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Version history

| Date | Data points containing amendments or additions ¹ and brief description | Document identifier and version number |
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| 1 14 : | | |
| ¹ It is suggested that SANCO/10180/20 | at applicants adopt a similar approach to showing revisions and 13 Chapter 4 How to revise an Assessment Report | Persion history as outlinedon |
| | | |

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CP 10 ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

A dossier on active substance amidosulfuron was submitted February 2002 by Bayer CropScience to the EU RMS Austria for agricultural use as a herbicide. Amidosulfuron was included into Annex I of the Council Directive 91/414/EEC by the Commission Directive 2008/40/EC published 4 April 2008, with an entry into force by 1 January 2009¹.

This Supplementary Dossier contains only detailed summaries of studies, which were not part of the dossier during the first Annex I inclusion of amidosulfuron and were, therefore, not evaluated during the first EU review of this compound. In order to facilitate discrimunation between new and old information, the new information is written in black whereas preyshaded text indicates the previously reviewed information.

All studies, which have been already submitted by Bayer CropScience for the first Anox I inclusion, are contained in the Draft Assessment Report (DAR) and its Addend@ and arc/included in the Baseline dossier provided by Bayer CropScience. The summaries on the different endpoints were taken from the Draft Assessment Report (DAR) and its Addenda and supplemented with new information (new studies, references, further comments).

The formulation Amidosulfuron WG 75 is the representative formulation for the inclusion of amidosulfuron at European level. The summaries of formulation studies and the risk assessment will be presented in this dossier.

Ecotoxicological endpoints used in the following risk assessment. We derived from studies with the formulated product Amidosulfuron WG 5, the active substance amidosulfuron and its metabolites listed in the residue definition for risk assessment.

In this Dossier only endpoints used for the risk assessment are presented. For an overview of all available endpoints for and outpart and its metabolite please refer to the respective section of the MCA document. In order to facilitate discrimination between new and information submitted during the Annex I inclusion process, the proviously value of information is written in grey letters.

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¹ COMMISSION DECISION of 10 October 2008 correcting Directive 2008/40/EC amending Council Directive 91/414/EEC to include amidosulfuron and nicosulfuron as active substances (notified under document number C(2008) 5703) (Text with EEA relevance) (2008/791/EC)

Use pattern considered in this risk assessment

| Table CP | [•] 10- | 1: | Intended | application | pattern |
|----------|------------------|----|----------|-------------|---------|
|----------|------------------|----|----------|-------------|---------|

| Сгор | Timing of application (range) | Number of applications | Application interval [days] | Maximum label rate per treatment [kg product/ha] | Application rate per treatment [g a.s./ha] Amidosulfuron |
|---------------------------------------|-------------------------------------|---------------------------|-----------------------------------|---|---|
| Winter corcels | BBCH 21-49 ¹⁾²⁾ | 1 | - | 0.04 | |
| winter cerears | BBCH 13-49 ¹⁾²⁾ | 1 | - | | A 15 5 |
| Spring cereals | BBCH 12-49 ¹⁾³⁾ | 1 | - 0 | 0.02-0.04 | |
| Flax | Before flower buds are visible | 1 | | 0.02-0.04 | م 15-30 کې ° |
| Grass/pasture (permanent grass) | Spring/Autumn | 1 | | | |

All EU except France/Italy (up to BBCH 32) ²⁾ at the end of winter dormancy / onset of weed growth in Spring v@getation*period

3) Spring

Risk envelope

For envelope type risk assessment, the critical application pattern in cerears is defined as single application of 1 × 30 g a.s./ha in spring cereals at BBCH @-49. The application patterns in winter cereals (1 × 30 g a.s./ha at BBCH21-49 and 1 × 18 g a.s./ha at BBCH 43,49) are considered as less critical. To enable a possible differentiation in mitigation measures adapted to the use rate, TER calculations for the less critical application pattern will also be provided in domains where exposure mitigation via use restriction may be needed to pass risk assessment for the critical GAP (envelope ¹ O Ş rate).

Definition of the residue for risk assessment

Due to changes in the requirements under EF Regulation 1497/2009, additional degradation products were proposed to be included in the esidue definition. All studies necessary to describe the ecotoxicological, profile of these metabolites in the relevant environmental compartments are summarized in document MCA. The osidue definition is presented in Table CP 10-2.



| Compartment | Residue Definition | Major Metabolite in |
|---------------|---|------------------------------|
| | Amidosulfuron | (parent substance) |
| | ADesmethyl (AE F101630) | Aerobic soil, anaerobic soil |
| Soil | ADesmethyl-chloropyrimidine (BCS-CO41838) | Aerobic soil |
| | AGuanidine (BCS-CO41839) | Aerobic soil |
| | ABiuret (BCS-CQ51287) | Agerobic soil & |
| | AADMP (AE F092944) | Aerobic soil |
| | Amidosulfuron 🔬 ° 🆧 | * parent substance) |
| | ADesmethyl (AE F101630) | Aerobic soil, anaerobic soil |
| | ADesmethyl-chloropyrimidine (BCS-CO41830) | Aerobic soil |
| Groundwater | AGuanidine (BCS-CO4189) | Aerobic soil |
| | ABiuret (BCS-CQ51287) | Aerobic soil |
| | AADMP (AE F02944) | Aerobic soft |
| | AADHP (AE F0942060 2000 2000 2000 2000 2000 2000 2000 | Lysimeter Cachate |
| | Amidos Quron O | (parent abstance) |
| | A -Desmethy (AE F401630) | Aerobic water/sediment, |
| | | Aerobic soil, anaerobic soil |
| | ADesmethyl-chloopyrinidine (BCS-CO42838) | Aerobic soil |
| Surface Water | A - Grenidine BCS-CQ41839) | Aerobic soil, |
| Surface water | | Aerobic water/sediment |
| | A -Binnet (BCS=005128) | Aerobic water/sediment, |
| | | Aerobic soil |
| | α ADMP (AF F002944) | Aerobic water/sediment, |
| | | Aerobic soil |
| | A Guanidinocarbonyl)sulfamic acid (BCS-BI49539) | Aerobic water/sediment |
| Air | Amidostalfuron O | (parent substance) |

| Table CP 10- 2: De | finition of the r | esidue relevant | for risk | assessment* |
|--------------------|-------------------|-----------------|----------|-------------|
|--------------------|-------------------|-----------------|----------|-------------|

*Justification for the residue definition for risk assessment see provided in MCA Sec.7, Point CA 7.4.

Q Q, A list of metabolites, which contains the structures, the synonyms and code numbers attributed, is presented in Document N3 of this dossier.

> K. \bigcirc

Effects on birds and other terrestrial vertebrates **CP 10.1**

The risk assessment has been performed according to "European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA" (EFSA Journal 2009; 7(12) (1438), referred to in the following as "EFSA GD 2009".

O Effects on birds **CP 10.1.1**

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Ecotoxicological entropoints used in risk assessment

One acute toxicity test on birds has been conducted with the product. The results from this test, and from tests with the technical active substance amidosulfuron as reported in document MCA, will be used for risk assessment.

All studies were previously EU reviewed for the first Annex I inclusion of Amidosulfuron. No new data has been generated and is submitted in the context of application for approval renewal.

An overview of the information relevant to this chapter is provided in the following tables.

Table CP 10.1.1-1: Endpoints of the formulation Amidosulfuron WG75 used in risk assessment

| Test substance | Test organism | Study type | Eı | ndpoint | Ű | Reference |
|------------------------|------------------|----------------|------------------|---------|----------|---|
| | Acute toxicity t | o bird | | | | |
| Amidosulfuron WG 75 | Japanese quail | acute, oral | LD ₅₀ | 2000 mg | Frod./kg | ; 1989; M-133059- 01 5 2 2 8.1 2 7/01 |
| prod = product by | y = body weight | | () | | " (| $\tilde{\mathcal{A}}$ \mathcal{O} \circ |

product; bw = body weight

The study confirmed a low acute oral toxicity of the formulated product, consistent with the data generated on the active substance and used in the detailed numeric risk assessments presented in the following.

| Table CP 10.1.1- 2: | Endpoints for the | activesub | <u>stance a</u> | midasulfu | <u>con</u> use | d in risk | assessment |
|---------------------|-------------------|-----------|-----------------|-----------|----------------|-----------|------------|
| | | | | | | | |



Bold values used for the risk assessment ~

a.s. = a tive substance; by = body weigh ppm = parts per million; d = day 1

Risk assessment for birds

The intended use of the formulation is based on the proposed use pattern (see Table CP 10-1). In the risk envelope, the product will be applied in a single application on spring cereals (covering the uses in winter cereals). The use on flax will be addressed by a risk assessment for surrogate crop oilseed rape.

| Crop scenario | Scenario | Generic focal species | Representative species | Short cut values based on | | |
|-----------------------------------|---|---|--|------------------------------|-------------------------|--|
| | | | (Ú | RUD90 | RUD _m | |
| | Early (shoots) BBCH 10-29 | Large herbivorous bird "goose" | Pink-foot goose (Auser brachyrlygachus) @ | 30.5 | 16.2 | |
| Cereals, 1 x 0.030 kg/ha, | BBCH 10-29 | Small omnivorous bird "lark" | Woodfark (Lullula arborea) | 24.0 | 140.9 | |
| BBCH 12-49 | BBCH 30 -39 | Small omnivorous bir "lark" | Woodlarty (Gillula arborea) | | 5.4 | |
| | $BBCH \geq 40$ | Small omnivorou orird | Woodlark (Lullulor arbored) | 754 | <u>√3</u> .3 | |
| | Late-late (with seeds) BBCH 30-99 | Small insectivorous bird "dunnyck" 📎 | Duppock (Pranella Amodulaxis) | 0 _{7.4} | 2.7 | |
| | early (shoots) BBCH 10-19 | Large herbworous bird | Greylag goose (Ancer anserio | 39.9 | 15.9 | |
| | BBCH 10-29 | Small omniverous bird "lark" | Woodlark (Lyllula arborea) | 024.0 | 10.9 | |
| | BBCH 30-39 | Small on vivorous bird | Woodlark (Lulkov arborev) | 7.2 | 3.3 | |
| Oilseed rape | BBCH≥40 | Small omnizorous bio | ~ Woodlaik Dullula arborea) | 6.0 | 2.7 | |
| (= surrogate crop for flax), | BBCH 10-19 | herbiv@ous/gravivorous bird "pigeon" | ♥ Wood pigeon <i>(©)lumba</i> <i>Salumbus)</i> | 55.6 | 22.7 | |
| before flower buds are visible | BBCH 20-2 | Berbivor us/grani@rous bird "pigeor" | Wood pigeon (Columba palumbus) | 4.0 | 3.5 | |
| | OBBCH30-39 | hetBivorous granivorous bird pigeon' | Wood pigeon (Columba palumbus) | 2.4 | 1.1 | |
| | 7 ₩BBCH ¥40 ~~ | ک medium herbivorous/gravivorous می bird "pigeon" | Wood pigeon (Columba palumbus) | 2.0 | 0.9 | |
| \$ | BBCH 10-19 | Staall insectivorous bird | Yellow wagtail (Motacilla flava) | 10.9 | 5.9 | |
| | ФВСН 20-29 | Small insectivorous bird | Yellow wagtail (Motacilla flava) | 7.7 | 2.8 | |
| | New sopyn grass seeds | Shall granivorous bird "Sparrow" | House sparrow (Passer domesticus) | 20.4 | 9.4 | |
| Grassland | Late season (seed <u>A</u> heads) <u>A</u> | Small granivorous bird "finch" | Linnet (<i>Carduelis cannabina</i>) | 24.7 | 11.4 | |
| spring/autumn | Growing shoots | Large herbivorous bird "goose" | Pink-foot goose (Anser brachyrhynchus) | 30.5 | 16.2 | |
| | Growing shoots | Small insectivorous bird "wagtail" | Yellow wagtail (<i>Motacilla flava</i>) | 26.8 | 11.3 | |

 Table CP 10.1.1-3:
 Relevant generic avian focal species for risk assessment

Bold: Species considered in risk assessment (only worst case for each species)

ACUTE DIETARY RISK ASSESSMENT

Table CP 10.1.1- 4: Tier 1 acute risk assessment for birds

| | | | DDD | - | | LD50 | | |
|--|---|--|---------------|----------|--------------------|----------------------|---------------------|-------------|
| Crop scenario | Generic focal species | Appl. rate [kg a.s./ha] | SV90 | MAF90 | DDD | [mg a.s/kg Øw] | TERA | Trigger |
| Amidosulfuron | | | | | ٩, | \sim | ° | |
| Cereals early shoots BBCH 10-29 | Large herbivorous bird "goose" | 0.030 | 30.5 | ° 1°0 | 0.67 | ₹ 2000 | >2186 | |
| Cereals BBCH 10-29 | Small omnivorous bird "lark" | | 24.0 | | 0.7 | | > 2778 | 10 |
| Oilseed rape [#] Late-late (with seeds) BBCH 30-99 | Small insectivorous bird "dunnock" | \$ (| | | 69.2 Ø | | 5 ⁹⁰⁰⁹ 4 | \$° ≫ 10 |
| Oilseed rape [#] early (shoots) BBCH 10-19 | Large herbivorous bird "goose" | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | 3900 | | ~15 ² / | 2000 - | ₹¥709 | 10 |
| Oilseed rape [#] BBCH 10-29 | Small omnivorous bird "lark" | | 24.0 | | , 0.7 | | > 2778 | 10 |
| Oilseed rape [#] BBCH 10-19 | medium herbivorous/granivoros bird "pigeon" | | 55.6 | | | | > 1199 | 10 |
| Oilseed rape [#] BBCH 10-19 | Small insectivorous bird "wagtail" | | , 10.9° | | 02 | | > 6116 | 10 |
| Grassland New sown grass seeds | Small granivorous bird | | ×20.4 | | \$0.9 | | > 2179 | 10 |
| Grassland Late season (seed heads) | Small ganivorog bird | 0.045 | 2007 | A.0 | 1.1 | > 2000 | > 1799 | 10 |
| Grassland Growing shoots | Large herbivorous bird "égose" | | 30.5 | X | 1.4 | | > 1457 | 10 |
| Grassland Growing shoots | Small insectivorsus bird | | 2 6 /8 | | 1.2 | | > 1658 | 10 |
| # surrogate crop f | or intended use on flax | | s, | | | | | |

The TER_A values calculated in the acute risk assessment on Tier 1 level exceed the *a-priori*acceptability trigger of 00 for all evaluated scenarios. Thus, the acute risk to birds can be considered as low and acceptable without need for wrther, more realistic risk assessment.

Acute risk assessment for birds drinking contaminated water from pools in leaf whorls

In the PSA (P) 200% section 5.5, step 1 the following guidance is given on the selection of relevant scenarios for assessing the risk of pesticides via drinking water to birds and mammals:

<u>Leaf scenario</u>: Birds taking water that is collected in leaf whorls after application of a pesticide to a crop and subsequent rainfall or irrigation.

<u>Puddle scenario</u> Birds and mammals taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil.

For the crops under assessment in this evaluation (cereals, oilseed rape (as surrogate for flax) and grassland) the leaf scenario is not considered relevant. The risk for birds from drinking water in puddles is addressed in Table CP 10.1.1-6.

LONG-TERM REPRODUCTIVE RISK ASSESSMENT

Table CP 10.1.1- 5: Tier 1 reproductive risk assessment for birds

| | Conorio focal | 1 | DDD | | | | NOEL | | |
|--|---|---|-------------|-------|------|------|-----------------------|--------------|-------------|
| Сгор | species | Appl. rate [kg a.s./ha] | SVm | MAFm | fтwa | DDD | [mg a.s./ kg þw/d] | TERLT | Trigger |
| Amidosulfuron | | | | • | • | • | , O | | |
| Cereals early shoots BBCH 10-29 | Large herbivorous bird "goose" | 0.030 | 16.2 | 1.0 | 0.53 | 0.3 | | 388 | 5Ô2 |
| Cereals BBCH 10-29 | Small omnivorous bird "lark" | 0.050 | 10.9 | | 0.55 | 0.2 | | 577× | الم م |
| Oilseed rape [#] Late-late (with seeds) BBCH 30-99 | Small insectivorous bird "dunnock" | Ļ | 2.J O | | | 6904 | | 52329 | ° S S |
| Oilseed rape [#] BBCH 10-19 | Large herbivorous bird "goose" | | 150 | | | 0.5 | | \$9 6 | 5 |
| Oilseed rape [#] BBCH 10-29 | Small omnivorous bird "lark" | \$0.030 \$10000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$100 | 0 10.9 | | 0.53 | 0.2 | | 577 | 5 |
| Oilseed rape [#] BBCH 10-19 | medium herbivorous/granivoros bird "pigeon" | | 22.7 | | | 0.4 | | 277 | 5 |
| Oilseed rape [#] BBCH 10-19 | Small insectivorous bird "wagtail" | | 5 D S | | | 0.1 | 2 | 1066 | 5 |
| Grassland New sown grass seeds | Small granis orous bited "Sparrow" | | 9.4 | | | 0.2 | | 446 | 5 |
| Grassland Late season (seed heads) | Small granivorous bird "finch?" | \$ 045 × | 0.4 | | 0.53 | 0.3 | 100 | 368 | 5 |
| Grassland Growing shoots | Carge freebivorous bird | | 1 62 | J.1.0 | 0.00 | 0.4 | 100 | 259 | 5 |
| Grassland Growing shoots | Small insectivorous bird | | 11.3 | | | 0.3 | | 371 | 5 |
| # surrogate crop@ | for intended use of flax 🖉 | | | | | | | | |

The TER_{LT} values calculated in the reproductive risk assessment on Tier 1 level exceed the *a-priori*-acceptability trigger of 5 for all evaluated scenarios. Thus, the risk to birds can be considered as low and acceptable without need for further more realistic risk assessment.

Long-term risk assessment for birds drinking contaminated water in puddles

Table CP 10.1.1-6: Evaluation of potential concern for exposure of birds drinking water (escape clause)

| Сгор | K _{oc} [L/kg] | Application rate * MAF [g as/ha] | NO(A)EL [mg as/ kg bw/d] | Ratio (Application rate * MAF) / NO(A)EL | "Escape clause" No concern Wratio | Conclusion |
|---------------------------|---------------------------|--|--------------------------------|--|--|------------|
| Amidosulfuron | | | | | | L |
| Cereals | 36.4 | 30 * 1.0 | 100 | 0.3 | ວ້ ≤ 500 | No concept |
| Oilseed rape [#] | 36.4 | 30 * 1.0 | 100 | 0.3 | ∕> ≲50 .∢ | No concern |
| Grassland | 36.4 | 45 * 1.0 | 100 | 0.45 | ≥≲≲50 √ | No concern |
| # anoma anto anom fau | interded use | an flan | | | | SK n |

surrogate crop for intended use on flax

RISK ASSESSMENT OF SECONDARY POISONING

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for birds feeding on contaminated prey like fish or carthworms. For organic chemicals, a log $P_{OW} > 3$ is used to trigger an in-depth evaluation of the potential for bioaccumulation.

As the log P_{OW} of the active substance amidosulfuron and its metabolites is below the trigger (< 3), no evaluation of secondary poisoning is needed see Sec.2, CA2.7).

CP 10.1.1.1 Acute oral toxicity

| | , Q | õ | | ~y" | |
|-------------------------|----------------|---------------------|--------------------|-------------------------------|-------|
| Report: | KCP 10.1.1.1/0 | L Î | ; 1989, M | -1233059-01-1 | |
| Title: | Hoe 🗱 5032 - 👸 | ater dispersible gr | anules (65 %) (6 | Que: Hoe 075032 OH WG75 | |
| | A105 Testing f | or acute oral toxic | ity in the male a | nd female japanese quail (Cot | urnix |
| | commix jzQnic | a) | | | |
| Report No.: | 340434 | Y O | ô 4 | | |
| Document No.: | ©M-123039-01-∦ | |)° _n Qʻ | | |
| Guideline(s): | Ĵ USEP& (=E₽Ø | 1: § 71 🖓 🖓 | | | |
| Guideline deviation(s): | | | S. | | |
| GLP/GEP: | Xes Do | N Ó | ~ | | |

[Study submitted and evaluated for the first inclusion of amidosulfuron on Annex I]

O The study reports on on acute oral togetcity test for Japanese quail on the formulated product. No mortalities occurred so intexication symptoms were observed and no macroscopically visible findings were seen at necropy. Acording 0 the 14 d LD₅₀ was reported to be >2000 mg product/kg bw.

The study was rated wild in the EU view for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

An EU agreed endpoint for acute oral toxicity of formulation "Gratil" of $LD_{50} > 2000$ mg product/kg bw was derived from this test.

Higher tier data on birds **CP 10.1.1.2**

No higher tier data on birds was generated, since risk assessments can be completed based on standard test results.

CP 10.1.2 Effects on terrestrial vertebrates other than birds

Ecotoxicological endpoints used in risk assessment

One acute toxicity test on rats has been conducted with the product. The results from this test, and from tests with the technical active substance amidosulfuron as reported in document MCA, will be used for risk assessment.

All studies were previously EU reviewed for the first Annex I inclusion of amidosulfuron. No new data has been generated and is submitted in the context of application for approver renewal.

An overview of the information relevant to this chapter is provided in the following tables.

| Table CP 10.1.2-1: | Endpoints of the formulation | Amidosulfuron | WG75 used in | n risk assessment |
|--------------------|--|---------------|--------------|-------------------|
| | ······································ | | | |

| Test substance | Test organism | Study type | End End | point A | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | Reference |
|------------------------|--|----------------|--|-------------------------|--|----------------------------------|
| | Acute toxici | ty to mammals | w Q | | | |
| Amidosulfuron WG 75 | Rat | acute, oral | SLD ₅₀ Q >50 | 06 mg prod.∕ ¢g bw ≪ | ; 1989 KCP 70 | ; %1-123295-01-1 .1/01 |
| prod. = product; bw | v = body weighted by weighted by weighted by weighted by the second se | nt A | - ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | | y Z | |

The study confirmed a low acute and used in the detailed numeric risk assessments presented in the following.

| | F I · · · · · · · · · · | | | | ~~~··· | |
|--------------------|--------------------------------|------------------------|----------------|-----------|------------|--------------|
| Table CP 10.1.2-2: | Endpoints of th | ie se tive subs | stance amidosi | iltüron u | sed in ris | k assessment |
| | | | | | | |

| Test substance | Test organism | Study type | | Endpoint | Reference |
|-------------------|------------------|---|--|--|---|
| | Acute toxicity | to manimals | Ş <u>î</u> ş _û | Ô. | |
| A mido- | Monse (| acuter acuter | | 5000 mg a.s./kg bw | 1988; M-120196- 01-1 KCA 5.2.1/02 |
| sulfuron | Long-term to | xicity to maynm | als $O^{'}$ | | |
| | Rat 2 | 2-geteration Greatery reproduction study | NOAEL _{parental} NOAEL _{repro} NOEL _{pup} | 10 000 ppm 570 mg a.s./kg bw/d 10 000 ppm 570 mg a.s./kg bw/d 2000 ppm 153* mg a.s./kg bw/d | K.; 1992; M-135662-01-1 KCA 5.6.1 /02 |

a.s. = active substance; bw = body weight

Bold values used for the rise assessment

* Group mean intake of amidosulfuron (mg/kg bw/day) of F_0 -females during gestation period at the dose level of 2000 ppm (Table B.6.6 T4 in the Annex B.6 of the DAR)

Risk assessment for other terrestrial vertebrates

Table CP 10.1.2- 3: Relevant generic focal species for Tier 1 risk assessment

| | | | | Shorte | ut value |
|-------------------------------|-----------------------------|--|---|--|-------------------------------|
| Crop group* | Scenario | Generic focal species | Representative species | Long- term RA based on RUD _m | acute RA based on RUD90 |
| | BBCH 10-19 | Small insectivorous mammal "shrew" | Common shrew (Sorex arangus) | [©] 4.2 | 7.6 |
| | $BBCH \ge 20$ | Small insectivorous mammal "shrew" | Common Shrew | B. | × 5.4 |
| | $\rm BBCH {\geq} 40$ | Small herbivorous mammal "vole" | Common vole (Microtus arvelis) | [©] 21.7 [©] | 40.9 |
| Cereals, 1 x 0.030 | Early (shoots) | Large herbivorous mammato "lagomorph" | Rabbit (Oryctolagus) | 22.3 | 42.1 |
| kg/ha, BBCH 12- 49 | BBCH 10-29 | Small omnivorous mammal "mouse" 🔬 | Wood mouse Kapodemas Sylvaticus) | 7.8 | 17.2 |
| | BBCH 30-39 | Small omnivorous mammal "modse" | Wood mouse (Apodemus Svaticus), C | 3.9 | 8.6 |
| | BBCH \ge 40 | Small on Vorous mammal | Wood mouse (Apodemus sylverticus) | 2.3 | 5.2 |
| | BBCH 10-19 | Small?nsectivorous mammal | Common shrew (Sovex araneus) | 4.2 | 7.6 |
| Oilaad | BBCH ≥ 20 | Small insectivorous mammal | Common shrew | 1.9 | 5.4 |
| rape | BBCH≥40 | Smallherbivorous manimal | Common vole (Macrotus arvalis) | 18.1 | 34.1 |
| crop for flax). | All seaon | Large herbivorous mamma | Report (Oryctolagus | 14.3 | 35.1 |
| 1 x 0.030 kg/ha, before | BBCH 10-29 | Smallomniverous manimal | Wood mouse (Apodemus sylvaticus) | 7.8 | 17.2 |
| flower buds are visible | BBCM30-39 | Small omnivorous mammal | Wood mouse (Apodemus sylvaticus) | 2.3 | 5.2 |
| | BBCH \$40 | Šmall omenvorous mammal | Wood mouse (Apodemus sylvaticus) | 1.9 | 4.3 |
| A A | Alleseason | Large herbivorous mammal "lagomorph" | Brown Hare (Lepus europaeus) | 17.3 | 32.6 |
| Grassland, | Late | Small insertivorous mammal | Common shrew (Sorex araneus) | 1.9 | 5.4 |
| kg/ha, | Al Season O | Small herbivorous mammal | Common vole (Microtus arvalis) | 72.3 | 136.4 |
| autumn | Late season (seed heads) | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 6.6 | 14.4 |
| | New sown grass seeds | Small omnivorous mammal "mouse" | Wood mouse (Apodemus sylvaticus) | 6.6 | 14.4 |

Bold: Species considered in risk assessment (only worst case for each species)

ACUTE DIETARY RISK ASSESSMENT

Table CP 10.1.2-4: Tier 1 acute DDD and TER calculation for mammals

| | DDD | | | | LD50 | | | |
|--|---|------------------|--------------|---------|-----------------------|--|--------|--------------|
| Сгор | Generic focal species | Appl. rate | SV90 | MAF90 | DDD | [mg/kg ⊮bwl | TERA | Trigger |
| Amidosulfuro | n | [Kg/IIa] | | | | | | |
| 1 initial summer of | • | | | | <u>م</u> | $\langle \rangle \sim \circ$ | | |
| Cereals BBCH 10-19 | Small insectivorous mammal "shrew" | | 7.6 | | 02. 2. | Ŵ | 21930 | |
| $\begin{array}{c} Cereals\\ BBCH \geq 40 \end{array}$ | Small herbivorous mammal "vole" | 0.020 | 46.9 | | ♥ 1.2 _≈ | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | 4075 | 2 2 10 |
| Cereals Early (shoots) | Large herbivorous mammal "lagomorph" | 0.030 | 42.1 | | | | 3959 | 10 |
| Cereals BBCH 10-29 | Small omnivorous mammal "mouse" | | 17,2 | , (| 0.5 ° | | 9690 / | \$10 |
| Oilseed rape [#] BBCH 10-19 | Small insectivorous mammal "shrew" | | 7.6 | | 0.2 | | 21050 | 10 |
| $\begin{array}{l} \text{Oilseed rape}^{\#} \\ \text{BBCH} \geq 40 \end{array}$ | Small herbivorous mammal "vole" | | 34 | |) 1.0 | 5000 | 4888 | 10 |
| Oilseed rape [#] All season | Large herbivorous mammal ``lagomorph'' | | 3 5.1 | | Į. | , 30000 , O | 4748 | 10 |
| Oilseed rape [#] 10-29 | Small omnivorous mammal | 6 ⁶ 6 | 172 | | 0.5 | | 9690 | 10 |
| Grassland All season | Large herbivorous mammal | | 32.6 | | 1.5 | | 3408 | 10 |
| Grassland Late | Small insectivorous mamman "shrey" | | 5.4 | | 0.2 | | 20576 | 10 |
| Grassland All season | Small herbivorous mummal | 0.045 | 136.4 | 1.9 | 6.1 | 5000 | 815 | 10 |
| Grassland Late season (seed heads) | Small on nivorous mammal | | HAGA K | | 0.6 | | 7716 | 10 |
| [#] surrogate crop | for intended ase on flax | |)sh | | | | | |

The TER_A values calculated in the acute risk assessment on Tier 1 level exceed the *a-priori* acceptability trigger of 10 for all evaluated scenarios. Thus, the acute risk to mammals can be considered as low and acceptable without need for further, more realistic risk assessment.



