5.00 g of grinded sample were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6.00 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

Mean recovery was 92.0% with RSD = 10.0% for first mass transition and 95.0% with RSD = 10.0% for the second mass transition in strawberry fruit.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
034SRHU19R39/N- EU/Hungary/2019	Strawberry/Elsanta	22/08/2016 05/2019 06/2019	1822	268	680	10/04/2019	BBCH 00	Fruit	n.d.	61	4 months Analytical report: 19.528632.0004

A 2.1.3.1.3 Study 3

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.10.5
Report	Magnitude of the residue of pendimethalin in strawberry (raw agricultural commodity) after one application of pendimethalin 33% EC – one harvest trial in Poland - 2018, T. XXX, Report No. 18SGS04 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-483228)

2. Test Commodity:

Crop: Strawberry

Crop part(s) or processed commodity: fruit

STUDY DESIGN AND METHODS

The objective of the study was to provide results from the magnitude of residues of pendimethalin in/on strawberries, grown in open field conditions, in order to support the registration of the plant protection product applied according Good Laboratory Practice (GLP).

One trial was conducted in Poland in 2018.

One application of the formulated product Pendimethalin 33% EC was applied at a target rate of 6.0 L / ha to strawberries, using conventional sprayer equipment, under open field condition before weed emergence.

Specimens (berries) was collected at harvest day, frozen and shipped deep frozen to analytical facility of ŁUKASIEWICZ Research Network for residue analysis. There was no unusual event that affected this phase of the study.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.10.6
Report	Magnitude of the residue of pendimethalin in strawberry (raw agricultural commodity) after one application of pendimethalin 33% EC – one harvest trial in Poland - 2018, M. XXX, Report No. 86/2020 (analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Strawberry

Crop parts(s) or processed commodity: fruit

The analytical phase of the study 86/2020 was conducted to determine the residual level of Pendimethalin in strawberry by LC-MS according to the validated method 130/2019 – “Development and validation of analytical procedure for the determination of pendimethalin in plant residues (apple, strawberry, soybean and barley) by LC-MS.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
18SGS04/ EU/Poland/2018	N- Strawberry/Albion	1. 16.05.2018 2. 3. 18.07.2018	1890.2	477.3		11.05.2018	BBCH 00	Fruit	0.01	70	Analytical report: 86/2020

A 2.1.3.2 Grapevine

Data already evaluated

Monograph Table 6.6.1.3.- Residue trials on berries and small fruits (grapes, strawberry) treated with pendimethalin formulations

Crop / Variety	Country (N, S) / Year	Formulation	Application rate (kg as/ha) (N° applica.)	Growth stage at last treatment	Portion Analyzed	PHI (days)	Residue (mg/kg) (No. Trials)	Report Reference
Grape	France (N) 1992-1993	PROWL 400 g/l SC	3.20 (1)	Pre bud burst.	Grape	161-207	<0.05 (8)	2813, 2911
			6.40 (1)		Grape	161-207	<0.05 (8)	
	Switzerland (N) 1979	STOMP 300 g/l EC	2.64 (1)	Beginning of spring growth.	Grape	207	<0.05 (1)	1214
			5.28 (1)		Grape	207	<0.05 (1)	
	Italy (S) 1992	STOMP 300 g/l EC	1.842 (1)	Swollen bud.	Grape	166-170	<0.05 (2)	STOMP 13 101-92

A 2.1.3.2.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:

KCP 8.3.11.1

Report

Residue study (Harvest) in grapevine following one application with Pendimethalin 33% EC in Germany 2017, S. XXX, 2018, Report No. CT17-1-51(Field phase)

Guideline(s):

OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009)
 EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials
 The Principles of Good Laboratory Practice, ChemG 25.07.1994, § 19, Annex 1 (BGBL 21, I, 2001, p. 843-855)
 OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999) 20, Paris 2002
 The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002
 The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9
 Rückstandsversuche, Teil 1 Prüfungen an Pflanzen, A: Allgemeiner Teil, B: Spezieller Teil, IVA-Guideline, Industrieverband Agrar e. V. 1992

Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Grape

Crop parts(s) or processed commodity: fruit

The purpose of the study was to generate specimens for the determination of residues after one application with Pendimethalin 33% EC in grapevine in Germany 2017. The study was carried out according to the study plan CT17-1-51 (accompanied by one study plan amendment), the guideline document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999 and the guidelines mentioned in the “Statement of Compliance”.

Two harvest trials CT17-1-51DE1 and CT17-1-51DE2 were carried out in South Germany. For each trial, two plots were measured out on a vineyard: one untreated control plot (= U / plot 1) and one treated plot (= T / plot 2). Plot 2 was treated once with the test item Pendimethalin 33% EC with the rate of 6.0 L/ha. The test item was applied onto the ground as a row treatment by using a lance sprayer with spray guard. The application was performed before weed emergence at crop stage BBCH 55. The used water volume was 600 L/ha.

Specimens of the raw agricultural commodity fruit were collected at the time of commercial harvest (crop stage BBCH 89). Specimens were taken from the untreated and treated plot. The specimens were stored frozen (targeting -18°C) at the test site in Neidenstein / Germany and at an external storage area in Wunstorf / Germany.

Comments of zRMS:	Study is accepted
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Reference: KCP 8.3.11.2

Report: Determination of Pendimethalin (CAS: 40487-42-1) in grapes by LC-MS according to SOPa-285-LABCHI-Rev. 0, M. XXX, 2018, Report No. 18.618095.0010 (Analytical phase)

Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: grape

Crop parts(s) or processed commodity: fruit

STUDY DESIGN AND METHODS

The analytical phase of the study 18.618095.0010 was conducted to determine the residual level of Pendimethalin in grapes by LC-MS according to the in-house validated methods codified as SOPa-286-LABCHI-Rev. 0 and as described in study No 16.566423.000 on the matrix potato.

SAMPLE EXTRACTION

About 5.00 g of grinded sample were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture were added to the sample. After vortexing for about 1 min, about 6 g of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

LIMIT OF QUANTIFICATION AND LIMIT OF DETECTION

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in grape fruit.

The LOD was set at < 30 % of the LOQ (0.003 mg/kg for grape fruit). The chromatographic peaks at the LOD were more than three times the background noise.

ACCURACY

Accuracy evaluation was performed on sample aliquots spiked with Pendimethalin at LOQ (about 0.01 mg/kg) 3 replicate analyses were performed for each spiking level.