LONG-TERM REPRODUCTIVE RISK ASSESSMENT

Table CP 10.1.2- 5: Tier 1 long-term DDD and TER calculation for mammals

| | | DDD | | | | NO(A)EL | | | |
|---|---|----------------------|------------|------|------------|------------------|------------------|-------------------|---------|
| Сгор | Generic focal species | Appl. rate [kg/ha | SVm | MAFm | ftwa | DDD | [mg kg/byy/d] | TER _{LT} | Trigger |
| Amidosulfuro | n | | | | | | Ç©` | | |
| Cereals BBCH 10-19 | Small insectivorous mammal "shrew" | | 4.2 | | | 0.1 | | °2295 | 500 S |
| Cereals $BBCH \ge 40$ | Small herbivorous mammal "vole" | 0.020 | 21.7 | 1.0 | ဂိ ၄၃ | | | A43 | 25 Z |
| Cereals Early (shoots) | Large herbivorous mammal "lagomorph" | 0.030 | 22.3 | | p0.53 | >0.4 | | 432~> | 5 |
| Cereals BBCH 10-29 | Small omnivorous mammal "mouse" | | 7.8 | | | 0 | | 234 | °5 Z |
| Oilseed rape [#] BBCH 10-19 | Small insectivorous mammal "shrew" | | 4.0 | | | Ø _{0.1} | | 229 | 5 |
| Oilseed rape [#] BBCH ≥ 40 | Small herbivorous mammal "vole" | 0.020@ | 18.1 | | | | 152 | 532 | 5 |
| Oilseed rape [#] All season | Large herbivorous mammal "lagomorph" | 0.030 | 14.3 | | 0.33 لا | 0.2 | | 673 | 5 |
| Oilseed rape [#] 10-29 | Small omnivorous mammal "mouse" | | 9 7.8 | Ş, | | | | 1234 | 5 |
| Grassland All season | Large herbivorous mammal "lagomorph" | | 173 | Ô | × 0. | \$ 0.4 | Č V | 371 | 5 |
| Grassland Late | Small insectivorous mammal "shrew" | | ر 1.9 م | ŝ | | 0.05 | ¢ | 3376 | 5 |
| Grassland All season | Small herbivorous mammal Sole" | 0.045 | 72.3 | 1.0¢ | 0.53 | 1.7 | 153 | 88.7 | 5 |
| Grassland Late season (seed heads) | Small opinivorous maminal "mouse" | | 6.6 | | | 0.2 | | 972 | 5 |
| # surrogate crop | for intended use on flax | | J. | - St | | | | | |

surrogate crop for incond d yay -

The TER_{LT} values calculated in the reproductive risk assessment on Tier 1 level exceed the *a-priori*acceptability forger of 5 for all evaluated scenarios. Thus, the risk to mammals can be considered as low and acceptable without weed for further, more realistic risk assessment. . K

Long-term risk assessment for planmak drinking contaminated water

O

O

The puddle scenario is relevant for the ong-term risk assessment.

0

Table CB 0.1.2- 6 Evaluation of potential concern for exposure of mammals drinking water

Ô

| Crop | Koc J [L/kg] | Application rate*MAF [g as/ha] | NO(A)EL [mg as/ kg bw/d] | Ratio (Application rate * MAF) / NO(A)EL | "Escape clause" No concern if ratio | Conclusion |
|---------------|-----------------|--------------------------------------|--------------------------------|--|--|------------|
| Amidosulfuron | 4 | 0 | | | | |
| Cereals | \$36.4 | 30 * 1.0 | 153 | 0.2 | ≤ 50 | No concern |
| Oilseed rape# | 36.4 | 30 * 1.0 | 153 | 0.2 | ≤ 50 | No concern |
| Grassland | 36.4 | 45 * 1.0 | 153 | 0.3 | ≤ 50 | No concern |

[#] surrogate crop for intended use on flax

RISK ASSESSMENT OF SECONDARY POISONING

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for mammals feeding on contaminated prey like fish or earthworms. For organic chemicals, a log $P_{OW} > 3$ is used to trigger an in-depth evaluation of the potential for bioaccumulation.

As the log P_{OW} of the active substance amidosulfuron and its metabolites is below the trigger (< 3), no evaluation of secondary poisoning is needed (see Sec.2, CA 2.7).

CP 10.1.2.1 Acute oral toxicity to mammals

One acute toxicity test for product Amidosulfuron WG75 or ats (**Mathematical**); **Mathematical**; 1989; M-123295-01-1); the study is found reported in the toxicology action of document MCP, study reference KCP 7.1.1/01. According to OECD guideline 401 the results of this study correspond to LD₅₀ >5000 mg/kg body weight.

CP 10.1.2.2 Higher tier data on mammars

No higher tier data on birds was generated, since risk assessments can be completed based on standard test results.

CP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

No additional studies are available or required under the data requirements of EC 1107/2009.

CP 10.2 Effects on aquatic organisms

The effect on aquatic organisms of the product Amidosulfuron WG75 has been characterised via a comprehensive set of studies, overview of which is shown in Table 10.2-1. All studies were previously EU reviewed for the first Annex L inclusion of amidosulfuron. No new data on the formulation has been generated and is submitted in the context of application for approval renewal.

Moreover, endpoints generated for the active substance and its individual metabolites will be used in risk assessments; an overview of this information is provided in Table 10.2-2, for study details reference is made to document MCA.

Metabolite

In the risk assessment for the aquatic compartment, the following metabolites of amidosulfuron have to be addressed.

Amidosulfuron-desmethyl^(AE) (AE⁽⁾ F101630), amidosulfuron-desmethyl-chloropyrimidine (BCS-CO41838), APMP (AE F092994), amidosulfuron-guanidine (BCS-CO41839), amidosulfuron-biuret BCS-CQ51287) and guanidinocarbonyl sulfamic acid (BCS-BI49539).

* Complete acute perimental data set is available for the metabolites amidosulfuron-desmethyl, ADMP.

* Amidosulfuron-biuret, amidosulfuron-guanidine and amidosulfuron-desmethyl-chloropyrimidine were only tested on aquatic macrophytes, the most sensitive organism to the parent compound.

* No tests are available for the metabolite guanidinocarbonyl sulfamic acid.

O

* Despite the presence of the structural group responsible for sulfonylureas herbicidal activity (Sinclair, 2009²), tests demonstrated a lack of herbicidal activity for both a-desmethyl (KCA 8.6.1 /02) and a-desmethyl-chloropyrimidine (KCA 8.6.1 /06). Moreover, the same results were obtained for the metabolites characterised by a cleaved sulfonylurea moiety, i.e. ADMP (KCA 8.6.1 /08), ADHP (KCA 8.6.1 /03), or a disintegrated pyrimidine ring, i.e. a-guanidine (KCA 8.6.1 /06) and a-biuret (KCA 8.6.1 /07). Therefore all tested metabolites lost the toxophore responsible for the biological target activity (i.e. herbicidal activity). According to the risk assessment scheme for metabolites (pp 143-144) of the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA, 2013³⁾, risk assessment for metabolites without toxophore can be based on active substance data.

No tests were performed to characterize neither the toxicity of guanidinocarbonyl suttamic acid nor its herbicidal activity. It is a tertiary metabolite resulting from the degradation of amidosulfuronguanidine and/or amidosulfuron-biuret which do not show any herbicidal activity. Consequently, it is assumed that the toxophore is no longer present in this metabolite and the osk assessment can be addressed using information from the parent substance.

* The trigger for chronic risk assessment (DT90 21d) is Det for all metabolites. According to the AGD stepwise approach, the parent chronic endpoints can be used in the metabolite risk assessment as surrogate values for all tier 1 taxonomic groups. As a further refinement step fron-testing methods, e.g. QSAR calculations, are possible before experimental chronic testing for metabolites is required. Thus the chronic risk assessment for all these thetabolites is based on parent endpoints



²CJ Sinclair PhD Thesis Oniversity of York Predicting the environmental fate and ecotoxicological and toxicological effects of pesticide transformation products

https://www.researckgate.net/publication/235934684 Predicting the environmental fate and ecotoxi cological and toxicological effects of pesticide transformation products

³ EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 268 pp. doi:10.2903/j.efsa.2013.3290

Ecotoxicological endpoints used in risk assessment

| Table CP 10.2-1: | Endpoints of the formulation | Amidosulfuron WO | G75 used in risk assessment |
|------------------|------------------------------|------------------|-----------------------------|
|------------------|------------------------------|------------------|-----------------------------|

| Test substance | Test organism | Study type | Endpoint | References | | | | | | |
|----------------|---|--|--|---|--|--|--|--|--|--|
| | Fish, acute | | | | | | | | | |
| | <i>Cyprinus carpio</i> (Mirror carp) | acute static 96 h | LC ₅₀ 449 mg prod L _(nom) | ;; 1989; M- °125130-01-1 KCIO 0.2.1/92 | | | | | | |
| | Oncorhynchus mykiss [former Salmo gairdneri] (rainbow trout) | acute static 96 h | 1500ng prod LC ₅₀ ° 4113.9 mg a.s./EApom | (1989; M5) (1989; M5) (125129€01-1 (KC) (0.2.1/02) | | | | | | |
| | Fish, long-term | | | Š. | | | | | | |
| | Oncorhynchus mykiss [former Salmo gairdneri] (rainbow trout) | flow-through, juvenile growth 21 d | NOEC 10 mg prod/L growth = 59 mg a s./L ^A non | 1989; M. 12540-01-1 KC@10.2.2/01 | | | | | | |
| | Aquatic invertebrates, acute | | | | | | | | | |
| Amidosulfuron | Daphnia magna (water flea) | acute static 48 h | $ \begin{array}{c} & 187 \text{ mg prod./L} \\ EC_{5} & \swarrow & = 14129 \text{ mg} \\ & & & & \\ & & & & \\ & & & & & \\ & & & & & \\ & & & & & \\ & & & & & \\ & & & & & \\ & & & & \\ & & & & & & \\ & & & & & \\ & & & & & \\ & & & & & \\ & & & & & & \\ & & & & & & \\ & & & & & & \\ & & & & & \\ & & & & & & \\ & & & & & \\ & & & & & \\ & & & & &$ | © 1989; M- 125182-01-1 KCP 10.2.1/03 | | | | | | |
| WG 75 | Aquatic invertebrates, teng-tentor S S S | | | | | | | | | |
| | Daphnia magna (water flea) | reproduction | NOEC 24/3 mg a.s./L | □; 1989; M- 125137-01-1 KCP 10.2.2/02 | | | | | | |
| | Daphnia magna (water fleat | reproduction, 21 | Calculated mixture A 1.3 mg prod./L | acc. EFSA Journal 11(7):3290 (2013) | | | | | | |
| | Algae | | 0. <u>~</u> | | | | | | | |
| 2 | Scenedesmus A subspication rgreen alga) | growth inhtbition, 72 h | $E_{b} \sum_{k=0}^{\infty} \frac{33.8 \text{ mg prod./L}}{= 25.8 \text{ mg a.s./L}^{A}}$ $\frac{2}{2} \sum_{k=0}^{\infty} E_{r} C_{50} = 93 \text{ mg a.s./L}^{A}_{(nom)}$ | ,; 1991; M- 129467-01-1 KCP 10.2.2/04 | | | | | | |
| | Aquatic macrophytes | <u>}</u> ~ | | | | | | | | |
| 5 | Semna gibba | growth inflybition, | $E_bC_{50} = \begin{array}{c} 0.0101 \text{ mg prod./L} \\ = 0.00773 \text{ mg a.s./L}^A \\ 0.010 \text{ mg prod./L} \end{array}$ | ,; 2003; M- | | | | | | |
| | | static, 7 d | $E_r C_{50}$ = 0.00765 mg a.s./L ^A | KCP 10.2.1/05 | | | | | | |

(nom) nominal concentration, prod = product; a.s. active substance

^A EFSA Scientific Report (2007) 116 7-86, Conclusion on the peer review of amidosulfuron

Mixture toxicity risk assessment according to the Aquatic Guidance document

The available data on the formulated product show that no synergy or antagonism (MDR between 0.2 and 5) is observed, except for the chronic study on *Daphnia magna*. The MDR for this study is 0.04 considering the amount of active substance in the formulation (Table JCP 1.4.1-1). The reason for this discrepancy is unknown; consequently the mixture toxicity long term risk assessment for invertebrates will also be conducted with the calculated mixture endpoint of 1.3 mg prod/L (i.e. based on the endpoint of the active substance and its amount in the formulation).

| Test substance | Test organism | Test system | - | Endpoint | References |
|----------------|---|---------------------------------------|--------------------------------|-------------------------------------|--|
| | Fish, acute | bystein | | | À- |
| Amidosulfuron | Fish, acuteOncorhynchus mykiss (rainbow trout)Lepomis macrochirus (bluegill sunfish)Cyprinodon variegates (sheepshead minnow) | Acute, static, 96 h | LC ₅₀ | > 100 mg a.s./L _(nom) | 1987; M- 117660-01-1 KC 2.1/0 ; 1987; M- 199377-01-1 KCA 0.1/02 ; 1988; M- 120514-012 ; 1988; M- 120514-012 ; 1988; M- 120514-012 ; 1989; M- 123929-01-1 KCA 2.1/0 |
| | Fish chronic | × 1 | | × × | N. 94 0.2.1094 |
| | Oncorhynchus mykiss (rainbow trout) | early by | NOJEC | 9.72 mg 2 a.s.#Lmm) | ; 2015; M-538454- 01 & KQA 8 2 2 /01 |
| | Aquatic invertebrates | acute S | `¥ | | 7 |
| | Daphnia magna () (water flea) | Acute static, × 48th | EC 50 | 36 mg & O a.s./LQnom) | ; 1987; M- 119379-01-1 KCA 8.2.4 /02 |
| | Aquatic invertebrates | ¢chronic⊖ [≫] | L) | . 👻 🖒 | |
| | Daphnia magna (water flead | chronic, semi static, 24-a | ŇŊØEC | (1.0 mg) a.s. (nom) | ; 1991; M- 130193-01-1 KCA 8.2.5.1 /01 |
| | | | L D | ŵ. | 1000 14 |
| ~ | Scenedesmus sucopicatur (green algo) | Growth inhibition, 486 | | \bigcirc 45 mg $a.s./L_{(nom)}^5$ | ; 1988; M- 120327-01-1 KCA 8.2.6.1 /01 |
| L. | | | | | ; 2016; M- 549424-01-1 KCA 8.2.6.1/08 |
| , Ô | Aqua 🕼 plant 🗸 | | | | |
| | Lemma gibla (točk weed) | Growth inhibition, semi-static, | E _r C ₅₀ | 0.0092 mg a.s./L | ; 2002; M- 208657-01-1 KCA 8.2.7 /02 |

 Table CP 10.2-2:
 Endpoints for the active substance amidosulfuron and metabolites used in risk assessment

⁴ An acute study on *Mysidopais bahia* is also available, the EC₅₀ is 75 mg a.s./L. The lowest endpoint for aquatic invertebrates acute studies was selected for risk assessment (EC₅₀ of 36 mg a.s./L on *Daphnia magna*). There is no need to perform a specific risk assessment with *Mysidopsis bahia* endpoint, because PECs are calculated for freshwater bodies only

⁵ The endpoint for the second algae species (*Navicula pelliculosa*) is an unbound value : $E_rC_{50} > 84.2 \text{ mg a.s./L}$. It has not been selected for risk assessment because 84.2 mg/L is the NOEC. According to the Aquatic Guidance document, EC_{50} have to be used for the risk assessment on algae. The most sensitive species of the two algae species is clearly the green alga as effects were observed at 10 mg/L and above while no effects were observed up to 84.2 mg/L for the diatom.

| Test substance | Test organism | Test | | Endpoint | References |
|----------------|-----------------------|----------------|------------------|----------------|--------------------------------|
| | | system | | | |
| Amidosulfuron- | Fish, acute | Ι. | | | |
| desmethyl | Oncorhynchus mykiss | Acute, | LC ₅₀ | >100 mg p.m./L | ; 1993; M- |
| | (rainbow trout) | static, | | | 131849-01-1 VCA 9.2.1 /05 |
| | Fish abronia | 96 h | | | Ka A 8.2.1 /05 |
| | FISH, CHFOHIC | oorly life | NOEC | 0.72 mg a g /I | |
| | (rainbow trout) | stage test | NOLC | 9.72 mg a.s./L | 20015: M 538454 (a) |
| | Parent endpoint | stuge test | | R R | 10% |
| | | | | | KCA 8.2.2.2.01 |
| | Aquatic invertebrates | , acute | | <u>or v v</u> | |
| | Daphnia magna | Acute, | EC50 🔬 | > 55 n@p.m./Ľ | ; 1993; M- |
| | (water flea) | static, | َنْ سُ | | 131833-012 |
| | | 48 h | | ví ví | DEA 8.2 0/04 |
| | Aquatic invertebrates | , chronic | | | |
| | Daphnia magna | chronic, | ~QOEC ~~ | 1.0 mg/a.s./L | ; 1991; M- |
| | (water flea) | semi static, « | | A A | 130093-01-10 |
| | Parent endpoint | 21 d | | | K X A 8.2 0.9 /01 |
| | Algae | Grout | | 01000 mg | () 1002. M |
| | subspicatus | inhibition | $L_{r}C_{50}$ | n m/k | , 1995; IVI- |
| | (green alga) | 7.7 K | °۳, | p.m. | 130028-01-1 KOA 8 2 6 1 /02 |
| | Aquatic plant | | | | NG/A 0.2.0.1702 |
| | Lemna gibha | Growt | E Son | 6 92 me m /L & | · 2003· M- |
| | (duck weed) | inhibition. | | | 213899-01-1 |
| | | semi-static, | y O | \sim \sim | KCA 8.2.7 /03 |
| | × . | Pa A | Q A | <i>♀</i> ∧ | |
| | | | | | |
| | Ö | | | | |

 $^{^{6}}$ EC $_{50}$ based on geomean measured concentration as some measurements were below 80% of nominal concentrations (see KCA 8.2.4.1/03 for further details).

| Test substance | Test organism | Test | | Endpoint | References |
|----------------|--|----------------------|---|-------------------------------------|------------------|
| | | system | | | |
| Amidaaulfurar | Fish, acute | • | | | |
| desmethyl- | Oncorhynchus mykiss | Acute, | LC ₅₀ | >100 mg a.s./L | ; 1987; M- |
| chloro- | (rainbow trout) | static, 96 h | | | 117660-01-1 |
| nvrimidine | Lepomis macrochirus | | | | KCA 8.2.1 /01 |
| pyrimaine | (bluegill sunfish) | | | | , (; 1987; M- |
| | Cyprinodon | | | | 119327-01-1 |
| | variegates | | | D' | KC @ 8.2.1 / @ 0 |
| | (sneepsnead minnow) Baront and noint | | | OY . | ; 1988; M |
| | r arent enupoint | | | | |
| | | | (| | • 1080 · M |
| | | | ×. | | 123029-01-1 |
| | | | | | K A 8 2 0 04 |
| | Fish chronic | | ×, | | |
| | Oncorhynchus mykiss | early life | NOFC. | $\bigcirc 72 \mod s/L e^{\bigcirc}$ | |
| | (rainbow trout | stage test | | 5).72 mg u.s.71 | · 0015· M&38454- |
| | Parent endpoint | suge test . | | L L | 0 |
| | | | Ň | 0, 0 | KCA 822/01 |
| | Aquatic invertebrates | , acute | | | y Of |
| | Daphnia magna | Acute, | EC ₅₀ | 36 mg a.s./L | : 1987: M- |
| | (water flea) | static, C | | | 109379-01-1 |
| | Parent endpoint | Q8 h _C → | ~~ | × .~ | CA 8.2.4 /02 |
| | Aquatic invertebrates | , chronic | | | |
| | Daphnia magna | chronic, 🦻 | NOEC | 1.0 m@a.s./L 🍾 | ; 1991; M- |
| | (water flea) | semi static, | i i i i i i i i i i i i i i i i i i i | | 130193-01-1 |
| | Parent endpoint [®] | ard 🔗 | 2 | × 65 | KCA 8.2.5.1 /01 |
| | Algae 🔬 🔿 | | × . | <u>\$,\$'</u> | |
| | Scenedesmus | Growth | E_rC_{50} | 145 mg a.s./L | ; 1988; M- |
| | subspicants | inhibition, | , O | \sim | 120327-01-1 |
| | (green alga) | 48h | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | | KCA 8.2.6.1 /01 |
| | Parent endpoint | | | 6× | ; 2016; M- |
| | Or Q' A | Į Į , | | | 549424-01-1 |
| | Aquationlant | L & Ô | r 💎 | | KCA 8.2.0.1/08 |
| \$¢ | Lamna nibbal. | Grouth | E | > 100 mg n m /I | · 2010· M |
| l III | (dura weed) | inhibition | 14080 · | 100 mg p.m./L | 365833-01-1 |
| ~ <i>V</i> | | statio 7 d / | | | KCA 8 2 7 /06 |
| | | <u>status, r u x</u> | ý | | 11011 0.2.7700 |
| r Di | | Ő, | | | |
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| Test substance | Test organism | Test | | Endpoint | References |
|----------------|--|--------------------------------------|--------------------|------------------|--|
| | Fish acuta | system | | | |
| Amidosulfuron- | rish, acute | | | | · 1087· M |
| guanidine | <i>Oncorhynchus mykiss</i> (rainbow trout) | Acute, static, 96 h | LC ₅₀ | > 100 mg a.s./L | 117660-01-1 K&A 8.2.1 /01 |
| | Lepomis macrochirus (bluegill sunfish) | | | | Ø [°] ∕ 119277-01-1 0 [°] ∕o |
| | Cyprinodon variegates | | | | |
| | (sneepsnead minnow) Parent endpoint | | * | | ; 1988; M- 120544-01-1 × KC@8.2.1 59 |
| | | | × | | 1989 M- |
| | | d | | | K 8.2.1 / F |
| | Fish, chronic | <u> </u> | `\`` | | <u> </u> |
| | Oncorhynchus mykiss (rainbow trout) | early offerst | ŃŒĊ | 9.72 mg a.s./L C | ; 20 [°] 15; M-538454- 01 <i>@</i> |
| | Farent enupoint | Å. | 4 | | KQA 8.2.2 /01 |
| | Aquatic invertebrates | acute | Ç. | | 2 . 1087. M |
| | Daphnia magna 🖕 | Acute, | EC ₅₀ (| ^ 36 m@.s./L ~>> | 119379-01-1 |
| | (water flea) | static, | , D | | KCA 8.2.4 /02 |
| | Parent endpoint " | o ^{sta} o | | | |
| | Aquatic invertebrates | , chronic | * | | |
| | Daphnia magna | chronic, | NOE | 1.0 mg a.s./L | ; 1991; M- 130193-01-1 |
| | Parent endpoint | 21 d | | | KCA 8.2.5.1 /01 |
| | Algae | | ý á | × | |
| * \$0 | Scenedesmus subspicatus (green . | Growth ^(V) Dinhibition | ErCo | 145 mg a.s./L | ; 1988; M- 120327-01-1 |
| \$\\\ | alga O O | 48h | жу" л | | KCA 8.2.6.1/01 |
| , Č | | | 2 | | ; 2016; M- 549424-01-1 |
| | | | | | KCA 8.2.6.1/08 |
| A | Aquatic plant | | | • | |
| | Lempa gibbaa | Growth | ErC50 | > 100 mg | ; 2010; M- |
| | (duck weed) | inhibition, | E1030 | p.m./L | 365913-01-1 KCA 8 2 7 /07 |
| | | static, | | | KCA 0.2.7/07 |
| | | 7 d | | | |
| Amidosulfuron | Fish, acute | | - | | |
| biuret | Oncorhynchus mykiss (rainbow trout) | Acute, static, 96 h | LC ₅₀ | > 100 mg a.s./L | ; 1987; M- 117660-01-1 KCA 8.2.1 /01 |
| | Lepomis macrochirus (bluegill sunfish) | | | | ; 1987; M- 119377-01-1 KCA 8.2.1 /02 |
| | | | 1 | | 1 |

| Test substance | Test organism | Test | Endpoint | References |
|--|------------------------------|--------------|-------------------------------------|------------------------------|
| | Coursia e de a | system | | . 1088. M |
| | Cyprinoaon | | | 120514 01 1 |
| | (sheenshead minnow) | | | KCA = 21/03 |
| | (sheepshead minitow) | | | KCA 0.2.1/05 |
| | Parent endpoint | | | () 1080: M |
| | | | | 1989; M- |
| | | | | KC@8.2.1/@ |
| | Fish, chronic | | Ś. | |
| | Oncorhynchus mykiss | early life | NOEC 28.72 mg a x/L | |
| | (rainbow trout) | stage test | | ² 2019, M-538454- |
| | Parent endpoint | C | | 101-1 |
| | Aquatic invertebrates | , acute | | |
| | i i quatte in (el test ates | | | · 1987 · M- |
| | Daphnia magna | Acute, | EC_{50} 36 mg a .s./L | 119379-01-1 |
| | (water flea) | static, | | K 8.2.47,2 |
| | Parent endpoint | 48 h | | R LY |
| | Aquatic invertebrates | , chronic | | |
| | Danhnia magna | chronic. | NOEC 1.0 mag a.s./L | ; 1991; M- |
| | (water flea) | semi static, | | 130493-01-1 |
| | Parent endpoint | Qid S | | EA 8.2.3.1 /01 |
| | | | | ð f |
| | ingue ô | | | ; 1988; M- |
| | Scenedesmus | Grøwth | E_rC_{50} 145 mg a.s./L | 120327-01-1 |
| | alga) | 18h | | KCA 8.2.6.1 /01 |
| | Parent endpoint | 4011 | | ; 2016; M- |
| | | | | 549424-01-1 |
| | Aquatic plant | | | KCA 8.2.0.1/08 |
| | | | | · 2015· M- |
| | Lemna gibba | Growth | $\mathbb{E}_{r}C_{50}$ 10 mg p.m./L | 510513-01-1 |
| | (duck weed) | infubition, | | KCA 8.2.7 /08 |
| \$/ | | static, 🚿 | | |
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| Test substance | Test organism | Test | | Endpoint | References |
|------------------------|---|---|-------------------|----------------------|--|
| | Fish. acute | system | I | | |
| Amidosulfuron- ADMP | Oncorhynchus mykiss (rainbow trout) | Acute, static | LC ₅₀ | 169.2 mg p.m./L | ; 1993; M- 131422-01-1 |
| | | 96 h | | Å | KCA 8.2.1/06 (2016; M- (549001-01-1) |
| | | | | | KCA8.2.1/10 05 |
| | Fish, chronic | 1 | T | | |
| | Oncorhynchus mykiss | early life | NOEC | %,72 mg a.s./L | $\sim 2010^{7} M 528 h 54$ |
| | (rainbow trout) | stage test | ~ | , Ç | 01-1 01-1 01-1 01-1 01-1 01-1 01-1 01-1 |
| | Parent endpoint | | Ő | | KCA 8.2.2001 。 |
| | Aquatic invertebrates | , acute | | v v | |
| | Daphnia magna | Acute, | EC ₅₀ | 223 mg Ø.m./L | ; 19 93 , M- |
| | (water flea) | static, | Ô, v | | K 8.2.1 |
| | | 48 h | ĺ "Ş | | |
| | Aquatic invertebrates | , chronic 🖇 | Q | | |
| | Daphnia magna | chrome, | NOEC | 1.0 mg a.s./L | ; 1991; M- |
| | (water flea) | semi static, |) L | | KQA 8.2.5.1 /01 |
| | Parent endpoint | Q1'd | | | |
| | Algae Ĉ | Ŷ. | K, | | |
| | Desmodesmus | Growth inhibition, | ErC ₅₀ | > 569 mg p.m/L | ; 1993; M- 131421-01-1 KCA 8.2.6.1 /05 |
| | (syn. Scenedesmus subspicatus) (green algo) | € /2 h | | | |
| | Aquatic plant | | | | |
| | Lemma gibba | Growth | | © © 100 mg n m /L | |
| | (duck weed) | intervition, | | y 100 mg p.m./L | 2000; M-186916-01-1 |
| 27 | | semi-static, | | | KCA 8.2.7/04 |
| | | $p^7 d \sim p^7 $ | | | |
| | | | 1 | | |
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Document MCP: Section 10 Ecotoxicological studies Amidosulfuron WG 75

| Test substance | Test organism | Test | | Endpoint | References |
|----------------|--|--------------------------|------------------|--------------------|---------------------------|
| | | system | | | |
| Amido sulfuron | Fish, acute | | T | 1 | |
| - | Oncorhynchus mykiss | Acute, | LC ₅₀ | > 100 mg a.s./L | ; 1987; M- |
| Guanidinocarbo | (rainbow trout) | static, 96 h | | | 117660-01-1 |
| nyl sulfamic | Lepomis macrochirus | | | | KCA 8.2.1 /01 |
| acid | (bluegill sunfish) | | | | ; 1987; M- |
| uoru | Cyprinodon | | | × | 119377-01-1 |
| | variegates | | | A A | KC 8.2.1/6° 6 |
| | (sheepshead minnow) | | | <u>O</u> Y | ; 1988; M |
| | Parent endpoint | | | s° 4° a | 120514-0T-1 |
| | | | ~ | O S in | ; 1989; M- |
| | | | Č | | 123929-01 |
| | Fish shuser's | | | | DEA 8.24 9/04 2 |
| | Fish, chronic | a antas tifa | | (h 72 | |
| | (rainhaus traut) | early life | | 9.72 mg-a.s./L | 2015 10 520454 |
| | (Tallibow Houl) Perent endneint | stage test « | | | 2015: 44-538454- |
| | i arent enupoint | | , St | | KCA 802/01 |
| | Aquatic invertebrates | , acute 🔊 | | | <u>> 0[×]</u> |
| | Daphnia magna | Açate, | EC50 | 36 mg/a, s./L | ; 1987; M- |
| | (water flea) | static, | | Û X | 109379-01-1 |
| | Parent endpoint | ≪¶8″h _⊘> | × | | SCA 8.2.4 /02 |
| | Aquatic invertebrates | <u>, chronic</u> | <u></u> | | <u></u> |
| | Daphnia magna 🔬 🖉 | chronic, 🦻 | NOEC | ∂ 1.0 m@å.s./L °∽ັ | ; 1991; M- |
| | (water flea) | semi static, | , Ro | | 130193-01-1 |
| | Parent endpoint [®] | 21rd 🔗 | | ~~ <u>6</u> | KCA 8.2.5.1 /01 |
| | Algae 🔬 🔿 | | °~y~ | <u>, Q , Q'</u> | |
| | Scenedesmûs 🖌 | Growth | E_rC_{50} | 145 mg/a.s./L | ; 1988; M- |
| | subspicatus (green | inhibition, | ¢0 | | 120327-01-1 |
| | alga) | 48h | <u></u> | | KCA 8.2.6.1 /01 |
| | Parent endpoint | | | 8 | ; 2016; M- |
| | ð _e r á | Ū, | Ň, | Ç ^a | 549424-01-1 |
| | <u>a</u> o ^v o ^v | | ď á | P | KCA 8.2.6.1/08 |
| 9/ | Aquatic plant 🖤 | N N | <u></u> | T | |
| Į S | Lemna gibba 🗶 🔍 | Growthy | EC 50 | 0.0092 mg a.s./L | ; 2002; M- |
| | (duQt weed)) O | inhibition, | \mathbb{N} | | 208657-01-1 |
| | Parent endpoint | semi ^z static | ¢ | | KCA 8.2.7 /02 |
| | | 70° Oʻ | 1 | | |

a.s. = active substance; pm. = pure metabolite, (nom) nominal concentration; (mm) mean measured concentration

Risk assessment for aquatic organisms

C

Predicted Environmental Concentrations used in risk assessment Formulated product

For the formulated product, meaningful PECsw can only be calculated for the direct entry route drift exposure. Indirect routes involving secondary movements of a soil deposit, such as drainage and runoff, would not lead to an exposure of the aquatic environment to the intact formulated spray solution. When hitting soil, the formulation will be disintegrated via dilution in the pore water, differential adsorption and retention of its components by soil particles, and rapid biological degradation of coformulants. Therefore, experimental endpoints from the product are to be compared with the drift exposure PEC_{sw} of the product. These are calculated in a simple tier 1 approach, considering standard drift rates and a standard water body, which is 30 cm deep and without riparian vegetation.

Table CP 10.2-3: Initial maximum PECsw values of the formulation, considering spray drift after one application as only route of entry relevant for the product (KCP 9.2.5/05; Table CP 9.2.5-17)

| Compound | Scenario | Drift rate | Winter cereals, 1 × 0.04 kg/ha | Winter cereals, 1 × 0.02 kg/ha | Spring cereals & Flax, & 0.04 kg/ha | Grass (Spring/ Autumn) |
|---------------------------------|--|-----------------------|--|-----------------------------------|---|------------------------------|
| | | | | | TO A | kg/ha |
| | | (arable crops) | PECsw, max [µg/L] √ | PECsw, max | PECsw, max μελμ | PECsw, max |
| Amidosulfuron WG 75 | small static ditch, at the edge of the treated field, water depth 0.3 m | 2.77 % (no buffer) | 0(369 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | | | 0.554 |
| PEC derived from $BBA (2006)^7$ | calculation of en | try in standard | Ditch via spray d | Off (water body | 000 cm depth), | according to |
| Bold values were | used for risk asse | ssment | O ^V Q ^V | | | |
| | | | | | | |



Active ingredient and metabolites

| Table CP 10.2- 4: | Initial max PECsw values of amidosulfuron and its metabolites – FOCUS Step 2 |
|-------------------|--|
| | (KCP 9.2.5/05; Tables CP 9.2.5-10 and -11) |

| Compound | FOCUS | Winter | Winter | Spring cereals | Grass | Grass |
|---------------------------------------|----------------------------|-------------------------|-------------------------|-------------------------|-----------------------|--------------------|
| | Scenario | $1 \times 30 \sigma/ha$ | $1 \times 15 \sigma/ha$ | $1 \times 30 \sigma/ha$ | (Spring) | (Autumn) |
| | | 1 ~ 50 g/lla | 1 ^ 15 g/lla | 1 ~ 30 g/lla | U × 45 g/ha | 1×45 g/ha |
| | | PECsw, max | PECsw, max | PECsw, mas | PECSW, max | PEC sw, max |
| | | [µg/L] | [µg/L] | [µg/L] | Jug/L] A | [µg/[L] |
| | STEP 1 | 10.034 | 5.0170 | 10.034 | y ⁹ 15.050 | ₹\$5.051 |
| Amidosulfuron | STEP 2 – North Single | 1.5446 | 0.938 | \$ 9.866 6 | 10 9889 | 5 1. 8944 |
| | STEP 2 – South Single | 2.8325 | Q7382 & | 3,764 | 1.5925 | Ø5925 |
| | STEP 1 | 6.4826 | 3.2413 | 6.4826 | 9 ,7240 (| 9.7240 |
| Amidosulfuron- desmethyl | STEP 2 – North Single | 0.8507 | Q\$267 | 1.0333 | 0.449 | 1.0100 |
| | STEP 2 – South Single | 1.6614 | 0 [×] 1.0334 | 2.0664 | \$ 8200 | 0.8200 |
| | STEP 1 | 01.23940* | 646197 | 1.2,394 | 1.8590 | 1.8590 |
| Amidosulfuron- desmethyl- | STEP 2 – North Single 🍾 | 0.1893 | 0.1183 | \$0.2366 \$ | 0.0887 | 0.2219 |
| chloropyrimidine | STEP 2 – South Single | 0.3786 | 0.2366 | 0.4733 | 0.1775 | 0.1775 |
| | SSEP 1 | 0.5686 | 0 [×] 0.2843 | 0.5686 | 0.8529 | 0.8529 |
| Amidosulfuron- ADMP | STEP 2 – North Single | 0.0778 | Q0481 | 0.0962 | 0.0405 | 0.0924 |
| | STEP 9- South | 034516 | Q 0.0943 | 0.1885 | 0.0751 | 0.0751 |
| | STER | ~4.37,1 <i>3</i> ~ | ×2.1857 | 4.3713 | 6.5570 | 6.5570 |
| Amidosulfuron guanidine | STEP 2 – North Single | 0.6882 | 0.4249 | 0.8499 | 0.3656 | 0.8202 |
| | STEP 2 & South Single | § 1.3348 | 0.8290 | 1.6581 | 0.6687 | 0.6687 |
| | STEP 1 | 12233 | 0.6116 | 1.2233 | 1.8349 | 1.8349 |
| Amidosulturon- biuret | SDEP 2 – Sorth Single | 0.1845 | 0.1128 | 0.2256 | 0.1074 | 0.2229 |
| | STEPQ – South | 0.3488 | 0.2155 | 0.4310 | 0.1844 | 0.1844 |
| | STEP 1 | 1.2063 | 0.6032 | 1.2063 | 1.8095 | 1.8095 |
| Amidosulfuron- (Guanidinocarbonyl) | STEP 2 – North Single | 0.1865 | 0.1126 | 0.2253 | 0.1200 | 0.2290 |
| sulfamic acid | STEP 2 – South Single | 0.3415 | 0.2095 | 0.4189 | 0.1926 | 0.1926 |

Bold values were used for risk assessment

| | Winter cer | eals (late), | Winter ce | reals (early), | |
|-------------------|--------------------|-------------------------|-----------------------------|--------------------|--|
| Use pattern | 1 × 30 g | a.s./ha | 1 × 15 | g a.s./ha | |
| FOCUS scenario | Entry route* | PECsw | Entry | PECsw 💊 | s ~ . |
| | | [µg/L] | route* | [µg/L] | |
| D1 (ditch) | S | 0.2653 | S | 0.1321 | V A |
| D1 (stream) | D | 0.2499 | D | 0.1033 | |
| D2 (ditch) | D | 4.1960 | D 🔬 | 2,0940 | |
| D2 (stream) | D | 2.6770 | D O | °≯.3370 | X Q |
| D3 (ditch) | S | 0.1916 | S∜Ű | 0.0957 | S S |
| D4 (pond) | S | 0.0112 | Å S | 0,0054 🏑 | |
| D4 (stream) | S | 0.1481 | S S | 0,0738 | ja "v |
| D5 (pond) | S | 0.0080 | s S | 0.004 | Ô' L |
| D5 (stream) | S | 0.1509 👌 | S S | 0.0753 | |
| D6 (ditch) | S | 0.1939 | LS Σ | ♥ 0 %9970 Ø | an a |
| R1 (pond) | R | 0.0079 | ^O R <i>K</i> | Ø.0040~ | Č, |
| R1 (stream) | R | 0.2550 | S R, ″ | 0.1270 | |
| R3 (stream) | R | 0.5171 × | ,≪R _ | 02601 🔊 | |
| R4 (stream) | R | © 0.3395 | [™] R [∪] | 0,1712 | |
| * Entry rout | e spray drift (S), | drainage (D), r | unoff (R) | | |
| | × | | | Q .Q | |
| Table CP 10.2- 6: | Maximum PE | Cov values of | amidosulfuron - | - FOCUS Step 3 | |
| | (KCP9.2.5/05 | Tables P 9.2 | 2.5-94) ° | | |
| | Spring cer | eals & flax | | ~ ⁰ | |
| Use pattern | | a a k | | 7 | |
| FOCUS | | | | | |
| FUCUS scenaria | Entry Foute* | ⊗ PFA_Sw http://L] ^ | | | |
| D1 (Ditch) | | 0 2973 | | | |
| D1 (Stream) | v av | 0.1953 | S S | | |
| D3 (Ditch) | | 0.123 | Ũ | | |
| D4 (Pond) | S & | Q0113 0 | A. | | |
| D4 (Stream) | | 0 1486 | | | |
| D5 (Pand) | | 0.0007 | | | |
| D5 Stream | | 01515 | | | |
| R4 (Stream) | S S | × 0.1252 | | | |
| * Entry rout | espray of the (S) | drainage (D) r | unoff(R) | | |
| | | y | | | |
| | ST Y | | | | |
| | "O" | | | | |

Table CP 10.2- 5:Maximum PECsw values of amidosulfuron – FOCUS Step 3
(KCP 9.2.5/05; Tables CP 9.2.5-12 and -13)

| Table CP 10.2- 7: | Maximum PECsw values of amidosulfuron and its metabolites – FOCUS Step 3 |
|-------------------|--|
| | (KCP 9.2.5/05; Tables CP 9.2.5-15 and Tables CP 9.2.5-16) |

| Grass (spring), | | Grass (a | utumn), | | | | | | |
|---|--------------------|-------------------|--------------|-------------------------------|---------|--|--|--|--|
| Use pattern | 1 × 45 g | g a.s./ha | 1 × 45 g | g a.s./ha | | | | | |
| FOCUS scenario | Entry route* | PECsw | Entry routo* | PECsw | Č. | | | | |
| | | [µg/L] | Entry route | [µg/L] | ý ¬° d. | | | | |
| D1 (Ditch) | S | 0.3072 | D | 0.7153 | | | | | |
| D1 (Stream) | S | 0.2524 | D | 0.464 | AN | | | | |
| D2 (Ditch) | D | 13.090 | D 沧 | ° 11.650 🔎 | | | | | |
| D2 (Stream) | D | 8.7960 | D 🖉 | \$\$990 ° | | | | | |
| D3 (Ditch) | S | 0.2872 | SĎ | × 0.2941 | | | | | |
| D4 (Pond) | S | 0.0105 | R | [≪] 0.022 0 ° | S & Z | | | | |
| D4 (Stream) | S | 0.2201 | Ĵ Ŝ | 0,22466 | v v v | | | | |
| D5 (Pond) | S | 0.0112 | | × 0,2222 | ð Ö | | | | |
| D5 (Stream) | S | 0.2359 | s, s | ×0.2661 | | | | | |
| R2 (Stream) | S | 0.2461 | × ® | 0.31420 | | | | | |
| R3 (Stream) | S | 0.2659 | j š 🔗 | Q.2630 | | | | | |
| * Entry rout | e spray drift (S), | drainage (D), rui | no®(R) | | - Ø | | | | |
| KS (Stream) S 0.2037 C S 4 4,2630 C Entry route spray drift (S), drainage (D), runotic (R) C C C C C C C C C C C C C C C C C C C | | | | | | | | | |

ACUTE RISK ASSESSMENT FOR AQUATIC ORGANISMS

| T (| - | | | DAG | DEC À | |
|--|---|-------------------|------------------------------------|--|-------------|---------|
| l est substance | Test species | Ei [µ; form | idpoint g a.s. or ulation/L] | RAC ₅₀ /100) | PECsw, mac | PEC/RAC |
| Winter cereals, 1 × 30 g a.s./ha | | | | | | y a k |
| Amidosulfuron WG 75 | Fish, acute Oncorhynchus mykiss | LC ₅₀ | 150000 | | 0.36¥ | |
| | Invertebrate, acute Daphnia magna | EC ₅₀ | 187000 | | ~0.369,~~ | \$0.1 × |
| ۸۱۴ | Fish, acute Oncorhynchus mykiss | LC ₅₀ | > 10,000 | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | 2.8325 | |
| T initial of a line of a l | Invertebrate, acute Daphnia magna | EC ₅₀ | 36000-Q | | × 2.8325 | 0.1 |
| Amidosulfuron -desmethyl | Fish, acute Oncorhynchus mykiss | Leso | > 100000 | | ¥.6614 | <0.1 |
| | Invertebrate, acute Daphnia magnag | EC | ×>55000 | 550 | 1.6614 | <0.1 |
| Amidosulfuron -desmethyl- | Fish, acute Oncorhynchus mykiss | PLC ₅₀ | £100000 | 8 1900 1 | ¢ 0.3786 | <0.1 |
| chloro- pyrimidine | Invertebrate, acute Daphnia magna | EQ.50 | 3000 | 360 | 0.3786 | <0.1 |
| Amidosulfuron | Fish, acute Oncorhymétius myhiss | LC ₅ | S> 100600 | 5 ⁴ 1000 | 1.3348 | <0.1 |
| -guanidine 😵 | V Invertebrate, acute Braphnia magna | EC ₅₀ | ~36000-Ç | 360 | 1.3348 | <0.1 |
| Amidosulfuron | Discort Sicher acute | | / > 100000 | > 1000 | 0.3488 | <0.1 |
| -biuret | Invertebrate, acute | EC ₅₀ | 2 36000 | 360 | 0.3488 | <0.1 |
| Amidosulfunor | F@h, acute Oncoshynchu@mykiss | €C50 | 169200 | 1692 | 0.1516 | <0.1 |
| -ADMP | Invertebtate, acuté Daphna magya | EC ₅₀ | 223000 | 2230 | 0.1516 | <0.1 |
| Guanidinocarb | Fish, acute One or hynchus mykiss | LC ₅₀ | > 100000 | > 1000 | 0.3415 | <0.1 |
| onyl sulfamic acid | Invertebrate, acute Daphnia magna | EC ₅₀ | 36000 | 360 | 0.3415 | <0.1 |

Table CP 10.2- 8:RACsw; exposure calculations based on drift entry for the formulation and on FOCUS
Step 2 for amidosulfuron and its metabolites

| Test substance | Test species | Eı [µ; form | ndpoint g a.s. or ulation/L] | RACsw; ac (LC50/100) | PECsw, max [µg/L] | PEC/RAC | |
|------------------------------|---------------------------------------|-------------------|------------------------------------|-------------------------|-----------------------|-----------------------|---|
| Winter cereals, | 1 × 15 g a.s./ha | | | | | | |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | 150000 | 1500 | 0.185 | °<0.1 | |
| WG 75 | Invertebrate, acute Daphnia magna | EC ₅₀ | 187000 | 1870 | 07185 × | | |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | > 100000 | ×1000 | 1.73.82 | | |
| 7 minuosunuron | Invertebrate, acute Daphnia magna | EC50 | 36000 « | | 01.7382 ⁵² | 2 0.1 5 | / |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | > 100000 | | 1.0334 | | |
| -desmethyl | Invertebrate, acute Daphnia magna | EC ₅₀ | 55000 55000 | 550 5 ⁵⁵⁰ | 1.004 | 0) 0) <0.1 | |
| Amidosulfuron -desmethyl- | Fish, acute Oncorhynchus mykiss | | 2100000 | > 1000 | 0.2366 | <0.1 | |
| chloro- pyrimidine | Invertebrate, acute | ECS | 36000 | | AQ 2366 | <0.1 | |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | | , \$9000 . \$ | 0.8290 | <0.1 | |
| -guanidine | Invertebrate, acore Daphnia magna | EC ₅₀ | 36000 | 2 366 × | 0.8290 | <0.1 | |
| Amidosulfuron | Fish, açûte Gncorhyndhus mytass | | > 106000 | S 1000 | 0.2155 | <0.1 | |
| -biuret | Invertebrate, acute | DEC ₅₀ | ~3600Q~ | 360 | 0.2155 | <0.1 | |
| Amidosulfuror | Fish acute O Oncorn nchus mykiss | ЬС 50 0 | 10200 | 1692 | 0.0943 | <0.1 | |
| | Invertebrate, acute | EC | 223000 | 2230 | 0.0943 | <0.1 | |
| Guanidinocato | Essh, acute Oncorhynchus mykiss | LC 50 | > 100000 | > 1000 | 0.2095 | <0.1 | |
| onyl sultañwc acid | Anvertebrate, acute Daphnia magora | EC ₅₀ | 36000 | 360 | 0.2095 | <0.1 | |
| | J' Y | | | | | | |

| Test substance | Test species | Eı [µ; form | ndpoint g a.s. or ulation/L] | RACsw; ac (LC50/100) | PECsw, max [µg/L] | PEC/RAC | |
|---|---------------------------------------|-------------------|------------------------------------|---------------------------|----------------------|-----------------------|--------|
| Spring cereals & Flax, 1 × 30 g a.s./ha | | | | | | | |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | 150000 | 1500 | 0.369 | °<0.1 | |
| WG 75 | Invertebrate, acute Daphnia magna | EC ₅₀ | 187000 | 1870 | | | Ø V |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | > 100000 | | 3.4764 | | |
| 7 mildosulturon | Invertebrate, acute Daphnia magna | EC50 | 36000 « | ~ 3.60 [~] | 03.4766 | 2 0.1 5 | 2 |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | > 100000 | | 2.0667 | | |
| -desmethyl | Invertebrate, acute Daphnia magna | EC ₅₀ | 55000 55000 | 5550 5 ⁵ 50 | 2.0667 | 0, <0.1 | |
| Amidosulfuron -desmethyl- | Fish, acute Oncorhynchus mykiss | | 2100000 | > 1000 | 0.4733 | <0.1 | |
| chloro- pyrimidine | Invertebrate, acute | ECS | 36000 | | AQ 4733 | <0.1 | |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | | , \$9000 . \$ | 1.6581 | <0.1 | |
| -guanidine | Invertebrate, acore Daphnia magna | EC ₅₀ | 36000 | 2 366 × | 1.6581 | <0.1 | |
| Amidosulfuron | Fish, açûte Gncorhyndhus mytass | | > 106000 | S 1000 | 0.4310 | <0.1 | |
| -biuret | Invertebrate, acute | DEC ₅₀ | ~3600Q~ | 360 | 0.4310 | <0.1 | |
| Amidosulfuror | Fish acute O Oncormonchus mykiss | | 10200 | 1692 | 0.1885 | <0.1 | |
| -ADMP | Invertebrate, acute | EC | 223000 | 2230 | 0.1885 | <0.1 | |
| Amido- sulfuron | Essh, acute Oncorhynchus mykiss | LC 50 | > 100000 | > 1000 | 0.4189 | <0.1 | |
| Guanidinoestb onyl sulfamic acid | Anvertebrate, acute Daphnia magora | EC ₅₀ | 36000 | 360 | 0.4189 | <0.1 | |
| | J'Y | | | | | | |

| Test substance | Test species | Eı [µ; form | ndpoint g a.s. or ulation/L] | RACsw; ac (LC50/100) | PECsw, max [µg/L] | PEC/RAC |
|------------------------------|--|-------------------|------------------------------------|-------------------------|--|---------|
| Grass (spring), | 1 × 45 g a.s./ha | | | | | |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | 150000 | 1500 | 0.554 | °<0.1 |
| WG 75 | Invertebrate, acute Daphnia magna | EC ₅₀ | 187000 | 1870 | \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ | |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC50 | > 100000 | | 1,5925 | |
| Amidosulfuron | Invertebrate, acute Daphnia magna | EC50 | 36000 « | | 01.5925 ⁵⁷ | |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | > 100000 | | 0.8200 | |
| -desmethyl | Invertebrate, acute Daphnia magna | EC ₅₀ | 55000 | 550 | 0.8200 | 0.1 |
| Amidosulfuron -desmethyl- | Fish, acute Oncorhynchus mykiss | | 2100000 | × > 1,000 , | 0.1775 0.1775 | <0.1 |
| chloro- pyrimidine | Invertebrate, acute Daphnia magna | ECS | 36000 | | AQ 1775 | <0.1 |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | | | 0.6687 | <0.1 |
| -guanidine | Invertebrate, acore Daphnia magha | EC ₅₀ | 36000 | 2 366 × × | 0.6687 | <0.1 |
| Amidosulfuron | Fish, açûte Gncorhyndhus myldiss | | > 100000 | <i>⇒</i> 1000 | 0.1844 | <0.1 |
| -biuret | Invertebrate, acute | EC ₅₀ | ~3600Q | 360 | 0.1844 | <0.1 |
| Amidosulfuror | Fish acute O Oncommonchus Mykiss | | 10200 | 1692 | 0.0751 | <0.1 |
| -ADMP | Lovertebrate, acute | EC | 223000 | 2230 | 0.0751 | <0.1 |
| Auto- sulfuron | Essh, acute Oncorhynchus mykiss | 10° LC50 | > 100000 | > 1000 | 0.1926 | <0.1 |
| onyl sulfamic acid | Anvertebrate, acute Daphnia magora | EC ₅₀ | 36000 | 360 | 0.1926 | <0.1 |
| | - The second sec | | | | | |

| Test substance | Test species | Eı [µ form | ndpoint g a.s. or wlation/L] | RACsw; ac (LC50/100) | PECsw, max [µg/L] | PEC/RAC | | |
|----------------------------------|---------------------------------------|------------------------|------------------------------------|-------------------------|----------------------|---------|--------|--|
| Grass (autumn), 1 × 45 g a.s./ha | | | | | | | | |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | 150000 | 1500 | 0.554 | °<0.1 | | |
| WG 75 | Invertebrate, acute Daphnia magna | EC ₅₀ | 187000 | 1870 | 0 ⁵⁵⁴ | | Ŭ V | |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | > 100000 | £1000 S | 1.8944 | | | |
| Annuosunuron | Invertebrate, acute Daphnia magna | EC ₅₀ | 36000 « | | 01.894 | 0.1 | 0 | |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC50 | > 100000 | | 1.0100 | | | |
| -desmethyl | Invertebrate, acute Daphnia magna | EC ₅₀ | 55000 | 550 | 1.0000 | © <0.1 | | |
| Amidosulfuron -desmethyl- | Fish, acute Oncorhynchus mykiss | | 2100000 | × > 1000 , | 0.2219 0.2219 | <0.1 | | |
| chloro- pyrimidine | Invertebrate, acute Daphnia magna | ECS | 36000 | | AQ. 2219 | <0.1 | | |
| Amidosulfuron | Fish, acute Oncorhynchus mykiss | LC ₅₀ | | | 0.8202 | <0.1 | | |
| -guanidine | Invertebrate, acore Daphnia magna | EC ₅₀ | 36000 | 2 366 × " | 0.8202 | <0.1 | | |
| Amidosulfuron | Fish, açûte Gncorhyndhus mytess | LC | > 100000 | <i>≸</i> 1000 | 0.2229 | <0.1 | | |
| -biuret | Invertebrate, acute | $\mathbb{C}_{EC_{50}}$ | ~36000° | 360 | 0.2229 | <0.1 | | |
| Amidosulfuror | Fish acute O Oncompachus mykiss | | 10200 | 1692 | 0.0924 | <0.1 | | |
| -ADMP | Invertebrate, acute | EC | 223000 | 2230 | 0.0924 | <0.1 | | |
| Amido- sulfuron | Fish, acute Oncorhynchus mykiss | LC 50 | > 100000 | > 1000 | 0.2290 | <0.1 | | |
| onyl sulfamic acid | Invertebrate, acute Daphnia maguta | EC ₅₀ | 36000 | 360 | 0.2290 | <0.1 | | |