Mean recovery was 100.2% with RSD = 3.0% for first mass transition and 100.3% with RSD = 4.0% for the second mass transition in grape fruit.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
CT17-1-51DE1/N-EU/Germany/2017	Grapevine/Acolon	2003 08-22/06/2017 21/09/2017	2025	600	337.5	26/05/2017	BBCH 55	Fruit	n.d.	117	5 months Analytical report: 18.618095.0010
CT17-1-51DE2/N-EU/Germany/2017	Grapevine/Silvaner	2010 11-23/06/2017 27/09/2017	2022	600	337	26/05/2017	BBCH 55	Fruit	n.d.	123	5 months Analytical report: 18.618095.0010

A 2.1.3.3 Potato

Data already evaluated

Potatoes	Germany (N) 1975-1977	STOMP 330 g/l EC	1.98 (1)	Pre emergence	Potato	42-134	<0.05(14)	544,752, 874
	Switzerland (N) 1975	STOMP 330 g/l EC	1.65 (1)	Pre emergence	Potato	139	<0.05 (1)	575
			1.98 (1)		Potato	139	<0.05 (1)	

A 2.1.3.3.1 Study

Comments of zRMS:	Study is accepted
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Reference:

KCP 8.3.12.1

Report

Determination of residues at harvest and decline of Pendimethalin in Potato, following one broadcast application of Pendimethalin 330 g/L EC, under open field conditions, Central Europe – Season 2016, K. XXX, Report No. FRS 050/16 (Field phase)

Guideline(s):

Directive 91/414/EEC

Deviations:

No

GLP:

Yes

Acceptability:

Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Potato

Crop parts(s) or processed commodity: tubers

STUDY DESIGN AND METHODS

The object of this study was to determine the magnitude and decline of residues of Pendimethalin in Potato resulting from broadcast soil application at the maximum anticipated labelled rate of Pendimethalin 330 g/L EC.

Raw agricultural commodity specimens have been generated from tubers harvested from treated and untreated plots 20(±2), 10(±2) days before harvest (DBH) and at commercial harvest for the decline trial and at commercial harvest for the harvest trial.

The study was conducted under field conditions in Central Europe.

Tubers of potatoes were harvested and bagged separately from 12 plants (or areas) distributed randomly throughout the plot. The untreated plot was sampled before the treated plot. Specimens were dry at sampling.

The samples were harvested from the central part of each plot (discarding 0.5 m at both ends of the plots and borders) by manual harvest equipment.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.12.2
Report	Determination of residues of Pendimethalin applied as “Pendimethalin 330 g/L” in potato at one site in Germany, 2016, J. XXX, Report No. ZBBZ-2016/12/DPL/4DE (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Potato

Crop parts(s) or processed commodity: tubers

The objective of this study was to determine the decline and the magnitude of residues of Pendimethalin in Potato samples taken from the field trial, after applications of Pendimethalin 330 g/L, under open field conditions. To achieve the objective appropriate analytical method for determination of Pendimethalin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validated limit of quantification is 0.01 mg/kg.

The general principles of the analytical procedure were based on the Final Report N. 1655423.002. In brief, samples of Potato were extracted with acidified acetonitrile. After addition of a buffer-salt mixture containing magnesium sulfate and sodium acetate the extract was shaken. After centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulfate addition.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
(a)	(a)	(b)				(c)			(d)	(e)	
FRS050/16-V1/N- EU/Germany/2018	Potato/Innovator	19/04/16 - 22/09/16	1665	200	833	13/05/16	BBCH 07	Tubers	n.d.	132	12 months Analytical report: ZBBZ- 2016/12/DPL/4DE
FRS050/16-V2/N- EU/Germany/2018	Potato/Orwell	04/04/16 - 02/08/16	1665	200	833	04/05/16	BBCH 07	Tubers	0.0028 (<LOQ) n.d. n.d.	69 79 89	12 months Analytical report: ZBBZ- 2016/12/DPL/4DE

A 2.1.3.3.2 Study 2

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.12.3
Report	Field phase residue trial – pre-emergence application of pendimethalin 330 g/L EC in potatoes (<i>Solanum tuberosum</i>) – decline – Central zone – Belgium 2016, M. XXX, Report No. GPE16KR (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Potato

Crop parts(s) or processed commodity: tubers

STUDY DESIGN AND METHODS

The aim of the study was to determine the residue level of pendimethalin 330 g/L EC in potatoes. The study includes a field phase and an analytical one. This report covers the field phase.

The trial (variety Bintje) was set up in a sandy soil at the trial site of the Research Centre in Kruishoutem, Belgium. One application of the formulated product of pendimethalin 330 g/L EC was applied prior to emergence at a rate of 4.0 L/ha. The herbicide application was performed with a backpack sprayer with a spraying volume of 300 L/ha. Specimens were collected at 5 different timings: 20 days before normal commercial harvest, 10 days before normal harvest, 5 days before harvest, 1 day before harvest and at the day of normal commercial harvest. A second trial with pendimethalin in potato (harvest) was set up at another site in Kruishoutem (Lozer), Belgium (different potato variety).

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.12.4
Report	Field phase residue trial – pre-emergence application of pendimethalin 330 g/L EC in potatoes (<i>Solanum tuberosum</i>) – harvest – central zone – Belgium 2016, M. XXX, Report No. GPE16LO (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Potato

Crop parts(s) or processed commodity: tubers

STUDY DESIGN AND METHODS

The aim of the study was to determine the residue level of pendimethalin 330 g/L EC in potatoes. The study includes a field phase and analytical one. This report covers the field phase.

The trial was set up in a sandy loam soil in a potato field in Lozer, Belgium. One application of the formulated product of pendimethalin 330 g/L EC was applied prior to emergence at a rate of 4.0 L/ha.

The herbicide application was performed with a backpack sprayer with a spraying volume of 300 l/ha. Specimens were collected at the day of normal commercial harvest.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.12.5
Report	Determination of residues of pendimethalin applied as “Pendimethalin 330 g/L” in potato at one site in Belgium, 2016, J. XXX, Report No. ZBBZ-2016/DPL/4BE (Analytical phase)

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC
 Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
 EU Guidance Document SANCO/3029/99 rev. 4
 EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No

GLP: Yes

Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Potato

Crop parts(s) or processed commodity: tubers

The objective of this study was to determine the decline and the magnitude of residues of Pendimethalin in Potato samples taken from the field trial, after applications of Pendimethalin 330 g/L, under open field conditions. To achieve the objective appropriate analytical method for determination of Pendimethalin was validated in accordance to the guidance document SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2016/12/DPL/4DE. The validated limit of quantification is 0.01 mg/kg. The general principles of the analytical procedure were based on the Final Report N. 16555423.002. In brief, samples of Potato were extracted with acidified acetonitrile. After addition of a buffer-salt mixture containing magnesium sulfate and sodium acetate the extract was shaken. After centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulfate addition. Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity.

Trial No./	Commodity/ Variety	Date of 1.Sowing or plant-	Application rate per treat- ment	Dates of treat- ment or no. of	Growth stage at last treatment	Portion ana- lyzed	Residues (mg/kg)	PHI (days)	Details on trial
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Location/ EU zone/ Year	(a)	ing 2. Flowering 3. Harvest (b)	g a.s./ ha	Water (l/ha)	g a.s./hl	treatments and last date (c)	or date		Pendimethalin	(d)	(e)
GPE16KR/N- EU/Belgium/2016		13/05/16 - 21/09/16	1320	300	440	23/05/16	BBCH 07	Tubers Tubers Tubers Tubers	n.d. n.d. n.d. n.d.	112 116 121 122	11 months Analytical report: ZBBZ- 2016/12/DPL/4BE
GPE16LO/N- EU/Belgium/2016	Potato/Fontane	12/05/2016 - 22/10/2016	1320	300	440	03/06/16	BBCH 07	Tubers	n.d.	142	11 months Analytical report: ZBBZ- 2016/12/DPL/4BE

A 2.1.3.3.3 Study

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.12.6
Report	Residue study of pendimethalin/Pendimethalin 33% EC (harvest) in potato, Poland (Central Europe) – Season 2016, Z. XXX, Report PL-PH/04/2016-1/1-H/1 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Potato

Crop parts(s) or processed commodity: tubers

STUDY DESIGN AND METHODS

The object of this study was to determine the magnitude of residues of pendimethalin/Pendimethalin 33% EC in potato (*Solanum tuberosum* L.) resulting from one soil applications at the maximum anticipated labelled rate Pendimethalin 33% EC. The study was conducted under field conditions in Poland (Central Europe) Raw potato specimens have been generated during vegetation period and during the harvest of potato, variety Smith Comet, from the plots treated with Pendimethalin 33% EC and untreated and separately for residue at harvest. The samples were collected at correct time, according to the plan of experiment. From each plot one sample was taken. Potato was picked by hand. During sampling the disposable clothing was worn and gloves were changed between each plot. Sampling equipment was cleaned from the soil between each plot. Potato in the samples was healthy, at normal heights, with typical colour, with no diseases, no injuries or abnormal symptoms. Specimens were placed into dry paper bags and labeled. After collecting samples from experiment, all bags with fresh material was delivered to analytical laboratory within one hour.