The quotient is always below 1 for all evaluated scenarios. Consequently, a safe use can be assumed according to the proposed GAP.
CHRONIC RISK ASSESSMENT FOR AQUATIC ORGANISMS

Table CP 10.2- 9:RACsw; exposure calculations based on drift entry for the formulation and on FOCUS
Step 2 for amidosulfuron and its metabolites

| Test substance | Test species | Endpoint [µg a.s. or | RACsw; LT (NOEC/10) | PECsw, max | PEC/RAC |
|------------------------------|--|------------------------------------|------------------------|------------|-----------------------|
| Winter cereals, | 1 × 30 g a.s./ha | Iormulation / | L] (ErC50/10) | | Ó Ø |
| | Fish, chronic Oncorhynchus mykiss | NOEC 100 | 00 00 000 | ~0,369 Å | |
| | Invertebrate, chronic Daphnia magna | NOEC 320 NOEC 130 | | × 0.369 | ≪0.1 <0,1 ℃ |
| Amidosulfuron WG 75 | Green algae, chronic Scenedesmus subspicatus | ErC50 122 | | | \$ \$ \$ 0.1 |
| | Aquatic plants, chronic Lemna gibba | E _r C ₅ C 10 | | ©*0.369 © | 0.4 |
| | Fish, chronic Oncorhynchus mykiss | SHOEC 97 | | \$325 | <0.1 |
| | Invertebrate, chronic Daphnia magma | NOEC 10 | | 2.8325 | <0.1 |
| Amidosulfuron | Green algae Chronic Scenedosmus subspicatus | ErC ₅₀ 1450 | | 2.8325 | <0.1 |
| | Aquatic plants, chronic Lemma gibba | Ercer 29 | 2 0.92 | 2.8325 | 3.1 |
| | Fish, chronic Oncorhynchus mykiss | NOEC 97 | 972 | 1.6614 | <0.1 |
| , Ĉ | Invertebrate, chronic Daphila magna | NOEC 0 10 | 00 100 | 1.6614 | <0.1 |
| Amidosulfuren -desmeth | Green algae, chronic Scene@esmus subspicatus | E S >100 | >10000 >100000 | 1.6614 | <0.1 |
| | Aquatic plants, chronic | $E_{\rm r}C_{50}$ 92 | 0 92 | 1.6614 | <0.1 |
| Amidosulfuron -desmethyl- | Fish, chronic Oncorhynchus mykiss | NOEC 972 | 20 972 | 0.3786 | <0.1 |

⁸ Observed NOEC from the study with formulated product

⁹ Calculated mixture toxicity based on the active substance endpoint and its amount in the formulated product

Amidosulfuror -ADMP

Amido-

sulfuron-

Dapinia magna

Green algae, chronie

Scenedesmus subspicature

Aquatic plants, chronic

Lemna gibba Fish, chronic

Oncorhynchus mykiss

O

 $E_r C_{50} \\$

 $E_r C_{50}$

NOEC

>560000

>100000

9720

>56000

>10000

972

0.1516

0.1516

0.3415

< 0.1

< 0.1

< 0.1

| Test substance | Test species | End [µg formul | lpoint a.s. or ation /L] | RACsw; lt (NOEC/10) (ErC50/10) | PECsw, max [µg/L] | PEC/RAC |
|-----------------------------|---|----------------------|--------------------------------|---|----------------------|---------|
| chloro- pyrimidine | Invertebrate, chronic Daphnia magna | NOEC | 1000 | 100 | 0.3786 | <0.1 |
| | Green algae, chronic Scenedesmus subspicatus | ErC ₅₀ | 145000 | 14500 | × × 0.3786 | |
| | Aquatic plants, chronic Lemna gibba | ErC ₅₀ | >100000 | ©_>10000 | 0.3786 0.3786 | × 0.1 |
| | Fish, chronic Oncorhynchus mykiss | NOEC | 9726 | 972 8 972 8 4 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | \$348 C | |
| | Invertebrate, chronic Daphnia magna | NOEC | 9000 | | 1.3648 | <0.1 |
| Amidosulfuron -guanidine | Green algae, chronic Scenedesmus subspicatus | E C % | 145000 1 | 2 14 50 0 | © 1.3348 | <0.1 |
| | Aquatic plants, chronic | Er C 39 | > 100000 | | 0 1.3348 | <0.1 |
| | Fish, chronic Oncorhynchus mykiss | NOECO | 97.20 | 972 S | 0.3488 | <0.1 |
| | Invertebeate, chronic Daphnia magna | NOEC | 0 ¹ 1000,0 | 100 | 0.3488 | <0.1 |
| Amidosulfuron -biuret | Green algae, chronic Scenedesmus subspicature | E C 50 | 545000 Å | ¥ 14500 | 0.3488 | <0.1 |
| <i>k</i> g | Aquatic plants, Chrome Lemha gibba | Ercso | >10000 | >1000 | 0.3488 | <0.1 |
| | Fish, chromic Oncorhynchus mykiss | | 9720 | 972 | 0.1516 | <0.1 |
| A | Invertebrate, chronic | ANOEC | 1000 | 100 | 0.1516 | <0.1 |

| Test | | End | point | RACsw; LT | PECsw, max | PEC/RAC |
|--|---|--------------------------------|---|--------------------------------------|-------------------------------------|-----------------------|
| substance | l est species | μg : formul | a.s. or ation /L] | (ROEC/10) (ErC ₅₀ /10) | [µg/L] | |
| Guanidinocarb onyl sulfamic acid | Invertebrate, chronic Daphnia magna | NOEC | 1000 | 100 | 0.3415 | <0.1 |
| | Green algae, chronic Scenedesmus subspicatus | E _r C ₅₀ | 145000 | 14500 | ° → 0.34 → 0.34 → 0.34 | |
| | Aquatic plants, chronic Lemna gibba | ErC50 | 9.2 | | € 0.3415 × 0.3415 × 0.3415 | × 5 ~ 0.4 ~ 0.4 |
| Winter cereals, | 1 × 15 g a.s./ha | | <u> </u> | | | |
| | Fish, chronic Oncorhynchus mykiss | NOEC | \$0000 × | | √ 0.185 √ | \$0.1 |
| Amidosulfuron WG 75 | Invertebrate, chronic Daphnia magna | NOEC NOEC | 32000 ⁹ 1300 ¹ | C3200, O [×] 130 | 0.185 | <0.1 <0.1 |
| | Green algae, chronic Scenedesmus subspicatus | C 50 | 122006/ 2 | | 0.585 | <0.1 |
| | Aquatic plants, chronic | | | | 0.185 | 0.2 |
| | Fish, chronic Oncorhynchus mysiss | NOEC | ,9720 | | 1.7382 | <0.1 |
| | Invertebrate, chronic Daphnia magna | ∮NOEC | 1000 | 100 | 1.7382 | <0.1 |
| Amidosulfuron | Green algae, chronic ^y Scenedesmus Subspicants | ČErC ₅₀ | 91450 00 | 14500 | 1.7382 | <0.1 |
| | Aquatic plants Aquatic plants Lenna gibba | ÆrC50 | ^(%) 9.2 | 0.92 | 1.7382 | 1.9 |
| ð A | Fish, chronic Oncorhynchus mylass | NÔEC | 9720 | 972 | 1.0334 | <0.1 |
| Amidesulfucon -desmethyd | Invertobrate, chronic | NOEC | 1000 | 100 | 1.0334 | <0.1 |
| | Green agae, chronic Scenedesmus Subspicatus | E _r C ₅₀ | >1000000 | >100000 | 1.0334 | <0.1 |

¹⁰ Observed NOEC from the study with formulated product

¹¹ Calculated mixture toxicity based on the active substance endpoint and its amount in the formulated product

| Test substance | Test species | Endpoint [µg a.s. or formulation /1] | | RACsw; LT (NOEC/10) (ErC50/10) | PECsw, max [µg/L] | PEC/RAC |
|--|--|---|---|--|----------------------|---------|
| | Aquatic plants, chronic Lemna gibba | E _r C ₅₀ | 920 | 92 | 1.03334 | <0.1 |
| | Fish, chronic Oncorhynchus mykiss | NOEC | 9720 | 972 | \$ 5 0.2366 | |
| Amidosulfuron | Invertebrate, chronic Daphnia magna | NOEC | 1000 | ° 100 | × 0.2366 0 | ×0.1 |
| -desmethyl- chloro- pyrimidine | Green algae, chronic Scenedesmus subspicatus | ErC50 | 145000 | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | | |
| | Aquatic plants, chronic Lemna gibba | ErC50 K | _>100000 | × × × × × × × × × × × × × × × × × × × | 0,2366 | <0.1 |
| | Fish, chronic Oncorhynchus mykiss | NOEC | € ⁹⁷²⁰ | | 0.82990 | <0.1 |
| Amidosulfuron -guanidine | Invertebrate, chronic Daphnia magna | NOEO | , 1090 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | | 0.8290 | <0.1 |
| | Green algae, chronic Scenedesmus subspicatus | ErC ₅₀ | * 145 60 0 | 14500 (S) | 0.8290 | <0.1 |
| | Aquany plants | ErC ₅₀ | 5 >1000 6 0 | ×10000 | 0.8290 | <0.1 |
| \$ | Fish, chronic Oncorhynchus mykiss | NOEC | Q ⁹⁷²⁰ | 972 | 0.2155 | <0.1 |
| je starter and the starter and | Invertebrate chronic | NQEO | 19900 % | 100 | 0.2155 | <0.1 |
| Amidosulfuron -biuret | Green aleae, chtonic Scenedesmus Ssubspictatus | ErCso | 0 ⁹ 145000 | 14500 | 0.2155 | <0.1 |
| | Aquatic plants Chronic Demna goba | ÉrC ₅₀ | >10000 | >1000 | 0.2155 | <0.1 |
| À C | A Fish chronic A Soncorhynchus mykiss | NOEC | 9720 | 972 | 0.0943 | <0.1 |
| Amidosulfuron -ADMP | Invertebrate, chronic Daphnia magna | NOEC | 1000 | 100 | 0.0943 | <0.1 |
| | Green algae, chronic Scenedesmus subspicatus | ErC ₅₀ | >560000 | >56000 | 0.0943 | <0.1 |

| Test substance | Test species | Endpoint [µg a.s. or formulation /L] | | RACsw; lt (NOEC/10) (ErC50/10) | PECsw, max [µg/L] | PEC/RAC |
|---|--|--|---|--------------------------------------|----------------------|---------------------|
| | Aquatic plants, chronic Lemna gibba | E_rC_{50} | >100000 | >10000 | 0.09943 | <0.1 |
| | Fish, chronic Oncorhynchus mykiss | NOEC | 9720 | 972 | 0.20 9 | |
| Amido- sulfuron- Guanidinocarb onyl sulfamic acid | Invertebrate, chronic Daphnia magna | NOEC | 1000 | 0° 100 × | 2095 O | √ [™] ≪0.1 |
| | Green algae, chronic Scenedesmus subspicatus | ErC50 | 145000 | ×14500 0° | 2095 C | |
| | Aquatic plants, chronic <i>Lemna gibba</i> | ErC ₅₀ | 9.2 9.2 | × × × × × × | 0,2095 | 0.2 |
| Spring cereals & | & Flax, 1 × 30 g a.s./ha | | | | 0, <u>16</u> | |
| | Fish, chronic Oncorhynchus mykiss | OF CONTRACTOR | 10000 | \$1000 \$ | \$369 | <0.1 |
| | Invertebrate, chronic Daphnia magna | NQEC | 32000 ¹² (1300 ¹³ | 32000 2130 | 0.369 | <0.1 <0.1 |
| Amidosulfuron WG 75 | Green algae chronic Scenedosmus subspicatus | E ₄ C ₅₀ | 122000 | | 0.369 | <0.1 |
| | Activatic plants, O chronic Lemnt gibba | ErC | | | 0.369 | 0.4 |
| | Fish, chronic Oncomynchus, mykiss | WOE C | 9720 * | 972 | 3.4764 | <0.1 |
| × | Invertebrate, chronic Daptinia magin | NOEC | [≪] ∕1000 | 100 | 3.4764 | <0.1 |
| Amidosulfuror | Green algae, chronic Scenedesmus subspicatus | Eisco | 145000 | 14500 | 3.4764 | <0.1 |
| | Acquatic plants, Chronic Lemma gibba | E _r C ₅₀ | 9.2 | 0.92 | 3.4764 | 3.8 |
| Amidosulfuron -desmethyl | Fish, chronfo Oncorhynchus mykiss | NOEC | 9720 | 972 | 2.0667 | <0.1 |

¹² Observed NOEC from the study with formulated product

¹³ Calculated mixture toxicity based on the active substance endpoint and its amount in the formulated product

Fish, chronic

Oncorhynchus mykiss

NOEC

9720

972

0.1885

< 0.1

Amidosulfuron

-ADMP

| Test substance | Test species | Endpoint [μg a.s. or formulation /L] | | RACsw; lt (NOEC/10) (ErC50/10) | PECsw, max [µg/L] | PEC/RAC |
|---|---|--|------------------------|--------------------------------------|--|--------------------------------|
| | Invertebrate, chronic Daphnia magna | NOEC | 1000 | 100 | 2.0667 | <0.1 |
| | Green algae, chronic Scenedesmus subspicatus | E _r C ₅₀ | >1000000 | >100000 | × × × × × × × × × × × × × × | |
| | Aquatic plants, chronic Lemna gibba | ErC ₅₀ | 920 _Č | | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | × × 0.1 |
| | Fish, chronic Oncorhynchus mykiss | NOEC | 9726 | 0 972 0 972 | 0 ³ 4733 c | |
| Amidosulfuron -desmethyl- chloro- pyrimidine | Invertebrate, chronic Daphnia magna | NOEC | 9000 | | 0.4033 | ∅<<0.1 |
| | Green algae, chronic Scenedesmus subspicatus | E C % | 145000 4 | 2 14 50 0 | © 0.4733 | <i>≈</i> <0.1 |
| | Aquatic plants, chronic | ErĈsy | > 100000 | | 0.4733 | <0.1 |
| | Fish, chronic | NOECO | 9720 | 972 P | 1.6581 | <0.1 |
| | Invertebrate, chronic Daphhia magna | NOEC | 0 ⁴ 1000,00 | 100 | 1.6581 | <0.1 |
| Amidosulfuron -guanidine | Green algae, chronic Scenedesmus subspicatus | Edgeso | 5000 2 2 2 | 14500 | 1.6581 | <0.1 |
| | Aquatic phants, chronic <i>Lemha</i> gibba | E _r iC ₅₀ | ~100000 | >10000 | 1.6581 | <0.1 |
| | F&h, chromie Oncorhynettys mykis | NOE S | 9720 | 972 | 0.4310 | <0.1 |
| | Invertebrate, chrónic Dapynia magna | ASOEC | 1000 | 100 | 0.4310 | <0.1 |
| Amidosulfuron -biuret | Green algae, chronie <i>Scenedesmus</i> <i>subspicatu</i> |) E _r C ₅₀ | 145000 | 14500 | 0.4310 | <0.1 |
| | <i>Aquatic plants,</i> chronic <i>Lemna gibba</i> | E_rC_{50} | >10000 | >1000 | 0.4310 | <0.1 |

| Test substance | Test species | Endpoint [µg a.s. or formulation /L] | | RACsw; lt (NOEC/10) (ErC50/10) | PECsw, max [µg/L] | PEC/RAC |
|--|---|--|---|--------------------------------------|--|--|
| | Invertebrate, chronic Daphnia magna | NOEC | 1000 | 100 | 0.1885 | <0.1 |
| | Green algae, chronic Scenedesmus subspicatus | $E_r C_{50}$ | >560000 | >56000 | ° ↓ 0.1885 ↓ ↓ ↓ ↓ | |
| | Aquatic plants, chronic Lemna gibba | ErC ₅₀ | >100000 | ب ۲۵۹۵ ۲۵۹۵ ۲۵۹۵ ۲۰۰۵ | °,~) ∧, 0.1885 × ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ |
| | Fish, chronic Oncorhynchus mykiss | NOEC | 9720 | 972 8 972 | 0¥189 0 | |
| Amido- sulfuron- | Invertebrate, chronic Daphnia magna | NOEC | 9000 | | 0.4089 | € € <0.1 |
| Guanidinocarb onyl sulfamic acid | Green algae, chronic Scenedesmus subspicatus | E C % | 145000 4 | 2 14 50 0 | 0.4189 0.4189 | <0.1 |
| | Aquatic plants, chronic | DY OF Er C sy | | | 0.4189 | 0.5 |
| Grass (spring), | 1 × 45 g a.s./ha | Š, Ő | × . ~ ? | | | |
| | Fish, chronic Oncorhynchus mysess | NOEC | 10000 | | 0.554 | <0.1 |
| | Invertebrate, chronic | NOEC NOEC | 32000 ¹⁴ 1300 ¹⁵ | 3200 130 | 0.554 | <0.1 <0.1 |
| Amidosulfuron WG 75 | Green algae, chronic ^y Scenedesmus Subspicatus | ErC ₅₀ | Q122000 | ¥ 12200 | 0.554 | <0.1 |
| | Aquatic plants whronic Lenna gibba | ÆrC50 | ۲۵ ۱0 | 1 | 0.554 | 0.6 |
| ď, | Fish, chronic Oncorhynchus mylass | NÔEC | 9720 | 972 | 1.5925 | <0.1 |
| Amidosulfuron | Invertebrate, chronic | NOEC | 1000 | 100 | 1.5925 | <0.1 |
| | Green atgae, chronic Scenedesmus Saubspicatus | ErC ₅₀ | 145000 | 14500 | 1.5925 | <0.1 |

¹⁴ Observed NOEC from the study with formulated product

¹⁵ Calculated mixture toxicity based on the active substance endpoint and its amount in the formulated product

| Test substance | Test species | End [µg : formul: | point a.s. or ation /L] | RACsw; LT (NOEC/10) (ErC50/10) | PECsw, max [µg/L] | PEC/RAC |
|---|---|-------------------------|-------------------------------|--------------------------------------|---|---------|
| | Aquatic plants, chronic Lemna gibba | ErC ₅₀ | 9.2 | 0.92 | 1.8925 | 1.7 |
| | Fish, chronic Oncorhynchus mykiss | NOEC | 9720 | 972 | 0.82 00 | |
| | Invertebrate, chronic Daphnia magna | NOEC | 1000 | ° 100 | × 0.8200 0 0 0 0 0 0 0 0 0 0 0 0 | ×0.1 |
| Amidosulfuron -desmethyl | Green algae, chronic Scenedesmus subspicatus | E_rC_{50} | >1000000 | م می کارون کی کلی کی | | |
| | Aquatic plants, chronic Lemna gibba | ErC50 | 920 2 | | 0,5200 200 | <0.1 |
| | Fish, chronic Oncorhynchus mykiss | NOEC | 6 ⁹⁷²⁰ | | 0.17725 | <0.1 |
| Amidosulfuron -desmethyl- chloro- pyrimidine | Invertebrate, chronic | NOEO | | | 0.1775 | <0.1 |
| | Green algae, chronic Scenedesmus subspigatus | ÈrC ₅₀ | ¥ 145600 | 14500 (5) | 0.1775 | <0.1 |
| | Aquates plants | ErC ₅₀ | | \$10000 | 0.1775 | <0.1 |
| \$ | Fish, chronic Oncorhynchus mykiss | NOEC | \$9720 ~~ | 972 | 0.6687 | <0.1 |
| | Invertebrate chronic | NQEO | 000 | 100 | 0.6687 | <0.1 |
| Amidosulfuron -guanidine | Green algae, chronic Scenedesmus Subsplicatus | ErC50 | 0 ⁹ 145000 | 14500 | 0.6687 | <0.1 |
| | Aquatic plants Chronic Benna goba | ÉrC ₅₀ | >100000 | >10000 | 0.6687 | <0.1 |
| À C | A Fish chronic A Soncorhynchus mykiss | NOEC | 9720 | 972 | 0.1844 | <0.1 |
| Amidosulfuron -biuret | Invertebrate, chronic Daphnia magna | NOEC | 1000 | 100 | 0.1844 | <0.1 |
| | Green algae, chronic Scenedesmus subspicatus | ErC ₅₀ | 145000 | 14500 | 0.1844 | <0.1 |

| Test substance | Test species | End [µg : formul: | point a.s. or ation /L] | RACsw; lt (NOEC/10) (ErC50/10) | PECsw, max [µg/L] | PEC/RAC |
|--|--|--------------------------------|--|--|------------------------------|--------------|
| | Aquatic plants, chronic Lemna gibba | E_rC_{50} | >10000 | >1000 | 0.18844 | <0.1 |
| | Fish, chronic Oncorhynchus mykiss | NOEC | 9720 | 972 | \$ 0.07 5 0.075 | |
| | Invertebrate, chronic Daphnia magna | NOEC | 1000 | 2° 100 × | × 9.0751 0 | \$0.1 |
| Amidosulturon -ADMP | Green algae, chronic Scenedesmus subspicatus | E_rC_{50} | >560000 | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | 00 ⁰⁷⁵¹ | |
| | Aquatic plants, chronic Lemna gibba | ErC ₅₀ | | × × × × × × × × × × × × × × × × × × × | 0,0751 | <0.1 |
| | Fish, chronic Oncorhynchus mykiss | NOEC | € ⁹⁷²⁰ | | 0.1926 | <0.1 |
| Amido- sulfuron- | Invertebrate, chronic (Daphnia magna | NOEO | | 5 ⁴ 100 ⁴ | 0.1926 | <0.1 |
| Guanidinocarb onyl sulfamic acid | Green algae, chromc Scenedesmus subspicentus | ErC ₅₀ | 4 5900 | 14500 (S) | 0.1926 | <0.1 |
| | Aquane plants | | 9.2 C | 0.92 | 0.1926 | 0.2 |
| Grass (autumn) | , 1 × 45 g a \$7ha → | J. | | Ş | | |
| | Fish, chronic Oncomynchus, mykiss | WOEG | 10060 | 1000 | 0.554 | <0.1 |
| S. | Invertebrate, chronic Daptinia maggia | NOEC NOEC | \$2000 ¹⁶ 0 1300 ¹⁷ | 3200 130 | 0.554 | <0.1 <0.1 |
| Amidosulfuron WG 75 | Green algae, chronic Scenedesmus subspicatus | Encon Encon | 122000 | 12200 | 0.554 | <0.1 |
| | Acquatic plants, Chronic | E _r C ₅₀ | 10 | 1 | 0.554 | 0.6 |
| Amidosulfuron | Fish, chronfor Oncorhynchus mykiss | NOEC | 9720 | 972 | 1.8944 | <0.1 |

¹⁶ Observed NOEC from the study with formulated product

¹⁷ Calculated mixture toxicity based on the active substance endpoint and its amount in the formulated product

| Test substance | Test species | End [µg : formul | lpoint a.s. or ation /L] | RACsw; lt (NOEC/10) (ErC50/10) | PECsw, max [µg/L] | PEC/RAC |
|--------------------------------------|---|--------------------------------|--------------------------------|--------------------------------------|---|---------|
| | Invertebrate, chronic Daphnia magna | NOEC | 1000 | 100 | 1.8944 | <0.1 |
| | Green algae, chronic Scenedesmus subspicatus | E_rC_{50} | 145000 | 14500 | × 1.8944 × × | |
| | Aquatic plants, chronic Lemna gibba | ErC ₅₀ | 9.2 | 0.92 0.92 | , , , , , , , , , , , , , , , , , , , | 2.1 |
| | Fish, chronic Oncorhynchus mykiss | NOEC | 9720 | 5 ⁹⁷² 5 ⁹⁷² | 0,000 ¢ | |
| Amidosulfuron -desmethyl | Invertebrate, chronic Daphnia magna | NOEC | 9000 | | 1.0000 | <0.1 |
| | Green algae, chronic Scenedesmus subspicatus | E.C.30 | >1000000 | 2 >106000 2 >106000 | 2 1.0100 2 2 | <0.1 |
| | Aquatic plants, chronic | ErCsy | × 420 × 920 | | Û 1.0100 | <0.1 |
| | Fish, chronic | NOECO | 9720 | 972 S | 0.2219 | <0.1 |
| Amidosulfuron | Invertebeate, chronic Daginnia magna | NOEC | 0 ⁴ 1000,00 | 700 | 0.2219 | <0.1 |
| -desmethyl- chloro- pyrimidine | Green algae, chronic Scenedesmus subspicatus | Edgeso | 1.45000 2 2 | ¥ 14500 | 0.2219 | <0.1 |
| E. | Aquatic plants, chrome <i>Lemka</i> gibba@ | ErG 50 | >100000 | >10000 | 0.2219 | <0.1 |
| | Fish, chromic Oncorhynchus mykixs | NOE | 9720 | 972 | 0.8202 | <0.1 |
| A O | Invertebrate, chrónic Daphnia magna | ANOEC | 1000 | 100 | 0.8202 | <0.1 |
| Amidosulfuron -guanidine | Green algae, chronie Scenedesmus subspicature | E _r C ₅₀ | 145000 | 14500 | 0.8202 | <0.1 |
| | chronic Lemna gibba | E _r C ₅₀ | >100000 | >10000 | 0.8202 | <0.1 |

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| Test substance | Test species | Endj µg a formula | point .s. or ition /L] | RACsw; lt (NOEC/10) (ErC50/10) | PECsw, max [µg/L] | PEC/RAC |
|---|--|-------------------------|------------------------------|--|---|---------|
| | Fish, chronic Oncorhynchus mykiss | NOEC | 9720 | 972 | 0.2229 | <0.1 |
| | Invertebrate, chronic Daphnia magna | NOEC | 1000 | 100 | ~~0.2229~° | |
| Amidosulfuron -biuret | Green algae, chronic Scenedesmus subspicatus | ErC ₅₀ | 145000 | ~14500~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | 02229 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | |
| | Aquatic plants, chronic Lemna gibba | ErC50 | >10000 | | | |
| | Fish, chronic Oncorhynchus mykiss | NOEC | 9720 9720 | | 0.0924 | <0.1 |
| | Invertebrate, chronic Daphnia magna | NOE | 1000 | | 0.0924 | ⊘ <0.1 |
| Amidosulfuron -ADMP | Green algae, chronic Scenedesmus subspicatus | ErCso | >560900 | ~~>560 00 / | Ø.0924 | <0.1 |
| | Aquatic plants chronic Lemna subba | ErC ₅₀ | />100000 | | 0.0924 | <0.1 |
| | Fish chronic Q Oncorbynchus mykiss | | 09720 0 | 772 | 0.2290 | <0.1 |
| Amido- sulfuron- | Invertebrate, chronic | NORE | A080 2 | Ş 100 | 0.2290 | <0.1 |
| sulturon- Guanidinocarb onyl sulfamac acid | Green algae, chronic Seenedesmus Subspicatus | ErC ⁵ | 145000 « | 14500 | 0.2290 | <0.1 |
| | Aquatic plants Chronic Cemna gibba | ErCso | 9.2 | 0.92 | 0.2290 | 0.2 |

The risk quotient is below 1 in the evaluations for all intended uses and organism types other than aquatic plants for the latter, only the parent substance amidosulfuron leads to trigger exceedances. Therefore, a refined risk assessment is required specifically for active substance amidosulfuron and aquatic plants. Such assessment conducted via the consideration of the more realistic FOCUS STEP 3 surface water appearent tions is presented below. surface water concentrations, is presented below.

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| Species | Endpoint [µg/L] | RACsw; lt (ErC50/10) | PECsw,max [µg/L] | FOCUS scenario | PEC/RAC | | | |
|---|-------------------------|-------------------------|-------------------------|-------------------|--------------|--|--|--|
| Amidosulfuron, winter cereals, 1 × 30 g a.s./ha | | | | | | | | |
| | | | 0.2653 | DI (ditch) | 0.3 | | | |
| | | | 0.2499 | D1 (stream) | 0.3 | | | |
| | | | A.1960 | D2 (ditch) | 34 .6 | | | |
| | | .K | 2.6750 | °⇒D2 (stream) | 2.9 | | | |
| | | | 071916 | D3 (ditch) | .@.2° | | | |
| | | | 0.01 | (pord) | 0.0 | | | |
| Aquatic plants, chronic | | | Q.1481 | D4 (stream) | 0.2 | | | |
| Lemna gibba | $E_r C_{50}$ 9.2 | 0.92 y X Q | 0.0080 | D5 (pond) | 0.0 | | | |
| | | | [∞] 0.1¥509 | ©D5 (stream) | 0.2 | | | |
| | | | £.1939 | D6 (ditch) | 0.2 | | | |
| | | | 0.0000 | CR1 (pond) | 0.0 | | | |
| | | l Ø | 6 . 2 550 | R1 (stream) | 0.3 | | | |
| | × °° C | | 0.5170° | R3 (stream) | 0.6 | | | |
| | | | Q. 33 95 | R4 (stream) | 0.4 | | | |
| Amidosulfuron, winter | reals, 1 × 15 g a.s./ha | , ^o | , O | | | | | |
| l ô | S A S | | 0.1321 | D1 (ditch) | 0.1 | | | |
| | | Ŷ. | 0.1035 | D1 (stream) | 0.1 | | | |
| | | , S | 2.0940 | D2 (ditch) | 2.3 | | | |
| | | 0 O | 1.3370 | D2 (stream) | 1.5 | | | |
| | | r | 0.0957 | D3 (ditch) | 0.1 | | | |
| | | | 0.0054 | D4 (pond) | 0.0 | | | |
| Aquathe plants chronic | | 0.92 | 0.0738 | D4 (stream) | 0.1 | | | |
| Ľemna Gibba 🔊 | | 0.92 | 0.0040 | D5 (pond) | 0.0 | | | |
| | | | 0.0753 | D5 (stream) | 0.1 | | | |
| y. | | | 0.0970 | D6 (ditch) | 0.1 | | | |
| 1 Ori | | | 0.0040 | R1 (pond) | 0.0 | | | |
| | | | 0.1270 | R1 (stream) | 0.1 | | | |
| | | | 0.2601 | R3 (stream) | 0.3 | | | |
| | | | 0.1712 | R4 (stream) | 0.2 | | | |

Table CP 10.2- 10: RACsw; exposure calculations based on FOCUS Step 3

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| Species | Endpoint [µg/L] | RACsw; lt (ErC50/10) | PECsw,max [µg/L] | FOCUS scenario | PEC/RAC |
|---------------------------|---|-------------------------|------------------------|-------------------|-------------|
| Amidosulfuron, spring cer | reals & Flax, 1 × 30 g a.s | s./ha | | | |
| | | | 0.2973 | Dlo Ditch) | 0.3 |
| | | | 0.1953 | Stream) | 0.2 |
| | | | 0.1927 | D3 (Ditch) | |
| Aquatic plants, chronic | E_rC_{50} 9.2 | 0.92 | ∂ , 0.0113€ | D# (Pond) | . 0 |
| Lemna gibba | E ₁ C ₅₀ 7.2 | 5.52 5 | 0.1486 | D4 (Stream) | 0.2 |
| | | ×, | <u>49</u> .0077 r | DS)(Pond) | 10.0 |
| | | | 0.15 | 05 (Stream) | 0.2 |
| | | | Ø.1252 | R4 (Stream) | 0.1 |
| Amidosulfuron, grass (spr | ring), 1 × 45 g a.s./ha | | | | Γ |
| | ⁴ γ ⁴ ⁴ γ ⁴ ⁵ γ ⁴ ⁵ γ ⁴ ⁵ γ ⁴ ⁶ γ | Ô, Ű | 0,3072 | D1 (Ditch) | 0.3 |
| | | | « 0.2524Q [″] | D4Q(Stream) | 0.3 |
| | | | 13,090 | D2 (Ditch) | 14.2 |
| | | £ | <u>.</u> | D2 (Stream) | 9.6 |
| | | °∼ °√0.92 ° | Q 0.287Q | D3 (Ditch) | 0.3 |
| Aquatic plants, chronic | | | Q 0705 | D4 (Pond) | 0.0 |
| Ű. | | | 0.2201 | D4 (Stream) | 0.2 |
| Č* | | 5 S | 0.0112 | D5 (Pond) | 0.0 |
| | | | 0.2359 | D5 (Stream) | 0.3 |
| | Ö Ö "Ø | , S | 0.2461 | R2 (Stream) | 0.3 |
| | | Ő | 0.2659 | R3 (Stream) | 0.3 |
| | | 9 | | | |

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| Species | Endp [µg/ | oint L] | RACsw; lt (ErC50/10) | PECsw,max [µg/L] | FOCUS scenario | PEC/RAC | | | |
|---|--------------|------------|-------------------------|---------------------|-------------------|---------|--|--|--|
| Amidosulfuron, grass (autumn), 1 × 45 g a.s./ha | | | | | | | | | |
| | | | | 0.7153 | D16Ditch) | 0.8 | | | |
| | | | | 0.4647 | Stream) | 0.5 | | | |
| | ErC50 9.2 | | | 11.670 | D2 (Ditch) | | | | |
| | | | °⊗,°8.5990Ç | D2 (Stream) | J .3 | | | | |
| | | | ×. | 0.2941 | D3 (Dutch) | 0.3 | | | |
| Aquatic plants, chronic Lemna gibba | | 9.2 | .2 0.92 | <u>\$9</u> .0224 | DD(Pond) | 200° | | | |
| Lemma gibba | | | | 0.2466 | 04 (Stream) | 0.3 | | | |
| | | | | 0. 2 222 | D5(Pond) | 0.2 | | | |
| | | A.S. | | @ 0.2664 | D5 (Stream) | 0.3 | | | |
| | | | 0,3120 | R2 (Spream) | 0.3 | | | | |
| | | | | ×0.2630Q | R3Q(Stream) | 0.3 | | | |

The refined risk assessment of anoidosulfir on for all intended use situations passes all FOCUS Step 3 scenarios, except D2. Since the PEC values simulated for scenario D2 are driven by the entry route drainage, mitigation options implemented in FOCOS Step 4 (e.g. drift buffer zones, vegetated filter strips) would not reduce the aquatic exposure to amidosulfuron for this particular scenario situation. Therefore, no further risk assessment based on FOCUS Step 4 calculations is presented. In the MSs concerned with the 102 scenario, this situation will be addressed in the national dossiers to be submitted in the post Approval re-registration process

Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and CP 10.2.1 macrophytes

Report: C; 1989; M-125130-01-1 10 2 1/0 ater digersible granule (Hoe 075032 00 WG75 A103) Effect to Title: Orinus co (Minor carp) in a Static-Acute Toxicity Test (method OECD) Report 1 Docum /-125.1*30-01 Guideline(s) Guideline d **GLP/GEP:**

The study reports on an acute oral toxicity test for mirror carp on the formulated product. No dead individuals were observed in the control and in the test concentrations up to 320 mg/L. 90 % and 100 % of the fish died at the treatment levels of 560 mg/L and 1000 mg/L. The 96 h LC_{50} was reported to be 449 mg product/L.

Although the fish used for testing were slightly larger than recommended by OECD guideline 203, the study was accepted in the EU review for the first inclusion of amidosulfuron on Annex I. A study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test, since a lower endpoint resulted from the corresponding study on rainbow trout, KCP 10.2.1/02.

| Report: | KCP 10.2.1/02 ;; 1989 |); M-125129-01-1 |
|-------------------------|----------------------------------|--|
| Title: | Hoe 075032 - water dispersible g | ranule (Hoe 075032 00 WG7 A103) Effect to |
| | Salmo gairdneri (Rainbow trout) | in a Static-Acute Toxicity Test (method OECD) |
| Report No.: | A42090 | |
| Document No.: | M-125129-01-1 | |
| Guideline(s): | OECD: 203 (1984) | |
| Guideline deviation(s): | | |
| GLP/GEP: | yes | |

The study reports on an acute oral toxicity test for rainbox trout on the formulated product. No dead individuals were observed in the control and in the test concentrations ap to 100 mg/K 80 % of the animals were found dead at a concentration of 180 mg/L and 700 % of the fish died at the treatment levels of 320 mg/L - 1000 mg/L. The 96 h LC₅₀ was reported to be 150 mg product/L.

The study was evaluated in the EU review for the first inclusion of amicosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

The study was considered to be acceptable. An ID agreed formulation endpoints expressed on pure active substance equivalent basis, of $ID_{30} = 113.9 \text{ mg a.s./L}$ for *Oncorhynchus mykiss* was derived based on this test.

It is to be noted that aquatic exposure for the present product is crearly driven by the entry routes drainage (maximum PEC values observed for scenarios D1, D2 ditch/stream), and <u>runoff</u> (maximum PEC values for scenarios R3 and R4 stream). Both of these predominant entry routes are indirect paths to surface water, via secondary movements of a deposit from infiltrated soil to water bodies, they will therefore not lead to an actual exposure of the aquatic environment to the intact formulated product. When in soil contact, the formulation will be disintegrated via dilution in the pore water, differential adsorption and retention of its components by soil particles, and biological degradation of its coformulants. The endpoint most relevant for the assessment therefore is considered to originate from the corresponding studies on pure active substance 4/CA 8.2.1 /01...04.

 Report:
 KCP 10.21/03
 B; 1989; Ø-125182-01-1

 Title:
 Hoe (\$5032)
 Oter dispersible \$4 nule (Hoe 075032 00 WG75 A103) Effect to Dap Qia magQi (Water Qiea) in a Static-Acute Toxicity Test (method OECD)

 Report No.:
 A42147

 Document No.:
 M-125182-01-1

 Guideline (s):
 GECD: 202 (194)

 Guideline de train(s)
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 Guideline (\$100, \$100,

The study reports on δ static acute toxicity test for *Daphnia magna* on the formulated product. No mortality was observed in concentrations up to 100 mg/L and in the control. 30 % and 100 % of animals died within 24 hours in test concentrations of 320 mg/L and higher. After 48 hours 45 % of the animals exposed to 100 mg/L were immobile and all animals were found dead at concentrations of 320 mg/L and higher. The 48 h EC₅₀ was reported to be 187 mg product/L, the 48 h NOEC was 100 mg product/L.

The study was evaluated in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

The study was considered to be acceptable. An EU agreed formulation endpoint, expressed on pure active substance equivalent basis, of $LC_{50} = 141.9 \text{ mg a.s./L}$ for *Daphnia magna* was derived based on this test.

It is to be noted that aquatic exposure for the present product is clearly driven by the entry routes $\frac{drainage}{drainage}$ (maximum PEC values were observed for scenarios D1, D2 ditch/stream), and <u>runoff</u> (maximum PEC values for scenarios R3 and R4 stream). Both of these predominant entry routes are indirect paths to surface water, via secondary movements of a deposit from infiltrated soil to water bodies, they will therefore not lead to an actual exposure of the aquatic environment to the intact formulated product. When in soil contact, the formulation will be disintegrated via fulution in the pre water, differential adsorption and retention of its components by soil particles, and biological degradation of its coformulants. The endpoint most relevant for fisk assessment therefore is considered to originate from the corresponding study on pure active substance, KCA 8.2.4/02.

| Report: | KCP 10.2.1/04 ,; 1991; 🖉 -129467201-1 🖉 🔊 🖉 |
|-------------------------|--|
| Title: | Hoe 075032 - water dispersible gradule 75% (Hoe 075032 0) WG75 (104) Exect to |
| | Scenedesmus subspicatus (Green alga) i Grow Inhibit In Test (hethod ECD) |
| Report No.: | A45325 |
| Document No.: | M-129467-01-1 |
| Guideline(s): | OECD: 201 (1984) |
| Guideline deviation(s): | |
| GLP/GEP: | ves X I. A K |
| | |
| Report: | KCP 10.2.1/06 2016; M-349414-91-1 |
| Title: | Validity check Or amides alfuror 75 WG study on Desmod mus subspicatus (M- |
| | 129467-01-1. 1991 1991 S |
| Report No.: | M-549414aa 1-1 |
| Document No.: | M-5494 14 01-1 |
| Guideline(s): | none , OF OF ST A OP |
| Guideline deviation(s): | none of the set of the |
| GLP/GEP: | $n_0 \partial^{\gamma} $ |
| | |
| TT1 / 1 | |

The study reports on a static 72-hour growth inhibition test for *Scenedesmus subspicatus* on the formulated product

The study was performed in 3 steps. The first definitive test was conducted without pH adjustment with concentrations ranging from 10 to \$20 mg/L.

As pH decreased in the first test and no NOEC was reached, the second test included 2 lower concentrations (from 3.2 to 320 mg/L) and pH was adjusted to 7.6 (except for 3.2 and 5.6 mg/L).

This concentration range did not allow to reach the NOEC.

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Consequently, the third test was performed with concentrations ranging from 0.56 to 1.8 mg/L.

The 72 h E₅C₅₀/E_rC₅₀ values were calculated by approximate EC₅₀ and binomial test to be 33.8 (95 % confidence limits 32 - 56 mg/L) and 122 mg/L (95 % confidence limits 100 - 180 mg/l) for the concentrations tested without pH adjustment. The 72 h E_bC₅₀/E_rC₅₀ values for the test concentrations with pH adjustment were calculated as 39.2 mg/L (95 % confidence limits 32 - 56 mg/L) and 157 mg/L (95 % confidence limits 100 - 180 mg/L). The 72 h NOEC was assessed as 1.8 mg/L (without pH adjustment).

The validity criteria of the new version of the OECD guideline 201 (July 2011) have been checked for this study on the 3 consecutive tests:

| | Test 1 | Test 2 | Test 3 | Criteria |
|---|------------|------------|------------|-------------|
| Biomass increase in control | Factor 117 | Factor 114 | Factor 117 | Factor > 16 |
| Mean coefficient of variation for section- by-section specific growth rates in control | 14.6% | 19.8% | 24.00 | 35% |
| Coefficient of variation of average specific growth rates during the whole test period in control | 4.1% | 1.8% | 2.0% | 9% J |
| ê | | | | |

All 3 criteria were met, the study is considered to be valid (M-549410-01-1

The study was evaluated in the EU review for the first inclusion of amidosulfuror on Advex I, a study summary is found in the previous Draft Assessment Report (2006). The study was considered to be acceptable. An EU agreed formulation endpoint, expressed on pure active substance equivalent basis, of $E_bC_{50} = 25.8$ mg a.s./L and $E_rC_{50} = 93$ mg a.s./B for *Scenedesmus subspicatus* were derived based on this test.

It is to be noted that aquatic exposure for the present product is clearly given by the entry routes <u>drainage</u> (maximum PEC values were observed for scenarios D1, D2 ditch/stream), and <u>runoff</u> (maximum PEC values for scenarios R5 and R4 stream). Both of these predominant entry routes are indirect paths to surface water, via scondars movements of a deposit from infiltrated soil to water bodies, they will therefore not lead to an actual exposure of the aquatic environment to the intact formulated product. When in soil contact, the formulation will be disintegrated via dilution in the pore water, differential adsorption and retention of its components by soil particles, and biological degradation of its coformulants. The endpoint most relevant for risk assessment therefore is considered to originate from the corresponding study on pure active substance KCA 8.2.6.1/01.

The study reports on a growth inhibition test for *Lemna gibba* on the formulated product. The frond numbers in the control reached an average of 184 fronds after 7 days corresponding to a doubling time of 1.8 days. Chlorofis, smaller fronds and inhibited separation of daughter plants were observed at a concentration of 0.96 µg formulation/L and above. No significant effects on growth (growth rates based on frond counts, log area under the growth curve and dry weights) were observed up to a test substance concentration of 2.96 µg/LOA 7-d $E_bC_{50} = 10.1 \mu g/L$, a $E_rC_{50} = 10 \mu g/L$, 7-d NOEC (visual effects) = 0.98 µg/L and a 7-d NOEC (growth) = 2.96 µg/L were reported.

The study was waluated in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

The study was considered to be acceptable. EU agreed formulation endpoints, expressed on pure active substance equivalent basis, of $E_bC_{50} = 0.00773$ mg a.s./L and $E_rC_{50} = 0.00765$ mg a.s./L for *Lemna gibba* were derived based on this test.

It is to be noted that aquatic exposure for the present product is clearly driven by the entry routes drainage (maximum PEC values were observed for scenarios D1, D2 ditch/stream), and runoff

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(maximum PEC values for scenarios R3 and R4 stream). Both of these predominant entry routes are indirect paths to surface water, via secondary movements of a deposit from infiltrated soil to water bodies, they will therefore not lead to an actual exposure of the aquatic environment to the intact formulated product. When in soil contact, the formulation will be disintegrated via dilution in the pore water, differential adsorption and retention of its components by soil particles, and biological degradation of its coformulants. Endpoint most relevant for risk assessment therefore is considered to originate from the corresponding study on pure active substance, KCA 8.2.7 /02

| CP 10.2.2 | Additional long-term and chronic toxicity studies on fish, aquatic |
|---------------------|---|
| | invertebrates and sediment dwelling organisms |
| | |
| Report: | KCP 10.2.2/01 |
| Title: | Hoe 075032 - water dispersible genule (My e 075032 00 W 55 A10) Effective |
| | Salmo gairdneri (Rainbow trout) in a 21 Gay Produged Toxicity Test (method |
| | OECD) |
| Report No.: | A42066 |
| Document No.: | M-125111-01-1 |
| Guideline(s): | OECD: 204 (1984) |
| Guideline deviation | on(s): |
| GLP/GEP: | yes A O' Q A A A |
| | |

The study reports on a flow-through 20 day polonge@toxicit@test for rainbow frout on the formulated product. Some fish showed slow reactions and swimming at the water surface and reduced uptake of feed at a concentration of 5 mg/L and above. No intoxication symptoms were observed up to a concentration of 1 mg/L. The growth was significantly reduced at a concentration level of 50 mg/L. Dead fish were observed at the highest test concentration of 50 mg/L contly. A 21-d LC₅₀ = 30.1 mg/L, a 21-d NOEC (growth) = 10 mg/L (= 7.59 mg a.s./L) and a 21-d NOEC (intoxication symptoms) = 1 mg/L (= 0.759 mg a.s./L) were reported.

The study was evaluated in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Diaft Assessment Report (2006).

The OECD Guideline 203 suggests an opper limit for the total water hardness of 250 mg CaCO₃. This limit was clearly exceeded and could have potentially influenced the test results. Nevertheless, the study was considered to be acceptable because amidosulfuron is of low acute toxicity to fish and the results of the chronic study with the unformulated a.s. suggest that the results of the chronic study with the unformulated a.s. suggest that the results of the chronic study with the unformulated a.s. suggest that the results of the chronic study with the unformulated a.s. suggest that the results of the chronic study with the unformulated a.s. suggest that the results of the chronic study with the substance equivalent basis, of NOEC growth = 7.59 mg a.s./L for *Oncorhynchus mykiss* was derived based on the test.

It is to be noted that addatic exposure for the present product is clearly driven by the entry routes drainage (maximum PEC values were observed for scenarios D1, D2 ditch/stream), and <u>runoff</u> (maximum PEC values for scenarios R3 and R4 stream). Both of these predominant entry routes are indirect paths to surface water, via secondary movements of a deposit from infiltrated soil to water bodies, they will therefore not lead to an actual exposure of the aquatic environment to the intact formulated product. When in soil contact, the formulation will be disintegrated via dilution in the pore water, differential adsorption and retention of its components by soil particles, and biological degradation of its coformulants. The endpoint most relevant for risk assessment therefore is considered to originate from the corresponding study on pure active substance, KCA 8.2.2 /01.

| Report: | KCP 10.2.2/02 | B; 1989; M-125137-01-1 | | | | |
|-------------------------|----------------------|-----------------------------------|---|---------|---------|---|
| Title: | Hoe 075032 - water (| dispersible granule (Hoe 07503) | 2 00 WG75 A1 | 03) Eff | fect to | |
| | Daphnia magna (Wa | terflea) in a 21-day Reproduction | on Test (method | 1 OECI | D) | |
| Report No.: | A42100 | · • • | | | | |
| Document No.: | M-125137-01-1 | | | | | |
| Guideline(s): | OECD: 202 (1984) | | Řo | | | |
| Guideline deviation(s): | | | | | | |
| GLP/GEP: | yes | | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ |)° | Ś | ۵ |

The study reports on a static renewal 21-day reproduction test for *Daphrod magna* on the formulated product. The mortality was not statistically different from the control. A reduced reproduction rate was found at a concentration of 10 mg/L on day 12. At day 06 this was compensated by a higher reproduction rate on day 16 and no significant difference was evident for this treatment level at the end of test. After 21 days a significant effect on the reproduction rate was observed at the highest treatment level only. A 21-d NOEC (reproduction) = 32 mg/L ($\ll 24.3$ mg/a.s./L) was reported.

The study was evaluated in the EU review for the first inclusion of amidosulfuron on Annexe, a study summary is found in the previous Draft Assessment Report (2006),

The study was considered to be acceptable. However no EU agreed endpoint was derived from this test.

It is to be noted that aquatic exposure for the present product is clearly driven by the entry routes $\frac{drainage}{drainage}$ (maximum PEC values were observed for scenarios D1, $\frac{1}{D2}$ ditch/stream), and $\frac{runoff}{runoff}$ (maximum PEC values for scenarios R3 and R4 stream). Both of these predominant entry routes are indirect paths to surface water, via secondary movements of a deposit from infiltrated soil to water bodies, they will therefore not lead to an actual exposure of the aquatic environment to the intact formulated product. When in soil contact, the formulation will be disintegrated via dilution in the pore water, differential adsorption and retention of its components by soil particles, and biological degradation of its coformulants. Endpoint most relevant for visk as essment therefore is considered to originate from the corresponding study on pure active substance, KCA 8.2.5.1/01.

CP 10.2.3 Further testing on aquatic organisms

Further data on the formulation are not required under \mathbb{C} ommission Regulation (EU) No 284/2013 in accordance with Regulation (EC) No \mathbb{Q} 07/2009.

CP 10.3 Effects on arthropods

CP 10.3.1 Effects on bees

The risk assessment has been performed according to the existing guidance in force at the time of the preparation and submission of this dossier namely the EU Guidance Document on Terrestrial Ecotoxicology (SANCO/ 10329/2002 rev 2) and EPPO Standard PP 3/10 (3) Environmental Risk Assessment Scheme for Plant Protection Products - Chapter 10: honey bees.