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.12.7
Report	Determination of the residues of pendimethalin applied as “Pendimethalin 330 g/L” in potato at one site in Poland, 2016, J. XXX, Report No. ZBBZ-2016/12/DPL/4PL (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Potato

Crop parts(s) or processed commodity: tubers

The objective of this study was to determine the decline and the magnitude of residues of Pendimethalin in Potato samples taken from the field trial, after applications of Pendimethalin 330 g/L, under open field conditions. To achieve the objective appropriate analytical method for determination of Pendimethalin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2016/12/DPL/4DE. The validated limit of quantification is 0.01 mg/kg. The general principles of the analytical procedure were based on the Final Report N. 16555423.002. In brief, samples of Potato were extracted with acidified acetonitrile. After addition of a buffer-salt mixture containing magnesium sulfate and sodium acetate the extract was shaken. After centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulfate addition. Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
	(a)	(b)				(c)			(d)	(e)	
PL-PH/04/2016-1/1-D/N- EU/Poland/2016	Potato/Smith Comet	10/05/2016 24/07/2016	1320	230	574	11/05/2016	8-10 days before transplanting	Tubers	<0.01 (<LOQ)	74	18 months Analytical report: ZBBZ- 2016/12/DPL/4PL

A 2.1.3.4 Lettuce

Data already evaluated

Monograph Table 6.6.6-1 Residue trials on leafy vegetables and fresh herbs (lettuce, dill) treated with pendimethalin formulations

Crop / Variety	Country (N, S) / Year	Formulat.	Application rate (kg as/ha) (N° applica)	Growth stage at last treatment	Portion Analysed	PHI (days)	Residue (mg/kg) (No. Trials)	Report Reference
Lettuce	Italy (S) 1986-1990	STOMP 330 g/l EC	1.272 (1)	Pre transplant	Lettuce	69	0.078 (1)	197/91
				Pre sowing		161	<0.05 (1)	198/91,
		Not specified	1.585 (1)	Pre transplant	Lettuce	36	0.20 (1)	STOMP 13 DF/UTA/454

A 2.1.3.4.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:

KCP 8.3.13.1

Report

Determination of residues at harvest and decline of Pendimethalin in Lettuce, following one broadcast application of PENDIMETHALIN 330 g/L EC, under open field conditions, Central Europe – Season 2016, K. XXX, Report No. FRS 054/16(Field phase)

Guideline(s):

Directive 91/414/EEC

Deviations:

No

GLP:

Yes

Acceptability:

Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: lettuce

Crop parts(s) or processed commodity: heads

The object of this study is to determine the magnitude and decline of residues of PENDIMETHALIN in Lettuce resulting from one broadcast soil application at the maximum anticipated labelled rate of PENDIMETHALIN 330 g/L EC.

Raw agricultural commodity specimens have been generated from Lettuce harvested from treated and untreated plots 20(±2), 10(±2) days before harvest (DBH) and at commercial harvest for the decline trial and at commercial harvest for the harvest trial.

The study was conducted under field conditions in Central Europe.

The heads were harvested from the central part of each plot (discarding 0.5 m at both ends of the plots and borders) by manual harvest. No diseased, injured or abnormal samples were taken. Duplicate samples were taken at each plot.

The plants were cut approximately 5 cm above the soil, without roots.

Heads were cut longitudinally in two pieces and one piece was used for the 'Ship' and the other for the 'Retain' specimen.

Comments of zRMS:	Study is accepted
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Reference:

KCP 8.3.13.2

Report

Determination of the residues of pendimethalin applied as "Pendimethalin 330 g/L" in lettuce at one site in Germany, 2016, J. XXX, Report No. ZBBZ-2016/12/DPL/2DE (Analytical phase)

Guideline(s):

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC
Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
EU Guidance Document SANCO/3029/99 rev. 4
EU Guidance Document SANCO/825/00 rev. 8.1

Deviations:

No

GLP:

Yes

Acceptability:

Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Lettuce

Crop part(s) or processed commodity: heads

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues of Pendimethalin in Lettuce samples taken from the field trial, after applications of Pendimethalin 330 g/L, under open field conditions. To achieve the objective appropriate analytical method for determination of Pendimethalin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2016/69/DPL/2ES. The validated limit of quantification is 0.01 mg/kg. The general principles of the analytical procedure were based on the Final Report N. 16555423.002. In brief, samples of Lettuce were extracted with acidified acetonitrile. After addition of a buffer-salt mixture containing magnesium sulfate and sodium acetate the extract was shaken. After centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulfate addition. Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
FRS054/16-V1/N- EU/Germany/2016	Lettuce/Kuala	02/06/2016 - 14/07/2016	1650	200	825	25/05/16	Pre-planting	Heads	n.d.	50	17 months Analytical report: ZBBZ- 2016/12/DPL/2DE
FRS054/16-V2/N-	Lettuce/Diamantinas	21/06/2016	1650	200	825	13/06/16	Pre-planting	Heads	0.0022 (<LOQ)	29	17 months

EU/Germany/2016		01/08/2016						Heads Heads	n.d. n.d.	39 48	Analytical report: ZBBZ- 2016/12/DPL/2DE
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A 2.1.3.4.2 Study 2

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.13.3
Report	Field phase residue trial Pendimethalin 330 g/L EC lettuce (<i>Lactuca sativa</i> var capitata) – Harvest – Central Zone – Belgium – 2016, S. XXX, Report No. OL16 SLRES1 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Lettuce

Crop parts(s) or processed commodity: heads

STUDY DESIGN AND METHODS

The objective of the study was to determine the residue level of pendimethalin 330 g/l EC after 1 application with the formulated product shortly before planting in lettuce. This study consisted of two phases, a field phase and an analytical phase. This report covers the field phase. The trial was set up at 1 site in Belgium (a research field in Kruishoutem, Belgium). The plot area was 22.5 m² and the variety planted was Almagro (Rijk Zwaan). In this trial one plot was treated once with 4l formulated product per ha (1320 g a.s./ha). The trial

treatment was performed by a backpack sprayer with a spray volume of 400 l/ha. The application was applied right before planting of the crop. Specimens were collected at normal harvest timing (43 days after application). Specimens were directly after sampling brought by car to the storage facility (15 minutes) and immediately frozen (-20 °C).