Commission Regulations (EU) 283/2013 and 284/2013 require where bees are likely to be exposed, testing by both acute (oral and contact) and chronic toxicity, including sub-lethal effects, to be conducted. Consequently in addition to the standard toxicity studies performed with adult bees (OECD 213 and 214) the following additional studies are also provided:

• Acute oral and contact toxicity of amidosulfuron and the representative formulation Amidosulfuron WG 75,

- Acute oral and contact toxicity of amidosulfuron to adult bumble bees under laboratory conditions,
- Chronic 10 day toxicity test with of Amidosulfuron WG 75 on adult bees under laboratory conditions,
- Colony feeding study with Amidosulfuron WG 75 according to et al. 1992 (using a realistic worse case spray solution concentration and covering exposure for effects on brood (eggs, young and old larvae) and their development,
- Semi-field brood feeding study with Amidosulfuron WG 75 following OECD GD 75 (using a more realistic spray scenario onto flowering Phacelia tangetifolia at the maximum application rate for the approval renewal of amidosulfuron and covering exposure for effects on brood (eggs) and their development and colony parameters).

Details of the honey bee testing with amidosulfuron are presented together with the ecotoxicological endpoints in Document MCA 8, point 8.3.1, as well as within the existing Draft Assessment Report (DAR) and the updated EU List of Endpoints of December 2010, Furthermore, oral and contact laboratory toxicity data for bumble bees indicated that non-Apis bees are not more sensitive than honey bees and consequently the risk assessment for honey bees is considered to be protective to other bees. \bigcirc

1991; M-135739-01-2, An acute oral laboratory study with Amidosulfurgn WG 75% KCP 10.3.1.1.1 /01) had been already available but was described and rated as invalid due to deficiencies in the test design (missing toxic standard) in the EU regiew for the first inclusion of amidosulfuron on Annex I. Furthermore, several laboratory studies had been available in the DAR, which however followed outdated test guidelines or had been performed following test designs that are no longer applicable today and an consequence do not meet surrent validity criteria and/or data requirements (i.e. contact exposure via filter paper or via direct overspray). Therefore, all these studies which are either invalid and hot performed according to state of the art methods are presented in the following table for reasons of completeness but are consequently superseded in the approval renewal process by a new guideline-conform state of the art acute oral and contact toxicity test on honey bees ; 2011; M-403727-00-1, KCP 10.3, 1.1.1 /04 and KCP 10.3.1.1.2 /07) that was performed with Amidosulfuron MG 75.

A summary of the critical endpoints for midos furon and the formulated product Amidosulfuron

A summary of the critical endpoints for amidosulfiuron and the formulated product Amidosulfuron WG 75 are provided in the following table. Endpoints chown in bold are considered relevant for risk assessment

| Table CP 10.3.1-1: | Endpoints of the active substance amidosulfuron (techn. and representative formulation |
|--------------------|--|
| | Amidosulfuron WG 75) |

| Test substance | Test | Study type | Endpoint | Reference | |
|------------------------|---------------------|---|---|----------------------|--|
| | organism | | p | | |
| Acute toxicity to | honey bees | | | | 1000 M |
| | | oral, 48 h | LD_{50} > 916.4 µg a. | s./bee ¹⁾ | ; 1989; M- 124106-01-1 KCA 8.3.1. k/ /01 |
| Amidosulfuron, | Apis | oral, 48 h | LD ₅₀ > 109.2 μg a . | s./bco> | ; 2014; € ⁄1- ©503119 =0 1-1 |
| tech. | mellifera | contact, 48 h | LD ₅₀ > 100 µg a.s. | /bee | KCA 3.3.1.1.2 /02 KCA 8.3.1.1.2 /02 |
| | | contact, 48 h | LD ₅₀ 100 49 a.s./ | | тористика Стана КСА- КСА- КСА- КСА- КСА- КСА- КСА- КСА- |
| | | oral, 48 h | LDQ ~ 106.6 µg a. | s./bee | ; 2011; M- 403727-014 • CP 10: 1 1 1/04 |
| | | contact, 48 h | LD ₅₀ >> 100 for a.s./ | 'bee ' | KCP f0.3.1.1.2 /07 |
| | | oral, 48 p | | ./bee_1 | ,; 1991; M- 135739-01-2 ©CP 10.3.1.1.1 /01 |
| | Apis mellifera L | oral ^O , 72 h Č | ≥ 100 bg pro LD ₅₀ = ≥05 µg аб | pee bee | ; 1992; M-130984- 01-1 |
| Amidosulfuron | | Qontact ♂, 72,07 | No effects f 0.04 & sol | ution | KCP 10.3.1.1.1 /02 KCP 10.3.1.1.2 /01 |
| | | ora ^{2) 4)} , 72 h | $\frac{\text{LD}_{50}}{\text{D}_{50}} > 135 \text{ yg prov}$ | Pee | 1991; M- 130976-01-2 |
| | | $ \begin{array}{c} \text{contact}^{395)}, \\ \begin{array}{c} & & \\ &$ | No effor of 0.00% sol | ution | KCP 10.3.1.1.1 /03 KCP 10.3.1.1.2 /03 |
| ** | | Chtact ³⁾ E h | Peffect of 0.04 % sol | ution | 1991; M-130728-01-2 KCP 10.3.1.1.2 /04 |
| E. | | conflict ⁵⁾ , 72, 9 | No effect of 0.04 % sol | ution | 1991; M- 130674-01-2 KCP 10.3.1.1.2 /02 |
| Acute toxicity to | bumble bees | | 0 | | |
| Amidosulfuron, | Ö Bombi | acai, 48 h O | $^{\nu}$ LD ₅₀ > 203 µg a.s./ | bee | ; 2016; M- 545712-01-1 KCA 8.3.1.1.1 /03 |
| tech | terrestris | contact, 48 h | LD_{50} > 100 µg a.s./ | bee | ; 2015; M- 525139-01-1 KCA 8.3.1.1.2 /03 |
| Chronic toxicity | to adult koney | bees | | | |
| Amidosulfuron WG 75 | Apis Mellifera | 10 d adult feeding study | $\begin{array}{ll} LC_{50} &> 3333 \text{ mg a.s.} \\ LDD_{50} &> 78.4 \ \mu \text{g a.s.} \end{array}$ | s./kg /bee/d | ,; 2016; M-549770-01-1 KCA 8.3.1.2 /01 KCP 10.3.1.2/01 |

| Test substance | Test organism | Study type | Endpoint | Reference |
|------------------------|-------------------|---|--|--|
| Honey bee broo | d feeding study | | | |
| Amidosulfuron WG 75 | Apis mellifera | Honey bee brood feeding (<i>definition</i> et <i>al.</i> , 1992) | No adverse effects on bee mortality (adult, pupae and larvae), bee brood development (eggs, young larvae, old larvae), and behaviour, by feeding honey bee colonies sugar syrup at a concentration typically present in the spray tank (0, P14 g as /L) | ; 2014; M-482118- 01-1 ° KGA 8.3.1 (5) 01 KCP 10.3.1.3/01 |
| Semi field honey | v bee brood stud | ly | | <u> </u> |
| Amidosulfuron WG 75 | Apis mellifera | Semi-field honey bee brood study (OECD No. 75; forced exposure conditions) in Phacelia; application during ful- bloom and bees actively for aging ~ | No adverse effects on mortality (adotts, purple and larvae), foraging activity behaviour, colony condition, colony strength and bee brood development at 45 a a.s./ha | Mi-5457Q0-01-1 KCA \$1.13/02 KCP 10.3.1.3/02 |

a.s. = active substance; prod. = produce **Bold:** values used in risk assessment ¹⁾ Study not considered valid Ô A,

²⁾ Study performed according to outdated wideline, not an appropriate test design to derive endpoints for use in current regulatory risk assessment

current regulatory risk assessment ³⁾ Direct contact of the bees to the residues of the test substance on filter paper, not an appropriate test design to derive endpoints for use in current regulatory fisk assessment ⁴⁾ EU agreed endpoint according to the updated EUList of Fourpoints for December 2010

5) Direct spraying of the dest substance of the honey bees, for an appropriate test design to derive endpoints for use in current regulatory risk assessment.

Risk assessment for bees

The risk assessment for bees is based on the maximum application rate of 1×30 g amidosulfuron/ha in cereals, for the maximum application rate of 1×30 g amidosulfuron/ha in flax and for the maximum application rate of 1/2/45 g apridosulfuron/ha in grassland.

Hazard Quotients

0 The risk assessment is based on Wazard Quotient approach (Q_H) by calculating the ratio between the application rate (expressed in g a.s./ha or in g total substance/ha) and the laboratory contact and oral LD₅₀ (expressed in µga.s./be@or in µg total substance/bee).

Q_H values can be calculated using data from the studies performed with the active substance and with the formulation Q_H values higher than 50 indicate the need of higher tiered activities to clarify the actual risk to honey bees.

 $Q_{HO} = \frac{\text{max. appl. rate}}{\text{LD}_{50} \text{ oral}} = \frac{[\text{g a.s./ha or g total substance/ha}]}{[\mu \text{g a.s./bee or } \mu \text{g total substance/bee}]}$ Hazard Quotient, oral:

Ô

Hazard Quotient, contact: $Q_{HC} = \frac{\max. appl. rate}{LD_{s0} \text{ contact}} = \frac{[g a.s./ha \text{ or } g \text{ total substance/ha}]}{[\mu g a.s./bee \text{ or } \mu g \text{ total substance/bee}]}$

| | Crop | LD50 [µg/bee] | Application rate [g/ha] | Hazard quotient Qно | Trigger |
|---------------|-----------|------------------|----------------------------|------------------------|-------------|
| | Cereals | | 30 | < 0.3 | 50 7 |
| Amidosulfuron | Flax | > 109.2 | 30 | < 0.3 | |
| | Grassland | | 45 | < 0.4 | JOSO OF A X |
| | | | | A 0 | |

 Table CP 10.3.1-2:
 Hazard quotients for bees – oral exposure

The hazard quotients for oral exposure are below the validated trigger value for higher tier testing (i.e. $Q_{HO} < 50$). Risk to bees from oral exposure is therefore acceptable for the intended product press.

Table CP 10.3.1- 3: Hazard quotients for bees – contact Q posure

| | | - | ~ | | | ~ |
|---------------|-----------|------------------|----------------------------|--|---------|------------|
| | Crop | LD50 [µg/bee] | Application rate [g/ha] | Hazard quotient | Trigger | j O |
| | Cereals | | 30 | \sim < 0 \sim | \$ 50 | 63 |
| Amidosulfuron | Flax | > 100 | 300 | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | 50 0 | °° |
| | Grassland | | <u>4</u> 3 | 20.45 | 50 | <i>a</i> 1 |
| | | | | | | 2 |

The hazard quotients for contact exposure are below the validated trigger value for higher tier testing (i.e. $Q_{HC} < 50$). Risk to bees from contact exposure is therefore acceptable for the intended product uses.

Further considerations for the risk assessment

Moreover, anidosulfurón (tested as Amidosulfuror, WG 75) was further subjected to chronic laboratory testing with adult oney hors (1997), 2016; M-549770-01-1; in CA 8.3.1.2).

This chronic study was designed as a limit test by exposing young worker bees for 10 consecutive days to a nominal concentration of 3313 mg anidosulfuron/kg feeding solution, respectively. The actual test was conducted by using the formulated product Amidosulfuron WG 75. After exposing honey bees for ten consecutive days exclusively to sugar solution containing amidosulfuron, the 10 day LC₅₀ (Lethal Concentration) was determined to be > 3333 mg amidosulfuron/kg, which corresponds to a LDD₅₀ (Lethal Dietary Dose) of >78.4 µg a.s./bee/day. The respective NOEC (No Observed Effect Concentration) for mortality was determined to be \geq 3333 mg amidosulfuron/kg, which corresponds to the NOCDD (No Observed Effect Dietary Dose) of \geq 78.4 µg a.s./bee/day.

In order to reveal whether amidosulfuron poses a risk to immature honey bee life stages, a bee brood feeding study (**1999**); **1999**; 2014; M-482118-01-1, in CA 8.3.1.3) has been conducted by following the provisions/method of **1999**. (OEPP/EPPO Bulletin 22:613-616 (1992)), which require, amongst other parameters to "...*use formulated products only... products are fed at a concentration recommended for high-volume use...*". The honey bee brood feeding test is a worst-case screening test, by feeding the honey bees directly in the hive with a treated sugar solution which contains the test substance at a concentration typically present in the spray tank (and as such at a very high concentration) and by investigating the development of eggs, young and old larvae by employing digital photo imaging technology.

This particular study was conducted with Amidosulfuron WG 75. The administration of amidosulfuron at a concentration of 0.114 g a.s to honeybee colonies via feeding of 1 litre spiked sucrose solution has neither resulted in adverse effects on brood development, worker, larval or pupal mortality compared to the control. Regarding brood development, the brood termination rates of the test item treatment were overall on a low level with 21.6, 11.1 and 6.2 % for eggs, young larvae and old larvae, respectively, which were not statistically significant different to the control with brood termination rates of 17.8, 10.2 and 6.4 % for eggs, young larvae and old larvae, respectively at the end of the brood observation period.

In order to clarify whether amidosulfuron poses a risk to honey bee brood and colony development in particular as well as on honey bees in general under realistic worst-case conditions, a higher tier semifield honey bee brood study (according to the provisions of the OPCD Grudance Document 75) was conducted under forced/confined exposure conditions using the formulation Amidosulturon WG 75, by application of 45 g a.s./ha under tunnel conditions to the orll flowering and highly bee attractive surrogate crop *Phacelia tanacetifolia* (2016; M-54572)-01-1; in CA 8.3.1.3).

The study included three treatment groups: Control (tap water), fest item (45 g s./ha) and Reference item (300 g fenoxycarb/ha) with all applications being carried out with a spray volume of 400 L water/ha. For all treatment groups, four replicates (tunnels) were set up The application of all treatments was conducted during daily bee flight activity at the time of full flowering of the crop. Thereafter, the bees were kept for 3 days within the turnels (confined exposure phase) and were then relocated out of the tunnels and transferred to a monitoring site without flowering crops and intensive agricultural area for further monitoring (day 4 to day 41 after treatment). Throughout the confined exposure phase, mortality of worker bees farvae and pupae was assessed daily along with assessments of foraging activity and behaviour. Daily mortality assessments were continued along with behaviour around the hive during the post-exposure observation period (day 4 to day 27 after treatment). Colony assessments (food stores, brood areas, colony strength) were made one day after application, on 5 occasions after applications and at the end of the study in order to cover two whole bee brood cycles. Detailed brood assessments (brood development, brood termination rate, brood index and brood compensation index) by employing digital photo imaging technology, investigating the fate of 250 individually marked cells was performed on 5 occasions (broughout the study, covering an entire brood cycle of honey bees)

The application of andosulfuron at the rate of 45 g a.s./ha under tunnel conditions to the full flowering and highly bee attractive surrogate crop *Phacelia tanacetifolia* did not cause any adverse effects on mortanity of worker bees or pupae, foraging activity, behaviour, colony development, colony strength as well as on bee brood development (brood termination rate: 47.4 %, brood index: 2.6, compensation index: 3.8 in test item compared to the control with brood termination rate: 29.7%, brood index 3.5, compensation index: 3.9). Weither brood termination rate nor brood or compensation index were significantly different in the test item as compared to the control, indicating that these indices performed comparable to the control, including compensations of previous brood losses.

All in all, it can be concluded from the acute and chronic laboratory studies in adult honey bees as well as from the bee brood feeding study (**1999**) *et al.* and OECD Guidance Document 75) investigating side-effects on jummature honey bee life stages, that amidosulfuron is of low general intrinsic toxicity to honey bees.

<u>Synopsis</u>

Amidosulfuron is of low acute toxicity to honey bees, with LD_{50} (oral and contact) above the highest tested dose levels.

The calculated Hazard Quotients for amidosulfuron are below the validated trigger value which would indicate the need for a refined risk assessment; no adverse effects on honey bee mortality are to be

expected at the maximum envisaged application rate. This conclusion is confirmed by the results of the bee brood feeding study as well as by the results of the bee brood semi-field study, which covered the maximum application rate of 45 g a.s./ha.

The acute laboratory studies conducted with bumble bees revealed no sensitivity differences between honey bee and bumble bee foragers.

It can be concluded from the acute and chronic laboratory studies in adult honey bees as well as from the bee brood feeding study (eet al.) and bee brood semi-field study (OECD 75), investigating side-effects on immature honey bee life stages that amidosulfuron is of low general intrinsic toxicity to honey bees.

Regarding potential side effects of amidosulfuron on immature honey bec/life stages, the conducted bee brood feeding study (*et al.*, 1992) found no statistically significant differences between test item and control in brood termination rates of eggs young and old larvae *avp.*114 g a.s./L overall the study revealed no adverse effects on the survival of adult bees and pupae. Thus, when considering the severity of the exposure situation in this worst-case screening test in combination with the absence of effects on the overall development of bee brood, it can be concluded even on the basis of this worst-case screening study that the use of amidosulturon does not pase an unacceptable risk for adult honey bees, immature honey bee life stages and honey bee colonies.

In order to clarify whether the conclusions on the basis of lower fiered honey bee studies are correct, amidosulfuron was subjected to contined sent-field testing (according to the provisions of OECD Guidance Document No. 75), by applying the rate of 45 gals./ha to full thewering *Phacelia* during honey bees actively foraging on the crop. This study design is from an apidological and apicultural point of view more realistic than an in-live feeding of the test compound via a treated sugar solution, which contains the test substance at a concentration typically present in the spray tank (and as such at a very high concentration). The results of this higher tier semi-field study confirmed the conclusions made above on the basis of the outcome of the lower-tiered studies, as no adverse direct or delayed effects on mortality of worker bees or pupae, foraging activity, behaviour, colony strength and colony development as well as the development of bee broop were observed, even under aggravated, forced exposure conditions and by digitally following-up in a very detailed manner the fate of individually marked brood cells (digital photographic assessment) from egg stage until emergence.

Conclusions

Overall, it can be concluded that an idosulf from, when applied in cereals and flax at the maximum application rate of 30 g as /ha and on grassland at the maximum rate of 45 g a.s./ha, as foreseen for the use of Amidesulfuren WG 35, does not pose an unacceptable risk to honey bees and honey bee colonies.

Acute to bees CP 10.3.1%1.1 cute or a toxicity to bees KCP 10.3.1.1.1/01 ; 1991; M-135739-01-2 **Report:** Hoe 075032; water dispersible granules; 75 % (Hoe 075032 00 WG75 A104) Title: Investigating the oral toxicity to the honey bee Apis mellifera L. Report No.: A51977 M-135739-01-2 Document No .: Guideline(s): MAFF: Working Document 7/3 (1986) Guideline deviation(s): **GLP/GEP:** ves

The study reports on the acute oral LD₅₀ of the formulated product AE F075032 00 WG75 A104 to be > 1400 μ g a.s./bee (48 h). However due to deficiencies in the test design (missing toxic standard) this study was rated invalid in the first EU review.

In consequence, no EU agreed endpoint for acute oral toxicity was derived from this test.

For approval renewal, the study is superseded by a new guideline-conform or a acute toxicity test on honey bees for the formulation, see reported below under KCP 10.3.1.1.1 /04

KCP 10.3.1.1.1/02 **Report:** 992; Ma 309844 Title: Toxicity testing of HOE 075032 00 W (Hymenoptera, Apidae) in laboratory Report No.: A47036 M-130984-01-1 Document No .: Guideline(s): BBA: Part VI, 23-1 Guideline deviation(s): --**GLP/GEP:** yes

The study reports on toxicity tests with the forbulated product AE F05032 00 WG75 A104 in four laboratory trials: exposure to vapour, to residues on the ated filter paper, to direct spray treatment and oral intake of contaminated food. The study confirmed an overall law toxicity of the formulation upon inhalation and contact exposure. In the oral toxicity part an LD3 > 100 µg product/bee (72 h) was concluded.

The study was rated valid in the EU review for the first inclusion of anidosulfuron on Annex I, a study summary is found in the previous Monograph. Since the previous EU endpoint for oral acute toxicity of the formulation was based on the result of study KCP 10.3. § 1.1/03 (see below), no formal EU endpoint was based on this test. However, since the study was performed according to an outdated guideline it is superseded by a new guideline-conform study performed with the product.

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Report: Title: ACCP 10C 1.1.1/03 ; 1995 M-136976-01-2 Investigating the side-effects of Lee 075 00 WG75 A104 on the honey bee (Apis mellifera) in the laboratory

Report No.: Document No Guideline(s): Guideline de**¢** GLP/GEP:

The study reports on toxicity tests with the formulated product AE F075032 00 WG75 A104 in four different laboratory trals: exposure to vapour, to residues on treated filter paper, to direct spray treatment and oral intake of contaminated food. The study confirmed an overall low toxicity of the formulation upon inhalation and contact exposure. In the oral toxicity part, an $LD_{50} > 135 \,\mu g$ product bee (72,h) was concluded.

The study was rated valid in the \underline{FU} review for the first inclusion of amidosulfuron on Annex I, a study summary is found to the previous Monograph.

An EU agreed endpoint for oral acute LD_{50} of > 101 µg a.s./bee - expressed in units of a.s.-was derived from this test. However, this study was performed according to an outdated test guideline and is superseded by a new guideline-conform study performed with the product (see KPC 10.3.1.1.1./04). The findings from the new study confirm the low toxicity of the product and are in agreement with the previously obtained findings.

New study:

The study that is summarized below was performed according to currently accepted and valid test guidelines and supersedes all previous performed studies that were conducted with Amidosulfuron WG 75 according to outdated or invalid test guidelines.

KCP 10.3.1.1.1/04 ; 2011; M-403727-01-1 **Report:** Effects of amidosulfuron WG 75 W (acute contact and oral) of honey bees (Apis Title: mellifera L.) in the laboratory Report No.: 60671035 Document No.: M-403727-01-1 Guideline(s): OECD 213 and 214 (1998) Guideline deviation(s): none **GLP/GEP:** yes

Executive Summary:

The purpose of this study was to determine the access contact and pral to pray to EAmid wilfuron WG 75 to the honey bee (A. mellifera L.) under laboratory conditions following the current valid test guideline (OECD 213 and 214). For this purpose 50 female worker bees were exposed for 48 hours to a single dose of 100.0 µg a.s. per bee by topical application (contact dest) and to a single dose of 106.6 µg a.s. per bee by feeding (oral test, value based on the actual intake of the test item). Mortality of the bees was used as the toxic endpoint. Sublethal effects, such as changes in behaviour, were also monitored.

166.6 µg a.s./bee. The contact LD₅₀ (48 h) was > 100.0 g å. s./bee. The gral LD (48 Ć

Material and methods:

Test item: Amidosulfuron WG 73 W; Specification No. 102000000550-02; Batch ID: EFKE001914; Analysed content of amidosukturon (AP F075032): 74.8 % w/by; Sample description: TOX 08735-00.

Test units were stainless steel capes of Jer cm x 8.5 cm a 5.5 cm (length x width x height). 10 bees were used per test unit. I test units were used per test iten dose vevel, control and reference item dose level, respectively. 50 worker bees (Apris mellitera) were exposed for 48 hours to a single dose of 100.0 µg a.s. per bee by topical application (contact test) and 50 worker bees were exposed for 48 hours to a single dose of 106.6 µg a@ per be by feeding (and test, Value based on the actual intake of the test item).

For the contact test, one 5 µL droplet of Apodosylfuron WG 75 in an appropriate carrier (tap water + 0.5 % Adhäsit) was placed on the dorsal bee thorax. For the control one 5 µL droplet of tap water containing 0.5 Adhäst was used. The reference item was also applied in 5 µL tap water (dimethoate made up in tap water containing 0.5 & Adhas ().

For the oral test, aqueous stock solutions of the test item and reference item were prepared and mixed with reacty-to-use sugar syrup (30 % sucrose, 31 % glucose, 39 % fructose) at a concentration of 50 % (w/w). For the control, water and sugar syrup was used at the same ratio (1 + 1). The treated food was offered in syringes, which were weighed before and after introduction into the cages. After a maximum of 35 minutes the uptake was complete (duration of uptake was 35 minutes for the test item treatments) and the syringes containing the treated food were removed, weighed and replaced by ones containing fresh, untreated food.

The number of dead bees was recorded after 4 hours (first day); 24 and 48 hours. Behavioural abnormalities (e.g. vomiting, apathy, intensive cleaning) were assessed after 4 hours (first day); 24 and 48 hours. Temperature during the test was 24 - 25 °C; relative humidity was 55 - 92 %. Bees were kept in darkness (except during observation).

August 18, 2010 – August 25, 2010 **Dates of work:**

Results:

Table CP 10.3.1.1.1-1: Validity criteria

| Validity Criteria | | Recommended | Obtained | |
|--|--------------------------------|-------------------------|------------------------|--|
| | Contact Test 🖏 | | | |
| Control mortality | CO ₂ /water control | < 10% | 0.0% | |
| | | Oral Test | | |
| | Water/sugar control | < 10% | | |
| | | Contact Test | | |
| LD ₅₀ of reference item (24 h) | | 0.10 - 0.30 μg/μ s²/bee | مُنْ 0.19 μgs/a.s./bge | |
| | | Ora, Test 🚬 | | |
| | | 0.10 - 0.35 ug a.s./bes | 🕵 0.109 μg a subee | |
| | | | | |

The contact and oral test is considered valid as the control motality in each control = 10% and the LD₅₀ values obtained with the reference item (dimethoate) were within the required ranges.

Biological results:

Contact Test:

At the end of the contact toxicity test (48 hours after application), no mortality occurred at 100.0 μ g a.s./bee. There was also no mortality in the control group (water $\neq 0.5$ % Adhäsit)

Oral Test:

In the oral toxicity test, the maximum nominal test level of amidos Ω furon WG 75 W (100 µg a.s./bee) corresponded to an actual intake of 100.6 µg a.s./bee. This dose level led to no mortality after 48 hours. In the control group (50 % storar solution), also no mortality occurred.

No test item induced behavoural effects were observed at any time

Table CP 10.3.1.1.1-2 Foxicity of Amidosulfuror WG 75 to honey bees; contact and oral laboratory test

| Test Item | Angedosulfu | ron WG 75 |
|-------------------------------|--------------------------------------|--------------------------|
| Test Object 🔍 🧟 🔊 | Reference Apis me | llifera |
| Exposure | (solution in Adhäsit (0.5 %)/ water) | oral (sugar solution) |
| Application rate us a.s./bet | | 106.6 |
| LD ₅₀ µg a.s./be | \swarrow > 100.0 | > 106.6 |
| LD ₂₀ µg a.s./bee* | \$ \$700.0 | > 106.6 |
| LD ₁₀ µg a.s Dree* | 100.0 | > 106.6 |
| NOED µg a.s./bee | ⊘ ≪ ≥ 100.0 | ≥ 106.6 |

* Since no mortality was observed at the tested dose, the values for NOED, LD_{20} and LD_{10} values are extraported to be above the tested dose.

The contact and oral LDs (24 h) values of the reference item (dimethoate) were calculated to be 0.19 μ g a.s./bee, respectively.

Conclusions:

The toxicity of Amidosulfuron WG 75 was tested in both, an acute contact and an acute oral toxicity test on honey bees. The contact LD_{50} (48 h) was > 100.0 µg a.s./bee. The oral LD_{50} (48 h) was > 106.6 µg a.s./bee.

CP 10.3.1.1.2 Acute contact toxicity to bees

| Report: | KCP 10.3.1.1.2/01 ; 1992; M-130984-01-1 |
|---------------------------------------|---|
| Title: | Toxicity testing of HOE 075032 00 WG 75 A104 to honey bees (Apis mellifera L) |
| | (Hymenoptera Apidae) in laboratory |
| Report No : | |
| Decument No : | M 120094 01 1 |
| Document No | IVI-150984-01-1 |
| Guideline(s): | BBA: Part VI, 23-1 |
| Guideline deviation(s): | |
| GLP/GEP: | yes |
| | |
| A brief study description | n has been provided in the section before, see KCP/10/3.1.1.1/02. |
| · · · · · · · · · · · · · · · · · · · | |
| The study reports on t | covisity tasts performed with the formulated protect ADE07500 00 WC75 |
| The study reports on t | oxicity tests performed with the formulated product Art F0/5052 00 WO/5 |
| A104 in four laborator | y trials: exposure to vapour, to residues on treated filter paper, to direct spray |
| treatment and oral inta | ke of contaminated food. The study confirmed an overall low toxicity of the |
| formulation upon conta | ct exposure (residues on treated filter paper direct spray). |
| 1 | |
| The study was rated w | alid in the EU ravious for the Arat in Algian Camidooulfuror an Annay I a |
| The study was falled v | and in the EU leview for the strict increasion of anneasuntrion on Annex I, a |
| study review is found | in the previous Monograph, Since the study by its design does not deliver |
| contact toxicity endpoi | ints suitable for scandard of a sessment, no formal EL endpoint for acute |
| contact toxicity was de | erived based on this test. However, the study was performed according to an |
| outdated guideline and | is superseded by a modeline conform study berformed with the product see |
| KCP 10 3 1 1 2 /07 | is supersedent of a Sourcement sourcement of white the product, see |
| KCI 10.5.1.1.2707. | |
| | |
| Report: | KCP 10.3.1.1.2.02 |
| Title: | Hoe 0.5032 ; wher dispersible granules; \mathcal{F}_5 % (H $_{0.5}075032$ 00 WG75 A104) |
| | Investigating the effects on the honey bey Apis myllifera L. caused by direct spraying |
| Report No.: | CAMA92 Q' G A A |
| Document No.: | M ² -130674401-2 V O |
| Guideline(s): | BBA: Pat VI, B-1 K O S |
| Guideline deviation | |
| GLP/GEP: | ver A O' A A |
| | |
| The study repairs | Construct Application with form dated and dust AF E075022 00 WC75 A104 |
| The study reports on a | Decontact toxicity test with formatiated product AE F0/5052 00 wG/5 A104 |
| directly over sprayed | to the bees. How was concluded that the LD_{50} after direct overspray with the |
| product is > 0.04 % (72 | \mathbf{h} |
| | |
| The study was rated w | And in the EU Priview for the first inclusion of amidosulfuron on Anney La |
| study ravia | in the prayies Monotroph Since the study by its design does not deliver |
| study leview as lound | in the previous working april since the study by its design does not deriver |
| contact toxicity enopoi | nts Suitable Oor standard risk assessment, no formal EU endpoint was derived |
| hased on this test | |

 Report:
 KCP (0.3.1.1 203)

 Title:
 Involution in the side-effects of Hoe 075032 00 WG75 A104 on the honey bee (Apis no filifera) in the laboratory

 Report No.:
 Collifera) in the laboratory

 Document No.:
 M-130976-01-2

 Guideline (s):
 BBA: Part VI, 23-1

 Guideline deviation(s):
 -

 GLP/GEP:
 yes

A brief study description has been provided in the section before, see KCP 10.3.1.1.1/03.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study review is found in the previous Monograph. Since the study by its design does not deliver contact toxicity endpoints suitable for standard risk assessment, no formal EU endpoint for contact toxicity was derived based on this test.

This study was performed according to an outdated test guideline and is superseded by a new guideline-conform study performed with the product (see KPC 10.3.1.1.2. /07)

| Report: | KCP 10.3.1.1.2/04 |
|-------------------------------|--|
| Title: | Hoe 075032; water dispersible granules; 75 % (Hoe 075032 06 VG75 104) |
| | treatment (filter paper) |
| Report No.: | A51982 |
| Document No.: Guideline(s) | M-130/28-01-2 BBA: Part VI 23-1 |
| Guideline deviation(s): | |
| GLP/GEP: | yes of the the of the |
| The study reports on a o | contact toxicity test with formulated product AE 6075032 00 WG75 A104 with |
| surface exposure via s | oaked filter paper disks. It was concluded that the LD50 with the product is |
| > 0.04 % (72h). | |
| The study was rated va | alid in the EU review for the first inclusion of amidosofturon on Annex I, a |
| study review is found | in the previous Monograph. Since the study by its design does not deliver |
| contact toxicity endpoi | nts suitable for standard risk assessment, no formal PU endpoint was derived |
| based on this test. | |
| Report: | KCP 10,3.1.1.2 95 1991; Moj 30675-01-2 |
| 1 itie: | He 07503 Owater Generic as respiratory passon on the noney bee (Apis mellifera L.) |
| Report No.: | Soldan Standard Sta |
| Document No.: | M-130675-01-2 |
| Guideline deviation(s). | |
| GLP/GEP: | |
| Report amended by: | |
| Report: | KOP 10.3 P.1.2/06 ; 1993; M-138714-01-2 |
| Title: | privestigating the fields as respiratory poison on the honey bee (Apis mellifera L.) |
| | Code/Hoe 075032 00 WG75 A104 |
| Report No: | C091496 C 45 |
| Document No.: | W -138714-01-2 |
| Guideline deviation(s). | |
| GLP/GEP: | |

The study reports on a toxicity test with formulated product AE F075032 00 WG75 A104 with exposure via respiratory uptake. No substance-related effects were observed after 72 hours in control, treatment, and toxic reference groups. The report amendment corrects a typing error only and remains with no effect on the study outcome (included for formal completeness only).

The study was rated not valid in the EU review for the first inclusion of amidosulfuron on Annex I, because of the low mortality in the toxic reference group. No EU endpoint was derived based on this test.

| Report: | KCP 10.3.1.1.2/07 ; 2011; M-403727-01-1 |
|-------------------------|---|
| Titte: | mellifera L) in the laboratory |
| Report No.: | 60671035 |
| Document No.: | M-403727-01-1 |
| Guideline(s): | OECD 213 and 214 (1998) |
| Guideline deviation(s): | none |
| GLP/GEP: | yes |
| The study reports on a | a combined test covering aspects of both data pounts acute oral (CP 10.3 J.1.1) |
| and acute contact (CP | 10.3.1.1.2) toxicity to honey bees. \bigcirc |
| A study summary has b | been provided before under point KCP 10.3 9.1.1 /04 2 2 |
| Study and naint for ac | ute contact to visity for honey best L D. \$ 100 up a s /bg |
| Study enupoint for ac | the contact toxicity for noney dee. LDs 9 100 gg a.s. dee |
| | |
| | |
| CP 10.3.1.2 Chron | hic toxicity to bees a contract of the contrac |
| | |
| Report: | KCP 10.3.1.2/01 |
| Title: | Amidosulfuron WG75A W: 10-day chronic feeding test on the honey bee (Apis |
| | mellifera L.) in the laboratory |
| Report No.: | $M-5497/0-014$ \sim |
| Guideline(s): | $\frac{M-349}{100} = \frac{1000}{100} = \frac{1000}{100}$ |
| Ouldefine(s). | OFCD 213 (1998) and CFB No. 330 with current recommendations of |
| | the rise test group by (1900) and construction the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction to the rise test group by (1900) and construction |
| | Directive 2008-01 (Eanada/PMRA) |
| | USEPA OCSPP Nov Applicable 0 2 |
| Guideline deviation(s): | prone 4 |
| GLP/GEP: | yes yes |
| Ŭ. | |
| This study has been | proviously summarised and evaluated on document MCA level, to deliver |
| information on the acti | ve substance amigosulfuron. Please refer to data point KCA 8.3.1.2 /01. |
| A A | y y Q Q X Y |
| | |
| CP 10.3.1.3 Fifect | s on howey bee development and other honey bee life stages |
| | |
| | |
| Report: O' | $KCP_{3}(0.3.1.301)$, $(1.5.0.1.100)$, $(2.5.0.1.100)$, $(2.5.0.1.100)$, $(2.5.0$ |
| Title: | Amidosulption WG (5A W (750 g/kg): Effects on honey bee brood (Apis mellifera |
| Penorta · A | \mathcal{A} |
| Document No | M-482118-01- |
| Guideline(s). | 1007 |
| Guideline deviation | nene |
| GLP/GEP: | ves |
| | |
| This study has hell | providually summarized and evaluated on desumant MCA level to deliver |

This study has been previously summarised and evaluated on document MCA level, to deliver information on the active substance amidosulfuron. Please refer to data point KCA 8.3.1.3 /01.

| Report: | KCP 10.3.1.3/02 ,; 2016; M-545720-01-1 |
|-------------------------|---|
| Title: | Amidosulfuron WG 75A W (750 g/kg): Effects on honey bee brood (Apis mellifera |
| | L.) under semi-field conditions - Tunnel Test - Final report |
| Report No.: | EBBEN041 |
| Document No.: | M-545720-01-1 |
| Guideline(s): | OECD No. 75 (2007); OEPP/EPPO No. 170 (4)(2010) |
| Guideline deviation(s): | Yes, see report |
| GLP/GEP: | yes of |

This study has been previously summarised and evaluated on document MQA level, to detiver information on the active substance amidosulfuron. Please refer to data wint KCA 8.3.1.3.02.

CP 10.3.1.4 Sub-lethal effects

There is no particular study design / test guideling to assess "sub-lethal effects" in honey bees. However, in each laboratory study as well as in any higher tier study, sub-lethal effects, if occurring, are described and reported.

CP 10.3.1.5 Cage and tunnel tests

Not necessary considering the outcome of the risk assessment and the results of the Decument 75 (The P; 2016; M-545720-01-1) has been conducted. This tudy is summarized under KCA 8.3.1.3 /02.

CP 10.3.1.6 Field tests with honeybees

Not necessary considering the outcome of the risk assessment and the results of lower-tiered studies. A honey bee brood feeding study according to the provisions of **according** *et al.* (**according** F; **according**; 2014; M-482118-01-1) bas been conducted. This study is summarized under KCA 8.3.1.3 /01.

CP 10.3.2 Effects on non-target arthropods other than bees

Toxicity tests on non-target arthropods, were conducted with the product on the sensitive standard species *Typhlodromus pri* and *Tphidice rhopalosiphi*, and five additional species.

All studies were previous EU reviewed for the first Annex I inclusion of Amidosulfuron. No new data has been generated and is submitted in the context of application for approval renewal.

A summary of the information is provided in the following table.

A

| Test species, | Tested Formulation, study | Ecotoxicological Endpoint |
|-------------------------------|--|---|
| Edition Number | type, Duration, exposure | |
| Reference | | |
| Aphidius rhopalosiphi | WG 75 | $LR_{50} > 60$ [g product/ha] |
| .; 1996; M- | Laboratory, glass plates | $ER_{50} > 60 [g product/ha]$ |
| 140500-01-1 | 14d | corr. Mortality 48h |
| Rep No [.] 961048014 | | |
| KCP 10.3.2.1/01 | 60 g prod/ha | 33.3 |
| Aphidius rhopalosiphi | WG 75 | $LR_{50} > 40$ [g product/g |
| B; 1999; M- | Laboratory, glass plates | $ER_{50} > 40 [g_product/ha] \sim \sqrt{3}$ |
| 184320-01-1 | 11d | corr Mortality 48h Effect & Reproduction |
| Rep.No: 98331/01-NLAp | | |
| KCP 10.3.2.1/02 | 40 g prod/ha | 0° 24,9° 4406° . |
| Aphidius rhopalosiphi | WG75 | LRS > 60 (g/product/na) |
| ,; 2003; M- | Extended Lab., exposure on | |
| 227766-01-1 | potted barley plants 14d | Corr. Mortality [%] Effect on Reproduction [%] |
| Rep.No: 15741002 | 3.75 g prod/ha 🔍 | ~06.9 U |
| KCP 10.3.2.2/01 | 7.5 g prod/ha 🔬 | 3.3 3.3 3.3 3.3 3.3 3.3 3.3 3.3 3.3 |
| | 15 g prod/ha | |
| | 30 g prod/ha 🔊 🔿 | |
| | 60 g prod/ha | |
| Typhlodromus pyri | WG 75 | $LR_{f0} > 60 [g_{product/ha}]$ |
| ,; 1998; | Laboratory, glass plates (>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>> | $ER_{50} > 60 $ (g/produce Qha) |
| M-181417-01-1 | 14d 0 0 | Corr. Morality [%] Effect on Reproduction |
| Rep.No:CW98/050 | | [eggs/female] |
| KCP 10.3.2.1/03 | Control 🖉 💍 💙 | - & ~ 8.81 |
| | 60 g prod/ha | Q2.3 Q 5 7.14 |
| Chrysoperla carnea | WGZ5 O | $LR_{50} > 60 [g \text{ product/ha}]$ |
| ,; 1992; M- | Laboratory, glass plates 14d | Corr. Mortality [%] Eggs/Female/Day Hatching [%] |
| 136220-01-2 | Control Q & C | - 118 - |
| Rep.No: CW91/116 | 🖗 g pro🖬 🖉 🔍 | -7.5 ^A 94 25.7 |
| KCP 10.3.2.1/06 | | o" all' |
| Coccinella | WG 75 🖉 🖧 | $\mathbb{Q}_{R_{50}} > \mathbb{Q}^{2}$ [g product/ha] |
| septempunctata O ^o | Laboratory, glass plates 14d | Corr. Mortality [%] Eggs/Female/Day |
| ,; 199₡ _₽ M- ∘ | Control | - 91 |
| 137157-01-2 | 80 g prod/ha _O | 46.1 310 |
| Rep.No:CW92722 | | |
| KCP 10.3.2.1/07 | | |
| Episyrphus balteats | ₩G 75 @ ÇŮ 🕺 | |
| ,; 1993, M- | Laboratory, glass plates 14d | Corr. Mortality Effect on Reproduction |
| 133073-01-2 | | [%] [%] |
| Rep.No:253 -Eb | 60%g/prod/hat 0° | 12 100 ^A |
| KCP 10.3.2.1/12 0 | | |
| | | |

Table CP 10.3.2-1: Endpoints of the formulation Amidosulfuron WG75

^A: EFSA conclusion (2007 page 25) stated: ^A study with the dipteran *Epishyrphus balteatus* showed a high impact on reproduction while the effect on survival was low. According to ESCORT II test systems with Diptera (*Epishyrphus balteatus* is explicitly mentioned) are not appropriate due to high variability in reproduction and therefore the applicant and the RMS argued that these results should not be taken as an indication of reproduction effects caused by apridosul furon since in the studies with other arthropods no indication of effects on reproduction was found.³ Overall it was concluded that the risk to non-target arthropods is low for the representative uses evaluated.

| Document MCP: Section | 10 Ecotoxicological studies |
|------------------------------|------------------------------------|
| Amidosulfuron WG 75 | _ |

| | | |
|---|-------------------------------|--|
| Test species, | Tested Formulation, study | Ecotoxicological Endpoint |
| Edition Number | type, Duration, exposure | |
| Reference | | |
| Aleochara bilineata | WG75 | $ER_{50} > 60 [g \text{ product/ha}]$ |
| □; 1992; M- | Laboratory, spray deposits on | |
| 136106-01-1 | quartz sand 28d | Effect on Reproduction [%] |
| Rep.No: CW91/111 | Control | |
| KCP 10.3.2.1/05 | 60 g prod/ha | -109 ^B |
| Aleochara bilineata | WG75 | $ER_{50} > 60 [g product/ha] $ |
| ; 1993; M- | Laboratory, spray deposits on | |
| 132685-01-2 | quartz sand 29d | Effect of Reproduction [%] |
| Rep.No: CW93/061 | Control | |
| KCP 10.3.2.1/04 | 60 g prod/ha | \mathbb{O} \mathbb{O} 1.4^{B} \mathbb{O} \mathbb{O} |
| Poecilus cupreus | WG75 | $LR_{50} \sim 60 [g product/hat/ 0 ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ $ |
| ,; 1992; M- | Laboratory, spray deposits on | |
| 136107-01-2 | quartz sand 15d | Corr. Mostality [%] Feeding Rate Dupae/beetle] |
| Rep.No:CW91/112 | Control | |
| KCP 10.3.2.1/08 | 60 g prod/ha | |
| Poecilus cupreus | WG75 | LR 60 [gproduct/ha] |
| • | Laboratory, spray deposits on | |
| ; 1991; M- | quartz sand 15d | Corr. Mortality [%] Feeding Rate [pupae/beetle] |
| 135791-01-1 | Control | 4.63 |
| Rep.No: CW91/099 | 60 g prod/ha 🖉 Ő | ري ^ن 0 کې کې 24.57 |
| KCP 10.3.2.1/09 | | |

^A: A negative value indicates a lower mortality in the treatment than in the control

^B: A negative value indicates a higher reproduction rate in the treatment that in the control.

Risk assessment for other non-targeOurthropods

The risk assessment was performed according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) and to the Guidance Document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods (ESCORT 2).

×)

In-field hazard quotient (HQ) tier Vrisk assessment

The following equation was used to calculate the hazard quotient (HQ) for the in-field scenario:

In field-HQ
$$\neq$$
 max single application rate $MAF \neq R_{50}$

 \mathcal{D}

For the risk assessment of the product Antidosulfaton WG 75 on non-target arthropods in (winter and spring) cereals and flax, the worst-case application rate of 1×40 g product/ha at BBCH 12-49 in spring cereals has been taken into account. This use pattern is considered to cover also the single applications in winter cereals (1×0.40 g product/ha at BBCH 21-49 and 1×0.20 g product/ha at BBCH 12-49) and flax (1×0.40 g product/ha before the flower buds are visible) as given in the intended use pattern for this product (see Table CP 10- 1). In addition, the product is applied at 1×60 g product/ha the multiple application factors (MAF) for the worst-case use in spring cereals and the use on grassiand were set at 1.0. Resulting HQ values are presented in the following table. The risk is considered acceptable if the calculated HQ is < 2.



| Crop | Species | Appl. rate [g product/ha] | MAF | LR50 [g product/ha] | HQ | Trigger |
|------------|-----------------|------------------------------|-----|------------------------|-------|---------|
| Cereals | A. rhopalosiphi | 40 | 1.0 | > 60 | < 0.7 | 2 |
| Flax | T. pyri | 40 | 1.0 | > 60 | 、<0.7 | 2 |
| Creationd | A. rhopalosiphi | 60 | 1.0 | > 60 | Q<0.7 | 2 |
| Orassialiu | T. pyri | 60 | 1.0 | > 60 | < 0.7 | 2 |

| Table CP 10.3.2- 2: | HQ for terrestrial non-target arthropods for the in-field scenario |
|---------------------|--|
| | ing for terrestrian non tanget artim optas for the in neta secondric |

The in-field HQ values for *Typhlodromus pyri* and *Aphidius rhopalosiph* are below the trigger of concern, indicating that **no unacceptable risk is to be expected for non-target arthropods in the in-field area** from the use of Amidosulfuron WG 75 according to the proposed use pattern

Off-field hazard quotient (HQ) tier 1 risk assessment

The following equation was used to calculate the hazard quotient (HQ) for the off field scenario

Off-field HQ = max. single application rate * MAF * (drift factor VDF)* forrection factor LR_{50}

MAF (multiple application factor) = 1 (single application)

Drift factor = $0.0277 (90^{\text{th}} \text{ percentile for 1 application in field crops, 1m distance; ESCORT 2)}$ VDF (vegetation distribution factor) = 10^{4}

Correction factor = 10 (uncertainty factor for the extrapolation from indicator species to other off-field non-target arthropods; default value for tier 10 isk assessment according to the Terrestrial Guidance Document)

The risk is considered acceptable if the calculated HQ is 2.

| Table CP 10.3.2- 3: | HQ for terrestria | l non-target a | rthropods fo | r the off-field | scenario |
|---------------------|-------------------|----------------|--------------|-----------------|----------|
| | | | 1 V | 7/ . | |

| Crop | Species 🖉 | Applarate | MAF | Drift | Ø F | Corr. | LR50 | HQ | Trigger |
|-----------|--------------------|-------------------|-----|---------------------------------|------------|---------------|-------------------|--------|---------|
| - | | لاً product/ha | | , [%] | S) | factor | [g product/ha] | | |
| Cereals | A. rhopæjosiphi | | | D D D T T T T | | 10 | > 60 | < 0.02 | 2 |
| Flax | A. pyri | | | ¥ X | × 10 | 10 | > 60 | < 0.02 | 2 |
| Grassland | A. rhopalosiph | | | | 10 | 10 | > 60 | < 0.03 | 2 |
| Grassland | J. pyri | \$ 60 S | | , 2.77 | 10 | 10 | > 60 | < 0.03 | 2 |

The calculated HQ values are below the trigger of concern, indicating that **no unacceptable risk is to be expected for non-farget arthropods in the off-field area** from the use of Amidosulfuron WG 75 according to the proposed use pattern.



CP 10.3.2.1 Standard laboratory testing for non-target arthropods

Aphidius rhopalosiphi:

| Report | |
|--------|--|
| Title: | |

Report No .:

Document No.:

Guideline(s):

GLP/GEP:

KCP 10.3.2.1/01 ; 1996; M-140500-01-1 Toxicity to the parasitoid Aphidius rhopalosiphi (DESTEF I-PEREZ) / Imagines according to IOBC Guideline (MEAD-BRIGGS 1992) How A56711 M-140500-01-1 **IOBC: Mead-Briggs 1992** Guideline deviation(s): yes

The study reports on a laboratory acute toxicity test for the parasitoid Aphidure' rhop dosphi on the formulated product. The parasitation efficacy of the surviving wasps of the treatment group was slightly reduced. The mean number of parasitized aphids per female wasp in the control group was 7.33. The mean number of parasitized aphids per female wasp in the treatment group was @14.

The study was rated valid in the EU review for the brst inclusion of ami@sulfur@s on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

An EU agreed endpoint for acute oral \hat{Q} icity of the active substance \hat{Q} midos \hat{Q} furon of LR₅₀ > 45 g a.s./ha was derived from this test. The effect on reproduction as 16.2%.

In the context of approval renewal an endpoint for acute oral toxicity of the formulated product of $LR_{50} > 60$ g product/ha was used for the risk assessment for non-target arthropods.

1999@M-184330-01-1 **Report:** 10.3 Toxicity to the Aphid Parasitoid, Aphidius Title: the Laboratory losiph Report No .: Document No .: 84320404 Guideline(s): Guideline devisit GLP/GEP:

The study reports on a aboratory acute toxicit test for the parasitoid Aphidius rhopalosphi on the formulated product. The exposure of Aphidius rhopalosiphi to the formulated product at a rate of 30 g a.s./ha resubed in a corrected mortality after K h of 24.3% and and effect on reproduction of 44.6%. ()

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summar g is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

Ø
Typhlodromus pyri:

| Report: Title: | KCP 10.3.2.1/03 Amidosulfuron water dispersible Typhlodromus pyri SCHEUTEN | granule 75% Toxicity to the predatory mite (Acari, Phytoseiidae) in the laboratory Code AE |
|-------------------------|--|---|
| Report No . | F075032 00 WG75 A110 C000890 | |
| Document No.: | M-181417-01-1 | |
| Guideline deviation(s): | ESCORT: 1994 | |
| GLP/GEP: | yes | |

The study reports on a laboratory acute toxicity test for the predatory mite *Typhlo fromus pyri* on the formulated product. The combined effect on mortality and production was calculated as 20.84 %...

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m

The study was rated valid in the EU review for the first inclusion of amidesulfuron on Amex I, a study summary is found in the previous Draft Assessment Report (2006).

An EU agreed endpoint for acute oral toxicity of the acrive substance anidos burn of $LR_{50} > 45$ g a.s./ha was derived from this test.

In the context of approval renewal an endpoint or acute oral toxicity of the formulated product of $LR_{50} > 60$ g product/ha was used for the risk assessment for non-farget anthropody.

Aleochara bilineata:

| Report: | KCP 10.3.2.1/04 (1997); 1999; M-132085-013 |
|---------------|--|
| Title: | Testing for side effects of Hoe 75032 000 VG75 4004 on the staphylinid Aleochara |
| | bilin sata Gyl, (Coleoptera, Staphilinidae) in the laboratory |
| Report No.: | C_{A} (493 Q Q Q Q Q Q |
| Document No · | NE13268 01-2 |

Document No.: Guideline(s): Guideline deviation(GLP/GEP:

The study reports on a laboratory exicity test for the staphylinid *Aleochara bilineata* on the formulated product. The mean emergency rate from the number of added pupae as indicator of the parasitation efficiency was 35.2% in the treated variant and therefore slightly higher than that from the control variant (34.7%). No negative impact was observed after treatment with the product at 58.5 g/ha.