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.13.4
Report	Field phase residue trial Pendimethalin 330 g/L EC lettuce (<i>Lactuca sativa</i> var capitata) – Decline – Central Zone – Belgium – 2016, S. XXX, Report No. OL16 SLRES2 (Field phase)
Guideline(s):	Directive 91/414/EEC
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Lettuce

Crop parts(s) or processed commodity: heads

STUDY DESIGN AND METHODS

The objective of the study was to determine the residue level of pendimethalin 330 g/l EC after 1 application with the formulated product shortly after planting in lettuce. This study consisted of two phases, a field phase and an analytical phase. This report covers the field phase.

The trial was set up at 1 site in Belgium (a research field in Kruishoutem, Belgium). The plot area was 30 m² and the variety sown was Almagro (Rijk Zwaan). In this trial one plot was treated once with 4l formulated product per ha (1320 g a.s./ha). The trial treatment was performed by a backpack sprayer with a spray volume of 400 l/ha. The application was applied right before the planting of the crop (BBCH 00). Specimens were collected at 5 different timings: 20 days before normal commercial harvest, 10 days before normal harvest, 5 days before harvest, 1 day before harvest, day of normal commercial harvest (42 days after application).

Comments of zRMS:	Study is accepted
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Reference:	KCP 8.3.13.5
Report	Determination of the residues of Pendimethalin applied as “Pendimethalin 330 g/L” in lettuce at one site in Belgium, 2016, J. XXX, Report No. ZBBZ-2016/12/DPL/2BE (Analytical phase)
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: lettuce

Crop parts(s) or processed commodity: heads

STUDY DESIGN AND METHODS

The objective of this study was to determine the decline and the magnitude of residues of Pendimethalin in Lettuce samples taken from the field trial, after applications of Pendimethalin 330 g/L, under open field conditions. To achieve the objective appropriate analytical method for determination of Pendimethalin was

validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2016/69/DPL/2ES. The validated limit of quantification is 0.01 mg/kg. The general principles of the analytical procedure were based on the Final Report N. 16555423.002. In brief, samples of Lettuce were extracted with acidified acetonitrile. After addition of a buffer-salt mixture containing magnesium sulfate and sodium acetate the extract was shaken. After centrifugation, an aliquot of the upper acetonitrile phase was cleaned by primary secondary amine (PSA) and dehydrated by magnesium sulfate addition.

- Quantification was performed by use of highly selective liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Pendimethalin		
OL16 SLRES1/N-EU/Belgium/2016	Lettuce/Almagro	25/05/2016 07/07/2016	1367	400	342	25/05/2016	BBCH 00	heads	0.0031 (<LOQ)	42	17 months Analytical report: ZBBZ- 2016/12/DPL/2BE
OL16 SLRES2/N-EU/Belgium/2016	Lettuce/Almagro	25/05/2016 06/07/2016	1330	400	332.5	25/05/2016	BBCH 00	heads	0.159 0.0602 0.0079 (<LOQ) 0.0054 (<LOQ) 0.0053 (<LOQ)	22 32 37 41 42	17 months Analytical report: ZBBZ- 2016/12/DPL/2BE

A 2.1.3.5 Brassica Vegetables (Cauliflower, Broccoli, Cabbage, Kale, Kholrabi)

Data already evaluated

Monograph Table 6.6.5-1 Residue trials on brassica vegetables (cauliflower, broccoli, cabbage, kale, kohlrabi) treated with pendimethalin formulations

Crop / Variety	Country (N, S) / Year	Formulat.	Application rate (kg as/ha) (N° applica)	Growth stage at last treatment	Portion Analyzed	PHI (days)	Residue (mg/kg) (No. Trials)	Report Reference
Cauliflower	Finland (N) 1978	STOMP 330 g/l EC	1.65 (1)	Not specified	Plant	54	<0.05 (1)	2040
	France(N) 1976-1989	STOMP 330 g/l EC PROWL 440 g/l SC	1.32 (1)	Pre planting	Head Head	83-127	<0.05 (6)	2247, 852, 2462
			2.64 (1)			83-127	<0.05 (6)	
	Germany (N) 1977	STOMP 330 g/l EC	1.98 (1)	Before transplanting	Cauliflower	65-93	<0.05 (4)	911
	Italy (S) 1986	Not specified	1.585 (1)	Pre transplanting	Head	76	<0.05 (1)	STOMP 13 DF/UTA/4
Spain (S) 1974	STOPMP 330 g/l EC	1.32 (1)	Pre and post transplanting	Cauliflower Cauliflower	189-196	<0.05 (2)	54 492	
		1.98 (1)			189-196	<0.05 (2)		
Broccoli	Finland (N) 1978	STOMP 330 g/l EC	1.65 (1)		Plant	40	<0.05 (1)	1978
	UK (N) 1975	STOMP 330 g/l EC	2.0 (1)	Transplanting seedling	Broccoli	132	<0.05 (1)	661
Cabbage	France (N)	STOMP	1.32 (1)	Pre planting	Cabbage	130	<0.05 (1)	853

Crop / Variety	Country (N, S) / Year	Formulat.	Application rate (kg as/ha) (N° applica)	Growth stage at last treatment	Portion Analyzed	PHI (days)	Residue (mg/kg) (No. Trials)	Report Reference
	1976	330 g/l EC	2.64 (1)		Cabbage	130	<0.05 (1)	
	Germany (N) 1975-1977	STOMP 330 g/l EC	1.485 (1) 1.98 (1)	2-3 leaf stage Before traspl	Cabbage Cabbage	90-120 63-91	<0.05 (4) <0.05 (4)	652, 905 905
Kale	Finland (N) 1978	STOMP 330 g/l EC	1.65 (1)	Not specified	Plant	67	<0.05 (1)	2097
	Germany (N) 1975	STOMP 330 g/l EC	1.485 (1)	2-3 leaf stage	Kale	90-120	<0.05 (2)	652
Kohlrabi	Germany (N) 1977	STOMP 330 g/l EC	1.98 (1)	Before transplanting	Whole Plant Leaves Bulb	41 55-69 55-69	<0.05 (1) <0.05 (3) <0.05 (3)	912

A 2.1.3.6 Stem Vegetables (artichoke, asparagus, celery leeks)

Data already evaluated

Table 8.3.5-01 Residue trials on stem vegetables (artichoke, celery, leeks) treated with pendimethalin formulations.

Crop / Variety	Country (N, S) / Year	Formulat.	Application rate (kg as/ha) (N° applica)	Growth stage at last treatment	Portion Analyzed	PHI (days)	Residue (mg/kg) (No. Trials)	Report Reference
Artichoke	France (N) 1987	PROWL 400 g/l SC	1.32 (1)	Pre emergence	Head	159	<0.05 (2)	2252
			2.64 (1)	Pre emergence	Head	159	<0.05 (2)	

Crop / Variety	Country (N, S) / Year	Formulat.	Application rate (kg as/ha) (N°applica)	Growth stage at last treatment	Portion Analyzed	PHI (days)	Residue (mg/kg) (No. Trials)	Report Reference		
Celery	France (N) 1986	PROWL 330 g/l SC	1.32 (1)	post planting stem diameter 2 cm	Stem	94	<0.05 (1)	2082		
			2.64 (1)		Stem	94	<0.05 (1)			
	France (N) 2003	PROWL 330 g.L ⁻¹ EC	1,32 (1)	after sowing after sowing	Stem	94	<0,05 (1)			
			2,64 (1)		Stem	94	<0,05 (1)			
	Germany 2002	STOMP 400 g.L ⁻¹ SC	1,6 (1)	BBCH 14	Stem	63	0,045		PW 01/01 RU-H-12 01 MV RO 1/1-2 a 01/024-025	
			1,6 (1)		BBCH13	Stem	86			<0,02
			1,6 (1)		BBCH 16	Foliage and stem	91			<0,02
			1,6 (1)		BBCH 19	Foliage and stem	90			<0,02
Leeks	France (N) 1976	STOMP 330 g/l EC	1.32 (1)		Leek	134, 184	<0.05 (2)	897		
			2.64 (1)			134, 184	< 0.05 (2)			
	France (N) 1987	PROWL 400 g/l SC	1.32 (1)		Leek	70	< 0.05 (1)	2256		
			2.64 (1)			70	< 0.05 (1)			

A 2.1.3.7 Plum

A 2.1.3.7.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:

8.3.14.1

Report

Determination of the residues of Pendimethalin in/on plum after one application of Pendimethalin 33% ECc in North-

	ern Europe - Hungary in 2021, Gábor XXX, 2021, Report No.: 065CPRHU21R55
Guideline(s):	Yes SANCO/3029/99 rev. 4, 11/07/2000 SANCO 7525/VI/95 rev. 10.3, 13/06/2017
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Pendimethalin 33% EC is a herbicide developed by Sharda Cropchem Ltd. for weed control in different crops. The objective of this study is to provide results from the magnitude of residues of pendimethalin in/on plum, grown in open field conditions, in order to support the registration of the plant protection product applied according to Good Laboratory Practice (GLP).

Two trials were conducted in Hungary in 2021. The field phase was performed in Sótöny (CPRHU21-340-065HR), and in Vönöck (CPRHU21-341-065HR). One application (before fruit setting at BBCH 70) of the formulated product Pendimethalin 33% EC was applied at a rate of 6.06 L formulated product/ha (2000 g active ingredient of pendimethalin/ha) onto the crop, under open field condition.

Specimens (fruit) were collected at normal commercial harvest (NCH) in harvest trial, frozen and shipped deep frozen to analytical facility of Łukasiewicz Research Network - Institute of Heavy Organic Synthesis „Blachownia” for residue analysis. There was no unusual event that affected this phase of the study.

Comments of zRMS:	Study is accepted
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Reference:	8.3.14.2
Report	Determination of the residues of Pendimethalin in/on plum after one applications of Pendimethalin 33% EC in Northern Europe – Hungary in 2021, Zofia XXX, 2021, Report No.: 74/2021
Guideline(s):	Yes SANCO/825/00 rev. 8 SANCO/3029/99 rev. 4
Deviations:	No

GLP: Yes

Acceptability: Yes

Specificity

The control samples (untreated sample, sample code: 74.1/2021 and 74.3/2021) were analyzed to investigate for possible residues of the analyte and to check for any background interferences at the expected retention time of the analyte.

No residues of Pendimethalin in control sample with sample code: 74.1/2021 and 74.3/2021 were detected. No background interferences at the expected retention time of the analyte were observed. The control specimen material was used for recovery determinations

One solvent blank (LC mobile phase solution) and two reagent blank samples, which is a sample work up without matrix present were conducted in the course of the study. No background interferences at the expected retention time of the analyte were observed.

Accuracy and precision

Accuracy was determined by fortification of control (untreated) samples with known amounts of the reference item and subsequent determination of the recoveries when applying the extraction procedure. Precision was determined by repeatability (relative standard deviation – RSD).

Three recovery determinations were performed at the LOQ (0.01 mg/kg) and 10xLOQ (0.1 mg/kg) for plum's matrix. Analysis was performed by extraction and single injection.

Analyte	Matrix	Fortification Level (mg/kg)	Recovery (%)	Mean Rec. (%)	RSD (%)	n
Pendimethalin	Ion Mass Transition m/z 282-211.9 (Quantification)					
	Stone fruits	0.01*	107/104/107	106	1.7	3
	Ion Mass Transition m/z 282-194.0 (Confirmation)					
	Stone fruits	0.01*	101/97/101	100	7.9	3
	Ion Mass Transition m/z 282-211.9 (Quantification)					
	Stone fruits	0.1	107/105/103	105	10.0	3
Ion Mass Transition m/z 282-194.0 (Confirmation)						
Stone fruits	0.1	105/103/101	103	9.4	3	

*- Limit of quantification, defined by the lowest validated fortification level

Linearity

Pendimethalin, PESTANAL® analytical standard 100% (HPLC) was used for calibration.

The linearity of the detector response for Pendimethalin was demonstrated by single injection of matrix-matched calibration standards at eight concentration levels ranging from 0.001 µg/mL to 0.1 µg/mL for pome fruits matrix. These ranges corresponds from 0.003 mg/kg to 0.2 mg/kg for pome fruits thus covering the range from no more than 30% of the LOQ and at least +20% of the highest analyte concentration level detected in sample.

Sample preparation

Prior to extraction, stones were removed- stones , flesh and fruit were weighted. Recorded weight and calculated weight ratio of flesh and fruit for each sample is presented in Table below.

Tested material code	Stone weight [g]	Flesh weight [g]	Fruit weight [mg]	Flesh/fruit weight ratio
74.1/2021	86.60	2082.74	2169.34	0.96
74.2/2021	88.81	1943.22	2032.03	0.96
74.3/2021	75.36	1915.44	1990.8	0.96
74.4/2021	100.22	2109.57	2209.79	0.95

Preparation of Sample Matrix

- Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.
- Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample extraction

- 10.00 g ± 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.
- If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard of Pendimethalin mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	2	50
10xLOQ (0.1 mg/kg)	20	50

- For extraction using an automatic pipette 10mL of acetonitrile was added.
- The PP centrifuge tube was closed tightly and shake for 1 min automatically.

Liquid-Liquid Partition

- A. Buffer-salt mixture (4 g ± 0.2 g of magnesium sulfate anhydrous, 1 g ± 0.05 g of sodium chloride, 0,5 g ± 0.03 g NaCitrate dibasic sesquihydrate, 1 g ± 0.05 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.
- B. The extract was centrifuged at >3000 g for 5 min

Sample Purification

- A. Using an automatic pipette 6 ml of sample extract supernatant was transferred to Dispersive SPE 12 ml centrifuge tubes containing 150 mg Supelclean PSA and 900 mg MgSO₄. The tube was shaken automatically for 30 sec.

Sample dilution

- A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+5% Vol. formic acid) and 0.05 mL of acetonitrile.
- B. Content was vortex gently and filtered through the 0.22 µm Teflon filter attached to a syringe direct into amber HPLC vial.
- C. Vial was labeled so that it may be identified.

Table A 5: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
	(a)	(b)				(c)			(d)	(e)	
CPRHU21-340- 065HR/ Hungary/ N- EU/ 2021	Plum	1. 10.03.2014 2. April 2021 3. August 2021	2000.0	400.0	-	12.04.2021	BBCH 65	Fruit flesh Whole fruit (with stone)	<0.003 (<LOD) <0.003 (<LOD)	123 123	Analytical report no.: 74/2021 LOD:0.003 mg/kg LOQ:0.01 mg/kg Time between sampling and extraction: 3 months

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin			
CPRHU21-341-065HR/ Hungary/ N-EU/ 2021	Plum	1. 2015 year 2. April 2021 3. September 2021	2000.0	400.0	-	12.04.2021	BBCH 63	Fruit flesh Whole fruit (with stone)	<0.003 (<LOD) <0.003 (<LOD)	161 161	Analytical report no.: 74/2021 LOD:0.003 mg/kg LOQ:0.01 mg/kg Time between sampling and extraction: 3 months	

A 2.1.3.7.2 Study 2

Comments of zRMS:	Study is accepted
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Reference:	8.3.14.3
Report	Magnitude of the residue of Pendimethalin in stone fruits (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – two harvest trials in Poland – 2018, Tomasz XXX, 2018, Report No.: 18SGS03
Guideline(s):	Yes SANCO/3029/99 rev. 4, 11/07/2000 SANCO/825/00 rev. 8.1, 16/11/2010
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Two harvest trials (HS) were established in Poland. Trials consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

Pendimethalin 33% EC was only mixed with water. No adjuvant was added to the spray mixture. Typical for herbicide applications Pendimethalin 33% EC was performed in the trial with boom sprayer on the treated plots at the target dose rate of 6,0 l/ha, equivalent to 2000 g a.s./ha pendimethalin. The reported dose rate actually was 5.131 and 5.505 l/ha. Applications were made at a target water volume of 200-800 litres per hectare of mixture according to Good Agricultural Practice. Foliar ground applications were performed at BBCH 69 of stone fruits.

The spray mixture volume remaining after the application were measured and the volume applied to the treated plot were calculated to verify delivery rates. The calculations and the delivery rates were verified by Study Director.

In the harvest study (HS), RAC specimens for analyses were collected:
-S1 (fruits without calyx) – commercial harvest

RAC specimens were put in deep freezing conditions at a target temperature of $\leq -18^{\circ}\text{C}$ on the day of sampling, within five hours after sampling. All specimens remained deep frozen during storage at the test site, during shipment to ŁUKASIEWICZ Research Network-Institute of Heavy Organic Synthesis “Blachownia”.

Analytical phase

Specificity

The control samples (untreated sample, sample code: 85.1/2020 and 75.3/2020) were analyzed to investigate for possible residues of the analyte and to check for any background interferences at the expected retention time of the analyte.

No residues of Pendimethalin in control sample with sample code: 85.1/2020 and 85.3/2020 were detected. No background interferences at the expected retention time of the analyte were observed. The control specimen material was used for recovery determinations

One solvent blank (LC mobile phase solution) and two reagent blank samples, which is a sample work up without matrix present were conducted in the course of the study. No background interferences at the expected retention time of the analyte were observed.

Accuracy and precision

Accuracy was determined by fortification of control (untreated) samples with known amounts of the reference item and subsequent determination of the recoveries when applying the extraction procedure. Precision was determined by repeatability (relative standard deviation – RSD).

Three recovery determinations were performed at the LOQ (0.01 mg/kg) and 10xLOQ (0.1 mg/kg) for stone fruits (plum) matrix. Analysis was performed by extraction and single injection.

Analyte	Matrix	Fortification Level (mg/kg)	Recovery (%)	Mean Rec. (%)	RSD (%)	n
Pendimethalin	Ion Mass Transition m/z 282-211.9 (Quantification)					
	Stone fruits (plum)	0.01*	78/85/73	79	7.7	3
	Stone fruits (plum)	0.1	72/84/76	77	7.6	3
	Ion Mass Transition m/z 282-194.0 (Confirmation)					
	Stone fruits (plum)	0.01*	77/83/74	78	6.4	3
Stone fruits (plum)	0.1	73/86/75	78	9.0	3	

*- Limit of quantification, defined by the lowest validated fortification level

Linearity

Pendimethalin, PESTANAL® analytical standard 98.7% (HPLC) was used for calibration.

The linearity of the detector response for Pendimethalin was demonstrated by single injection of matrix-matched calibration standards at eight concentration levels ranging from 0.001 µg/mL to 0.1 µg/mL, what corresponds to the range from 0.003 mg/kg to 0.2 mg/kg, thus covering the range from no more than 30% of the LOQ and at least +20% of the highest analyte concentration level detected in sample.

Sample preparation

Prior to extraction, stones were removed- stones , flesh and fruit were weighted. Recorded weight and calculated weight ratio of flesh and fruit for each sample is presented in Table below.

Tested material code	Stone weight [g]	Flesh weight [g]	Fruit weight [mg]	Flesh/fruit weight ratio
85.1/2020	101.9	1905.5	2007.4	0.95
85.2/2020	101.4	1897.0	1998.4	0.95
85.3/2020	105.0	1922.6	2027.6	0.95
85.4/2020	90.7	1925.1	2015.8	0.96

Preparation of Sample Matrix

- A. Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.
- B. Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample extraction

- A. 10.00 g \pm 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.
- B. If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard of Pendimethalin mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Concentration of individual standard ($\mu\text{g/mL}$)	Volume used (μL)
LOQ (0.01 mg/kg)	2	50
10xLOQ (0.1 mg/kg)	20	50

- C. For extraction using an automatic pipette 10mL of acetonitrile was added.
- D. The PP centrifuge tube was closed tightly and shake for 1 min automatically.

Liquid-Liquid Partition

- A. Buffer-salt mixture (4 g \pm 0.2 g of magnesium sulfate anhydrous, 1 g \pm 0.05 g of sodium chloride, 0,5 g \pm 0.03 g NaCitrate dibasic sesquihydrate, 1 g \pm 0.05 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.
- B. The extract was centrifuged at >3000 g for 5 min for Stone fruits (plum).

Sample Purification

- A. Using an automatic pipette 6 ml of sample extract supernatant was transferred Supel Que PSA (EN) Tube. The tube was shaken automatically.
- B. The extract was centrifuged at > 3000 rpm for 5 min for Stone fruits (plum).

Sample dilution

- A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+5% Vol. formic acid) and 0.05 mL of acetonitrile.
- B. Content was vortex gently and filtered through the 0.22 μm Teflon filter attached to a syringe direct into amber HPLC vial.
- C. Vial was labeled so that it may be identified.

Table A 6: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
18SGS03 PL01/ Poland/ N-EU/ 2018	Plum	1. 03.03.2003 2. - 3. 12.09.2018	2000.00	500.00	-	08.05.2018	BBCH 69	Fruit flesh Whole fruit (with stone)	<0.003 (<LOD) <0.003 (<LOD)	118 118	Analytical report no.: 85/2020 LOD:0.003 mg/kg LOQ:0.01 mg/kg Time between sampling and extraction: 22 months
18SGS03 PL02/ Poland/ N-EU/ 2018	Plum	1. 03.03.2015 2. - 3. 28.08.2018	2000.00	500.00	-	08.05.2018	BBCH 69	Fruit flesh Whole fruit (with stone)	<0.003 (<LOD) <0.003 (<LOD)	118 118	Analytical report no.: 85/2020 LOD:0.003 mg/kg LOQ:0.01 mg/kg Time between sampling and extraction: 22 months

A 2.1.4 Magnitude of residues in livestock

No new data were submitted in the framework of this application.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new data were submitted in the framework of this application.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new data were submitted in the framework of this application.

A 2.1.7 Other/Special Studies

No new data were submitted in the framework of this application.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations



Pendimethalin (F) (F)			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.125	ARID (mg/kg bw):	0.3
Source of ADI:		Source of ARID:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

		No of diets exceeding the ADI : ---						Exposure resulting from		
Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI(NED)/IEDI calculation (based on average food consumption)	4%	NL toddler	5.15	1.0%	Milk: Cattle	0.6%	Carrots	0.4%	Apples	2%
	3%	SE general	3.89	1%	Lettuces	0.5%	Carrots	0.2%	Milk: Cattle	2%
	3%	DE child	3.52	0.6%	Carrots	0.5%	Apples	0.3%	Milk: Cattle	2%
	3%	GEMS/Food G10	3.30	1%	Lettuces	0.2%	Wheat	0.2%	Carrots	2%
	3%	ES child	3.14	1%	Lettuces	0.2%	Milk: Cattle	0.2%	Wheat	2%
	2%	GEMS/Food G07	3.10	0.8%	Lettuces	0.2%	Carrots	0.2%	Wheat	2%
	2%	NL child	3.07	0.4%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Lettuces	1%
	2%	DK child	3.06	0.8%	Carrots	0.5%	Lettuces	0.2%	Rye	2%
	2%	ES adult	3.05	2%	Lettuces	0.1%	Wheat	0.1%	Carrots	2%
	2%	GEMS/Food G08	2.98	0.6%	Lettuces	0.3%	Carrots	0.2%	Wheat	1%
	2%	GEMS/Food G11	2.83	0.4%	Carrots	0.3%	Lettuces	0.2%	Potatoes	1%
	2%	UK infant	2.78	0.7%	Carrots	0.6%	Milk: Cattle	0.1%	Potatoes	1%
	2%	GEMS/Food G15	2.62	0.4%	Lettuces	0.2%	Carrots	0.2%	Wheat	1%
	2%	IE adult	2.47	0.3%	Lettuces	0.2%	Carrots	0.1%	Sweet potatoes	0.9%
	2%	GEMS/Food G06	2.43	0.3%	Lettuces	0.3%	Wheat	0.1%	Tomatoes	1.0%
	2%	FR child 3 15 yr	2.38	0.4%	Milk: Cattle	0.3%	Carrots	0.2%	Wheat	0.8%
	2%	FR toddler 2 3 yr	2.36	0.5%	Milk: Cattle	0.4%	Carrots	0.1%	Apples	0.8%
	2%	IT adult	2.25	1%	Lettuces	0.2%	Wheat	0.1%	Carrots	1%
	2%	IT toddler	2.15	0.9%	Lettuces	0.3%	Wheat	0.1%	Carrots	1%
	2%	UK toddler	2.10	0.3%	Milk: Cattle	0.3%	Carrots	0.2%	Wheat	0.8%
	2%	DE women 14-50 yr	2.04	0.4%	Lettuces	0.2%	Milk: Cattle	0.2%	Sugar beet roots	0.9%
	2%	PT general	2.01	0.4%	Carrots	0.3%	Lettuces	0.2%	Potatoes	1%
	2%	DE general	1.90	0.3%	Lettuces	0.2%	Milk: Cattle	0.2%	Sugar beet roots	0.8%
	1%	RO general	1.78	0.3%	Carrots	0.2%	Wheat	0.2%	Milk: Cattle	0.8%
	1%	FR infant	1.77	0.6%	Carrots	0.3%	Milk: Cattle	0.1%	Potatoes	0.9%
	1%	NL general	1.70	0.3%	Lettuces	0.1%	Milk: Cattle	0.1%	Carrots	0.8%
	1%	FI 3 yr	1.57	0.5%	Carrots	0.2%	Potatoes	0.1%	Lettuces	0.9%
	1%	FI adult	1.43	0.5%	Lettuces	0.2%	Coffee beans	0.2%	Carrots	0.8%
	1%	FI 6 yr	1.42	0.3%	Carrots	0.3%	Lettuces	0.2%	Potatoes	0.9%
	1%	UK vegetarian	1.39	0.5%	Lettuces	0.1%	Carrots	0.1%	Wheat	0.8%
1%	DK adult	1.37	0.3%	Lettuces	0.3%	Carrots	0.1%	Milk: Cattle	0.8%	
0.9%	UK adult	1.18	0.4%	Lettuces	0.1%	Carrots	0.1%	Wheat	0.7%	
0.8%	FR adult	1.05	0.1%	Carrots	0.1%	Wine grapes	0.1%	Wheat	0.4%	
0.8%	LT adult	1.05	0.2%	Lettuces	0.1%	Potatoes	0.1%	Carrots	0.6%	
0.6%	PL general	0.80	0.2%	Carrots	0.1%	Potatoes	0.1%	Apples	0.6%	
0.4%	IE child	0.46	0.1%	Carrots	0.1%	Milk: Cattle	0.0%	Wheat	0.2%	

Conclusion:
 The estimated long-term dietary intake (TMDI/NED)/IEDI) was below the ADI.
 The long-term intake of residues of Pendimethalin (F) (F) is unlikely to present a public health concern.

A 3.2 IEDI calculations

Not relevant.

A 3.3 IESTI calculations - Raw commodities

Acute risk assessment /children				Acute risk assessment / adults / general population				Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment/adults				Hide IESTI new calculations				Show IESTI new calculations				
The acute risk assessment is based on the ARID. The calculation is based on the large portion of the most critical consumer group.								IESTI new calculations: The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.								
Show results of IESTI calculation only for crops with GAPs under assessment																
Unprocessed commodities	Results for children				Results for adults				IESTI new Results for children				IESTI new Results for adults			
	No. of commodities for which ARID/ADI is exceeded (IESTI):				---				No. of commodities for which ARID/ADI is exceeded (IESTI):				---			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)
	51%	Lettuces	4 / 4	152	16%	Lettuces	4 / 4	49	30%	Lettuces	4 / 4	91	10%	Lettuces	4 / 4	29
	15%	Carrots	0.7 / 0.7	44	5%	Carrots	0.7 / 0.7	14	6%	Carrots	0.7 / 0.7	19	3%	Carrots	0.7 / 0.7	8.3
3%	Potatoes	0.05 / 0.05	7.7	0.7%	Head cabbages	0.05 / 0.05	2.1	1%	Oranges	0.05 / 0.05	3.3	0.8%	Oranges	0.05 / 0.05	2.3	
2%	Pears	0.05 / 0.05	6.9	0.6%	Table grapes	0.05 / 0.05	1.7	1%	Potatoes	0.05 / 0.05	3.3	0.7%	Plums	0.05 / 0.05	2.0	
2%	Oranges	0.05 / 0.05	6.6	0.5%	Oranges	0.05 / 0.05	1.5	1%	Apples	0.05 / 0.05	3.1	0.6%	Pears	0.05 / 0.05	1.8	
2%	Apples	0.05 / 0.05	5.4	0.5%	Pears	0.05 / 0.05	1.5	1.0%	Pears	0.05 / 0.05	3.0	0.5%	Mandarins	0.05 / 0.05	1.6	
2%	Peaches	0.05 / 0.05	4.8	0.5%	Potatoes	0.05 / 0.05	1.5	0.9%	Beans	0.15 / 0.15	2.7	0.5%	Potatoes	0.05 / 0.05	1.6	
1%	Grapefruits	0.05 / 0.05	3.9	0.5%	Apples	0.05 / 0.05	1.4	0.9%	Peaches	0.05 / 0.05	2.7	0.5%	Apples	0.05 / 0.05	1.5	
1%	Table grapes	0.05 / 0.05	3.6	0.5%	Aubergines/egg plants	0.05 / 0.05	1.4	0.8%	Apricots	0.05 / 0.05	2.5	0.4%	Head cabbages	0.05 / 0.05	1.3	
1.0%	Sweet peppers/bell	0.05 / 0.05	3.0	0.4%	Broccoli	0.05 / 0.05	1.2	0.8%	Grapefruits	0.05 / 0.05	2.4	0.4%	Wine grapes	0.05 / 0.05	1.2	
1.0%	Mandarins	0.05 / 0.05	3.0	0.4%	Wine grapes	0.05 / 0.05	1.2	0.7%	Table grapes	0.05 / 0.05	2.2	0.3%	Grapefruits	0.05 / 0.05	1.0	
1.0%	Tomatoes	0.05 / 0.05	2.9	0.4%	Cauliflowers	0.05 / 0.05	1.2	0.6%	Mandarins	0.05 / 0.05	1.9	0.3%	Peaches	0.05 / 0.05	1.0	
1.0%	Cauliflowers	0.05 / 0.05	2.9	0.3%	Beans	0.15 / 0.15	0.99	0.6%	Cauliflowers	0.05 / 0.05	1.7	0.3%	Table grapes	0.05 / 0.05	1.0	
0.9%	Beans	0.15 / 0.15	2.7	0.3%	Peaches	0.05 / 0.05	0.94	0.5%	Tomatoes	0.05 / 0.05	1.5	0.3%	Beans	0.15 / 0.15	0.99	
0.7%	Head cabbages	0.05 / 0.05	2.2	0.3%	Mandarins	0.05 / 0.05	0.90	0.4%	Head cabbages	0.05 / 0.05	1.3	0.3%	Broccoli	0.05 / 0.05	0.97	
Expand/collapse list																
Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARID/ADI in children and adult diets (IESTI new calculation)								

A 3.4 IESTI calculations - Processed commodities

Processed commodities	Results for children				Results for adults				Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI new):				No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			
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IESTI		MRL / input for RA Exposure (µg/kg bw)		IESTI		MRL / input for RA Exposure (µg/kg bw)		IESTI new		MRL / input for RA Exposure (µg/kg bw)		IESTI new		MRL / input for RA Exposure (µg/kg bw)		
Highest % of ARfD/ADI	Processed commodities	(mg/kg)	(µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	(mg/kg)	(µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	(mg/kg)	(µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	(mg/kg)	(µg/kg bw)	
8%	Carrots / juice	0.7 / 0.7	25	2%	Carrots / canned	0.7 / 0.7	5.7	8%	Carrots / juice	0.7 / 0.7	25	2%	Carrots / canned	0.7 / 0.7	5.7	
2%	Potatoes / fried	0.05 / 0.05	4.7	0.7%	Cauliflowers / boiled	0.05 / 0.05	2.1	1.0%	Potatoes / dried (flakes)	0.05 / 0.23	3.0	0.6%	Apples / juice	0.05 / 0.05	1.7	
1%	Broccoli / boiled	0.05 / 0.05	3.9	0.6%	Apples / juice	0.05 / 0.05	1.7	0.9%	Apples / juice	0.05 / 0.05	2.7	0.4%	Cauliflowers / boiled	0.05 / 0.05	1.2	
1%	Cauliflowers / boiled	0.05 / 0.05	3.5	0.4%	Broccoli / boiled	0.05 / 0.05	1.2	0.9%	Oranges / juice	0.05 / 0.05	2.6	0.4%	Beans / canned	0.15 / 0.15	1.1	
1.0%	Potatoes / dried (flakes)	0.05 / 0.23	3.0	0.4%	Beans / canned	0.15 / 0.15	1.1	0.8%	Broccoli / boiled	0.05 / 0.05	2.4	0.3%	Wine grapes / juice	0.05 / 0.05	1.0	
0.9%	Apples / juice	0.05 / 0.05	2.7	0.3%	Wine grapes / juice	0.05 / 0.05	1.0	0.7%	Potatoes / fried	0.05 / 0.05	2.2	0.3%	Broccoli / boiled	0.05 / 0.05	1.0	
0.9%	Oranges / juice	0.05 / 0.05	2.6	0.3%	Oranges / juice	0.05 / 0.05	0.76	0.7%	Wine grapes / juice	0.05 / 0.05	2.2	0.3%	Oranges / juice	0.05 / 0.05	0.76	
0.7%	Wine grapes / juice	0.05 / 0.05	2.2	0.2%	Grapes / juice	0.05 / 0.05	0.54	0.7%	Cauliflowers / boiled	0.05 / 0.05	2.1	0.2%	Grapes / juice	0.05 / 0.05	0.54	
0.5%	Pears / juice	0.05 / 0.05	1.6	0.2%	Wine grapes / wine	0.05 / 0.05	0.47	0.5%	Pears / juice	0.05 / 0.05	1.6	0.2%	Wine grapes / wine	0.05 / 0.05	0.47	
0.4%	Peaches / canned	0.05 / 0.05	1.3	0.2%	Onions / boiled	0.05 / 0.05	0.47	0.4%	Peas / canned	0.15 / 0.06	1.1	0.2%	Head cabbages / canned	0.05 / 0.05	0.47	
0.4%	Peas / canned	0.15 / 0.06	1.1	0.2%	Head cabbages / canned	0.05 / 0.05	0.47	0.3%	Peaches / canned	0.05 / 0.05	0.97	0.1%	Potatoes / chips	0.05 / 0.05	0.42	
0.3%	Tomatoes / juice	0.05 / 0.05	0.95	0.1%	Potatoes / chips	0.05 / 0.05	0.42	0.3%	Tomatoes / juice	0.05 / 0.05	0.95	0.1%	Tomatoes / sauce/puree	0.05 / 0.05	0.41	
0.3%	Peaches / juice	0.05 / 0.05	0.83	0.1%	Tomatoes / sauce/puree	0.05 / 0.05	0.41	0.3%	Peaches / juice	0.05 / 0.05	0.83	0.1%	Peaches / canned	0.05 / 0.05	0.41	
0.2%	Beans (with pods) / boiled	0.05 / 0.05	0.63	0.1%	Peaches / canned	0.05 / 0.05	0.41	0.2%	Beans (with pods) /	0.05 / 0.05	0.63	0.1%	Peas / canned	0.15 / 0.06	0.40	
0.2%	Brussels sprouts / boiled	0.05 / 0.05	0.51	0.1%	Peas / canned	0.15 / 0.06	0.40	0.2%	Brussels sprouts / boiled	0.05 / 0.05	0.51	0.1%	Onions / boiled	0.05 / 0.05	0.36	
Expand/collapse list																
<p>Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Pendimethalin (F) (F) is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.</p>																

Appendix 4 Additional information provided by the applicant

Not relevant.