The study was rated validon the DU review for the first inclusion of amidosulfuron on Annex I, a study symmary is found in the previous Braft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

| Report: | KCP 10,3,2.1/05 B; 1992; M-136106-01-1 |
|-------------------------|---|
| Title: | Effects of Hoe 075032 00 WG75 A104 on the reproduction of Aleochara bilineata |
| Ŷ. | Gyll. (Coleoptera, Staphylinidae) in laboratory |
| Report No.: 🛛 🖉 | A47612 |
| Document No.: | M-136106-01-1 |
| Guideline(s): | IOBC: Naton E. 1988 |
| Guideline deviation(s): | |
| GLP/GEP: | yes |
| | |

The study reports on a laboratory toxicity test for the staphylinid *Aleochara bilineata* on the formulated product. The average parasitation of pupae of *Delia antiqua* was 83 % in the treated variants and 77 % in the control. Hence, no negative impact was obvious after treatment with the product at 60 g/ha.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

Chrysoperla carnea:

Report:
Title:KCP 10.3.2.1/06; 1992; M-136220-01-2Determination of side-effects of Ho@ 75032 to WGS A104 with e gran lace wing
Chrysoperla carnea Steph. in the Boraton
Chrysoperla carnea Steph. in the Boraton
Guideline(s):
GLP/GEP:M-136220-01-2Guideline deviation(s):
GLP/GEP:--

The study reports on a laboratory toxicity test for the green laboratory *Chrysoperla carnea* on the formulated product. Mortalities in the control and the test item treatment goup were 17.3 % and 11.1 %, respectively. The pre-imaginal mortality of *Chrysoperla carnea* was therefore not increased as compared to the control, the corrected mortality rate is -7.5 %. The egg4aying capacity of the test organisms was 81 fertile eggs per female on the average as compared with 109 fertile eggs per female in the control. This is equivalent to a decrease of 25.7%. Based on these values, the relative decrease of beneficial effects for *Chrysoperla carnea* was calculated to be 20.5%.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

Coccinella septempunctata:

GLP/

 Report:
 KCP 10.3.2.1/07
 I; 1992; M-137157-01-2

 Title:
 Seterming on of side-effect of Hoe 075032 00 WG75 A103 on the seven spot

 Report No.:
 Adybical soccime is septempunctata L. in the laboratory

 A51997
 BIPA: Part 1, 23-2, 35

 Guideling deviation(s):
 Guideling deviation(s):

The study reports on a laboratory toxicity test for the ladybird *Coccinella septempunctata* on the formulated product. Mortalities in the control and the test item treatment group were 20 % and 56.9 %, respectively. The corrected pre-imaginal mortality of *Coccinella septempunctata* was 46.1 %. The egg-laying capacity of the test organisms was 310 fertile eggs per female on the average as compared with 91 fertile eggs per female in the control. This is equivalent with an increase of 240.7 %. Both values, however, are within the natural range of variation and different stress conditions might be responsible for the varying reproductive capacity (higher density and strong competition in the control group). In the report the overall effect on the beneficial capacity was calculated to be -38.8 % (the negative figure is equivalent to an enhancement). This value should be regarded cautiously, however, the observed effects on ladybirds were not detrimental.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

Poecilus cupreus:

| i occuus cupicus. | |
|--|---|
| Report: | KCP 10.3.2.1/08 |
| Title: | Determination of the side-effects of Hoe 075032 00 Jos A had on the ground beetle |
| Depart No : | Poecilus cupreus L. in the laboratory |
| Document No : | M-136107-01-2 |
| Guideline(s): | BBA: Part VI, 23-2.1.8 |
| Guideline deviation(s): | |
| GLP/GEP: | yes O O O O O |
| The study reports on | a laboratory tovicity together the ground boather Boasing automatic |
| formulated product No | a laboratory toxicity test for the porties from the control and the text item treated |
| group while 90 % of t | he animals of the toxic standard died within 2 days A mean of 3 83 and 5 00 |
| pupae were consumed | per beetle in the control and test stem group, respectively. Hence, no test |
| substance related effect | on food-consumption was bserved. |
| | |
| The study was rated v | alid in the EU review for the first inclusion of amidosulfuron on Annex I, a |
| study summary is found | 1 in the previous Draft Assessment Report (2606). |
| No FU agreed endpoint | t was derived from this tast |
| No EO agreed endpoint | |
| Report: | KCP 10.3.2 4/09 C ; C ; C ; C ; C ; C ; C ; C ; C ; C |
| Title: | The Effect of HOL 75032 0 WG7, A104 magines of POECILUS CUPREUS |
| Dement Max | D? (COLCOPTERA : CARABIDAG) in the valoratory |
| Document No · | M-135791-04 |
| Guideline(s): | BEAL VI, 22.1.8 S |
| Guideline deviation(s): | |
| GLP/GEP: | yes & o o o |
| ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | |
| The study reports on | a Jahoratory toxicity test for the ground beetle Poecilus cupreus on the |
| formulated product. No | mortality occurred among the beetles from the control and the test item treated |
| 10, V (Co) | |

group, while 76.7 % of the animals of the toxic standard died within 2 days. No intoxication symptom was observed among beetles of the treatment group and no test substance related effect on food-consumption was observed.

The study was rated valid if the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

Pardosa amentata:

Report:KCP 10.3.2.1/10;; 1995; M-138327-03-1Title:Effects of HOE 075032 00 WG 75 A104 on Pardosa amentata (Clerck) (Araneae,
Lycosidae) in LaboratoryReport No.:A49259Document No.:M-138327-03-1Guideline(s):BBA: Draft guideline (1992)Guideline deviation(s):--gLP/GEP:yes

The study reports on a laboratory toxicity test for the wolf spicer *Pardosa amentata* on the formulated product.

The study was evaluated in the EU review for the first inclusion of anordosulfuron on Annex 1. The evaluation resulted in the conclusion that **the study has to be considered invalid** due the high control mortality (42%). The study review has been provided in the previous Draft Assessment Report (2006).

Syrphus corollae:

KCP 10.3.2.1/11 **Report:** 993; MJ\$2620401 The Effects of Larvay and Pmal Exp@ure 🖉 75 A 104 on Title: wonidae) in the n.: Eupeodes co Syrphus corolla Laboratory A51711 Report No .: Document No .: M-1326202 Guideline(s): BBA Guideline deviation(s): **GLP/GEP:** The study reports on a laboratory oxicity test for Oyrphus Corolla Vabr. on the formulated product. The study was evaluated in the EU view for the first inclusion of amidosulfuron on Annex I. The Ø evaluation resulted in the conclusion that the study has to be considered invalid due the high control mortality (45.8%) The study review has been provided in the previous Draft Assessment Report (2006).



The study reports on a laboratory toxicity test for the hover-fly *Episyrphus balteatus* on the formulated product. Pre-imaginal mortalities were 20 % and 29.6 % in the control and the test item treatment group, respectively. The corrected pre-imaginal mortality of *Episyrphus balteatus* following exposure to the formulated product was 12.0%. The mean number of eggs laid per female in the test item variant was 12.4, but they did not hatch out. The number of eggs laid in the control was considerably higher, with a mean value of 102.8. The number of fertile eggs/female was 67.5.

Aphidius rhopalosiphi,

Document MCP: Section 10 Ecotoxicological studies Amidosulfuron WG 75

An impairment of reproduction of 100 % was obtained for the females of the test item variant. The results of the fecundity test are difficult to assess, because the reproductive capacity in hover flies is determined by a complex pattern of internal and external stimuli. As is reported by the study author, this may lead to a high individual variation of egg numbers. As a consequence the observed impairment of reproduction cannot be attributed to one single factor, i.e. the formulated product alone.

The study was rated valid in the EU review for the first inclusion of amidosal furon on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

KCP 10.3.2.2%

Effects of 🔗

ended

EFSA conclusion (2007, page 25) stated: "A study with the dipteran Epishyrphus balteatus showed a high impact on reproduction while the effect on survival was low. According to ESCORT II test systems with Diptera (Epishyrphus balteatus is explicitly mentioned) are not appropriate due to high variability in reproduction and therefore the applicant and the RMS argued that these results should not be taken as an indication of reproduction effects caused by amidosulfuron since in the studies with other arthropods no indication of effects on reproduction was found."

| CP 10.3.2.2 | Extended laborator | ry testing, | aged | residue | studie | s with | non-target |
|-------------|--------------------|-------------|------|---------|--------|---------|------------|
| | arthropods | A | O. | Ś. | Ô, | ÌN N | Q. |

Report: Title:

Report No.: Document No.: Guideline(s): Guideline deviation(s): GLP/GEP:

The study reports on an extended aboratory test for the parasitoid *Aphidius rhopalosiphi* on the formulated product. The effects of the product on mortality and parasitation of *Aphidius rhopalosiphi* are presented in the following table.

20¢3≱ M

 Table CP 10.3.2.2-12 Effects of Amidosulfuron WG 5 on mortality and parasitation of Aphidius

 Image: state of the state of

| Group Corrected mortality (4804) | Mummies/female | Reduction of parasitation efficiency* [%] |
|------------------------------------|----------------|---|
| Control O | 56.3 | - |
| 3.75 product/ha | 52.4 | 6.9 |
| 7.5 g product/ha | 56.5 | -0.4 |
| 15 g product/ha | 66.5 | -18.1 |
| 30 g product/tg | 53.6 | 4.8 |
| $60 \text{ g product/ha} \qquad 0$ | 52.7 | 6.4 |
| Toxic reference 70 | = | - |

* negative value means increased parasitation efficiency compared to control

No behavioural abnormalities and no repellent effect were observed. Differences between the product treated groups and the control were not statistically significant. The LR_{50} of the product under extended laboratory conditions is reported to be > 60 g product/ha.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

CP 10.3.2.3 Semi-field studies with non-target arthropods

In view of the results presented above, no semi-field studies were deemed

Field studies with non-target arthropods **CP 10.3.2.4**

In view of the results presented above, no field studies were deemed necessa

arthropods CP 10.3.2.5 Other routes of exposure for non-tagget

2 are considered the main The exposure routes of non-target arthropod as assessed in route of exposure for non-target arthropods?

CP 10.4 Effects on non-target soil meso- and macrofauna

The risk assessment procedure follows the requirements as given in the EW Regulation 1107/2009 and the Guidance Document on Terrestrial Epotoxicology.

Predicted environmental concentrations used in risk assessment

Predicted environmental concentrations of the active substance and the metabolites in soil (PEC_{soil}) values were calculated and reported in MCP 9.1.3.

The relevant PEC alues considered for FER calculations are summarised in the table below. Maximum values are used or risk assessments.



| Compound | Winter cereals, 1 × 30 g a.s./ha (20% interception) | | Winter cereals, 1 × 15 g a.s./ha (0% interception) | | Spring cereals and flax, 1 × 30 g a.s./ha (0% intercention) | | Grass (spring and autumn), 1 × 45 g a.s./ha (90% interception) | |
|--|---|-------------------------|--|-------------------------|--|-------------------------|---|---------------------------|
| | PECsoil,max [mg/kg] | PECsoil,accu [mg/kg] | PECsoil,max [mg/kg] | PECsoil,accu [mg/kg] | PEC _{soil,max} [mg/kg] | PECsoil,accu [mg/kg] | PEC _{soil,max} | PECsoil,accu [mg/kg] |
| Amidosulfuron WG 75 | 0.043 ^A | - | 0.027 ^B | - | 0.053 ^C | 2ª | 9 ,008 ^D | 5 ⁷ - <i>Q</i> |
| Amidosulfuron | 0.032 | 0.033 | 0.020 | 0.020 | 0.040 | 0.041 | 0.00 | 0:406 |
| Amidosulfuron- desmethyl | 0.015 | 0.015 | 0.010 | 0.010 | 09.019 | × 0.019 | 0.003 | \$0.003 |
| Amidosulfuron- desmethyl- chloropyrimidine | 0.004 | 0.004 | 0.003 | 0.00 | 0:695 | \$ 0 ,006 | × 0.001 | < 0,001 |
| Amidosulfuron- ADMP | 0.001 | 0.001 | < 0.001 | £0.001 | ©0.002 | 0.002 | < 0.001 | 0.001 |
| Amidosulfuron- guanidine | 0.009 | 0.014 | 0.006 | 0.000 | 0:011 | \$9.018 | ♀ 0.002 | 0.003 |
| Amidosulfuron-biuret | 0.001 | 0.002 | < 0.001 | < 0001 | Ø.002 [%] | 0.002 | < 0.901 | < 0.001 |

Table CP 10.4-1: Maximum PEC_{soil} values

Bold values: worst case considered in risk assessment

- Based on an application rate of 0.04 kg product/ha, considering 5 cm coil depth 1.5 g/n@ soil density and Α 20 % crop interception. Ø
- Based on an application rate of 0.02 kg product/ka, considering 5 cm soil depth, 1.5 mL soil density and no в
- crop interception. Based on an application rate of 0.04 kg product/ha, considering 5 cm sol depth, ¥.5 g/mL soil density and no С
- Based on an application rate of 0.06 kg product/ha, considering 5 cm soil denth, 1.5 g/mL soil density and D 90 % crop interception.

CP 10.4.1 Earthworms

Ecotoxicological endpoints used in risk assessment

Table CP 10.41-1: Endpoints of the formulation Amide affuron WG75 used in risk assessment

| Test substance | •Test (organism | Study type | Endpoint | t | References |
|------------------------|-----------------------|---|----------|--------------------|--|
| Amidosulfuron WG 75 | Earthworm, Eisenia | reproduction, 56 d (10% Preat in test soil), test item mixed into soil | NOEC | 56 mg prod./kg dws | ;; 2015; M-524933- 01-1 KCP 10.4.1.1/02 |

dws = try weight soil; prod. = product Bold values used for the risk assessment

| Test substance | Test organism | Study type | Endpoint | References |
|---|---------------------|---|---|---|
| | Earthworr | n, chronic | | |
| Amidosulfuron WG 75 | Eisenia fetida | reproduction, 56 d (10% peat in test soil), test item mixed into soil | NOEC 42.5 mg a.s./kg dwsy | ,; 2015; M-524933- 201-1 KCA 8.4.1/03, |
| Amidosulfuron- desmethyl | Eisenia fetida | reproduction, 56 d (10% peat in test soil), test item mixed into soil | NOEC 295.8 mgp.m./kg dws^A) | 2015: M 529709-01-1 KCAS.4.1/04 |
| Amidosulfuron- desmethyl- chloropyrimidine | Eisenia fetida | reproduction, 56 d (10% peat in test soil), test item mixed into soil | NOEC 2887 mg p.m./kg dws ^B | 2009; NC359724- 01-1 KCA 8.4.1/01 |
| Amidosulfuron- guanidine | Eisenia fetida | reproduction, 56 d (10% peat in test soil), test item mixed into soil | $NOEC \neq 2983 \text{ for } p.m. \text{ and } g \text{ dws} \neq 2$ | ; 2009; M-358183- 01-1 KCA 8.4.1/02 |
| Amidosulfuron- biuret (estimated from amidosulfuron- guanidine, endpoint divided by 10) | Eisenia fetida | reproduction \$6 d (10% pears in test søil), test iteto mixed into soil | NOFC \geq 9803 mg pspi./kg dws ^C | ; 2009; M-358183- 01-1 KCA 8.4.1/02 |
| Amidosulfuron- ADMP | EDenia fetida, O | reproduction, 56 d (10% peat in test soil) test intest soil | NOEC 998 mg p.m./kg dws ^{D)} | ; 2013; M-461051- 01-1 KCA 8.4.1/05 |
| Amidosulfuron- ADHP | Elsenia fetida | reproduction, 56 (10% peat in test soil test item mixed into | $\frac{\sqrt{5}}{100} \ge 99.5 \text{ mg p.m./kg } \text{dws}^{\text{E}}$ | ; 2015; M- 533011-01-1 KCA 8.4.1/06 |

| Table CP 10.4.1- 2: | Endpoints of the active substance amidosulfuron and metabolites used in risk |
|---------------------|--|
| | assessment |

dws = dry wight soil A.s. = active substance; p.m. = pure metabolite ^{A)} corrected to an anysed purity of 98.8 % ^{B)} corrected to an anysed purity of 88.7 % ^{C)} corrected to an anysed purity of 98.3 % NOEC for Amidosulfuron-biuret has been estimated from the NOEC for Amidosulfuron-guandine by dividing this values by 10. ^{E)} corrected to an anysed purity of 99.8 %

^{E)} corrected to an anyysed purity of 99.5 % **Bold values** used for the tisk assessment

-The second se

The metabolite amidosulfuron-biuret was detected as a minor and transient soil metabolite. Maximum occurrence detected in soil was 6.3 %. No potential for persistence of amidosulfuron-biuret is indicated based on the soil half-life calculated to range from 18.6 to 65.7 days.

The chemical structure of amidosulfuron-biuret is very close to the structure of the metabolite amidosulfurone-guanidine, so that similar ecotoxicological properties of both substances may be expected. The latter component, being formed in soil in more relevant quantity and being characterized by longer degradation half-life, has been tested in reproductive toxicity studies on Eisenia fetida and indicated a low toxicity (NOEC ≥ 983 mg p.m./kg dws). Therefore, for amidosulfuron-biuret no reproductive toxicity testing on *Eisenia fetida* was deemed required. Formal

| Compound | Species | Endpoint [mg/kg soil] | PEC _{soil,max} [mg/kg soil] | TERLT | Trig- ger | | |
|---|--------------------------|------------------------------|---|---------------|-----------------------|--|--|
| | Wint | er cereals | | | | | |
| Amidosulfuron WG 75 | Earthworm, reproduction | NOEC 56 | 0.043 | 1302 | 5 | | |
| Amidosulfuron ^{A)} | Earthworm, reproduction | NOEC 42.5 | 0.033 | 1288 | 5 | | |
| Amidosulfuron- desmethyl | Earthworm, reproduction | NOEC ≥ 95.8 | 0.015 | 6387 Ć | 5 | | |
| Amidosulfuron- desmethyl- chloropyrimidine | Earthworm, reproduction | NOEC ≥ ? | | ≥ 251750 | 2) 2) 5) 7) | | |
| Amidosulfuron- guanidine | Earthworm, reproduction | | 0,014 | $\neq 27024$ | <i>S</i> [°] | | |
| Amidosulfuron-biuret ^{B)} | Earthworm, reproduction | NOR ≥ 95.3 | 0.002 | ≥ 499150 | Ø 5 | | |
| Amidosulfuron-ADMP | Earthworm, reproduction | NOEC 79.98 . | 0.001 | چ 9980 گ | 5 | | |
| | Spring ce | ereals antofiax 💉 | | | | | |
| Amidosulfuron WG 75 | Earthworm, reproduction | NOEC 50 | \$0.053 | 1057 | 5 | | |
| Amidosulfuron ^{A)} | Earthworm, reproduction | NOEC 22.5 | 0.040 | 1037 | 5 | | |
| Amidosulfuron- desmethyl | Earthworm, reproduction | $NOEC = 95.80^{\circ}$ | 0.919 | $2 \ge 5042$ | 5 | | |
| Amidosulfuron- desmethyl- chloropyrimidine | Earthworm, reproduction | NŐEC 8887 | 0.006 V | ≥ 147833 | 5 | | |
| Amidosulfuron- guanidine | Earthworm, reproduction | NOEC ≥ 983 | 0.018 | ≥ 54611 | 5 | | |
| Amidosulfuron-biuret ^{B)} | Earthworm reproduction | NOEC ≥ 98.3 | 0.002 | \geq 499150 | 5 | | |
| Amidosulfuron-ADMP | Earthworm, reproduction | QOEC 9.98 | 0.002 | 4990 | 5 | | |
| | Grass (spri | ng and autumo | | | | | |
| Amidosulfuron WGO5 | Earthworm, reproduction | NOEC 56 | 0.008 | 7000 | 5 | | |
| Amidosulfuro (A) | Earthwoon, reproduction | OEC 42.5 | 0.006 | 7083 | 5 | | |
| Amidosulfuron- « desmethyl | Earthworm, reproduction | $NOEC \geq 95.8$ | 0.003 | ≥ 31933 | 5 | | |
| Amidosulfuron-y desmethyly chloropyringdine | Carthworth, reproduction | \mathbf{O} NOEC ≥ 887 | < 0.001 | ≥ 887000 | 5 | | |
| Amidosulfuron- | Earthworm | NOEC ≥ 983 | 0.003 | ≥ 327667 | 5 | | |
| Amidosulfuron-biuret ^{B)} | Earthworm, reproduction | NOEC ≥ 98.3 | 0.001 | ≥ 998300 | 5 | | |
| Amidoculfuron ADMD | Farthurm reproduction | NOEC 0.08 | < 0.001 | > 0080 | 5 | | |

Table CP 10.4.1-3: TER calculations for earthworms

 Amidosulfuron ADML
 Earthworm, reproduction
 NOEC
 9.98
 < 0.001</th>
 > 9980
 5

 A) conducted with the formulation Amidosulfuron WG 75
 B) endpoint from amidosulfuron-guanidine divided by 10

 All TER values exceed the trigger value of 5 indicating that no unacceptable adverse effects on earthworms are to be expected from the intended use of the product.

CP 10.4.1.1 Earthwormssub-lethal effects

| Report: | KCP 10.4.1.1/02 ; 2015; M-524933-01-1 |
|-------------------------|--|
| Title: | Amidosulfuron WG 75 W: Effects on survival, growth and reproduction of the |
| | earthworm Eisenia fetida tested in artificial soil |
| Report No.: | kra/Rg-R-164/14 |
| Document No.: | M-524933-01-1 |
| Guideline(s): | International Standards ISO 11268-2: 1998 (E); OECD 222 (2004) |
| | Regulation (EC) No. 1107/2009 |
| | US EPA OCSPP Not Applicable |
| Guideline deviation(s): | minor de la companya de la comp |
| GLP/GEP: | yes O S in the in |
| | |
| This study has been | previously summarised and evaluated on document MCA level, to deliver |
| information on the acti | ve substance amidosulfuron. Please refeoto data point KOA 8.4 903. |

A44101

M-12702

Supportive information contained in the baseline dossion and in the List of Endpoints from the first EU review but no longer required for risk assessment according regulation (EU) \$107/2009:

Report:KCP 10.4.1.1/01Title:Hoe 075032 - Or disposible granule 75 (Hoe 075032 WG75 A104) Effect to
Eisenia fetida@earthworm) in 24 day OlificiatSoil Test@method OECD)

Report No.: Document No.: Guideline(s): Guideline deviation(s): GLP/GEP:

This study has been previously evaluated on document MCA Nevel, to deliver information on the active substance aminosulfuron.

The study was rated valio in the EU review for the first inclusion of amidosulfuron on Annex I, a study review is found in the previous Monograph.

An EU agreed endpoint of $LC_{50} > 1000 \text{ mg/s}$./kg d.w.soil was derived from this test.

 \bigcirc

<u>Note:</u> In context of application for EU approval renewal of amidosulfuron, this endpoint is ranked as supportive information, since acute earthworm testing and risk assessment is no longer a data requirement under Regulation 11072009. The updated List of Endpoints will include only data from a corresponding chronic earthworm test.

CP 10.4.1.2 Earthworkmsfield studies

Not required as the risk to earthworms is acceptable.

CP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Ecotoxicological endpoints used in risk assessment

Table CP 10.4.2-1: Endpoints of the formulation Amidosulfuron WG75 used in risk assessment

| Test substance | Test | Study type | Endpoint | References |
|------------------------|---|-------------------|---------------------------------|--|
| | organism | | \$\$\$ | |
| | Soil meso- and | l macrofauna (oth | er than earthworms) | |
| Amidosulfuron WG 75 | <i>Hypoaspis</i> <i>aculeifer</i> (soil mite) | reproduction test | NOEC \geq 1000 mg prod./kg dw | 507488-01-1 507488-01-1 56CP 10.4(2.1/01 |
| | Folsomia candida (collembolan) | reproduction test | NOEC ≥ 1000 mg prod./kg dw | ° 2014 № -506088- 01-0 4 CP 10.4 € 1/02 |

dws = dry weight soil; prod. = product; a.s. = active substance Bold values used for the risk assessment

Table CP 10.4.2- 2: Endpoints of the active substance amidosulfuron and metabolites used in risk assessment ŝ æ.

| Test substance | Test organism | Study type | Enterpoint O S | References |
|-----------------------------|---|----------------------|--|--|
| | Soil meso- and | macrofanna (ot | her than earthworms) 🔗 | |
| Amidosulfuron WG75 | Hypoaspis aculeifer | reproduction | $NOE \leq 1000 \text{ mg proc} \text{ kg dws}$ $\geq 759 \text{ mg a.s. kg dws}$ | `; 2015; M- 507488-01-1 KCP 10.4.2.1/01 |
| | Folsonia canarda (Collembolari) | reproduction test | $NOE \bigcirc \geq 100\%$ hg prod./kg dws $\geq 750\%$ mg a.s./kg dws | ,; 2014; M-506088-01- 1 KCP 10.4.2.1/02 |
| Amidosulfuron- desmethyl | Hypoasons aculeiter (sorDmite) (extimated from amidosulfuron, endpoint divided by 10) | remoduction | NOEC \geq 75.9 mg p.m./kg dws ^{B)} | ;; 2015; M-507488- 01-1 KCP 10.4.2.1/01 |
| | Folsomia Sandida (collembolan) | Groduction Vest | NOEC 8 mg p.m./kg dws | ; 2016; M-551645-01- 1 KCA 8.4.2.1/03 |
| Amidosulfuron | Hypoaspis Aculeifer (soil mite) | reproduction test | NOEC ≥89 mg p.m./kg dws | ; 2015; M- 507479-01-1 KCA 8.4.2.1/04 |
| chloropyrimidine | Folsomia candida (collembolan) | reproduction test | NOEC 56 mg p.m./kg dws | ; 2015; M-524473-01- 1 KCA 8.4.2.1/05 |
| Amidosulfuron- guanidine | <i>Hypoaspis</i> <i>aculeifer</i> (soil mite) | reproduction test | NOEC ≥ 100 mg p.m./kg dws | ; 2014; M- 503851-01-1 KCA 8.4.2.1/06 |

| Test substance | Test organism | Study type | Endpoint | References |
|---|---|----------------------|---|--|
| | Folsomia candida (collembolan) | reproduction test | NOEC ≥ 100 mg p.m./kg dws | ; 2014; M-506089-01- 1 KCA 8.4.2.1/07 |
| Amidosulfuron- biuret (estimated from | <i>Hypoaspis</i> <i>aculeifer</i> (soil mite) | reproduction test | NOEC ≥ 10 mg p.m./kg dws | ; 2014; M- 503851-014 KCA 8.4.2.1/06 |
| amidosulfuron- guanidine, endpoints divided by 10) | Folsomia candida (collembolan) | reproduction test | NOEC ≥ 10 mg p.m./kg dws | 2014 M-506089-01- 1 1 ScA 8.421/07 |
| Amidosulfuron- | <i>Hypoaspis</i> <i>aculeifer</i> (soil mite) | reproduction test | NOEG \geq 99.8 mg p.m./kg dws | ; 2012; M- 4540⊕-01-1. KC@ 8.4.2. @8 |
| ADMP | Folsomia candida (collembolan) | reproduction test | NOEC 99.8 mg p.m./kg dws ^{D)} | ; 2013; M-451142-01-1 KCA & 4.2.1/09 |

dws = dry weight soil; prod. = product; a.s. = active substance; p.m. upure merab

^{A)} conducted with WG 75 formulation

^{B)} Endpoint derived from amidosulfuron divided by 10

^{C)} Endpoint derived from amidosulfuron-guandine divided by 10 ^(C) ^{D)} corrected to an anlysed purity of 00 ° ^(C)

Bold values used for the risk assessmen

Testing metabolite amidosulfurion-despitethyl (with Hypoaspic) aculeifer is not considered to be required since Folsomia candida and earthworks have been tested with this metabolite and available test results for earthworms, Colsomia candida, and Hyposaspis acuteffer of the parent compound and the other metabolites indicate a low sensitivity of Hypoaspis aculetfer following the exposure to these compounds. Formal risk assessment for Hyposaspis achleifer and amidosulfuron-desmethyl will be based on the endpoint estimated from amidos afturon which has been divided by a factor of 10.

The metabolite amidosuffuron-biuret was detected as a minor and transient soil metabolite. Maximum occurrence detected in soil was 6.3 % No potential for persistence of amidosulfuron-biuret is indicated based on the soil half-life calculated to range from 18.6 to 65.7 days.

The chemical structure of amidos furon-buret is very close to the structure of the metabolite amidosulfurone-graniding, so that similar ecotoxicological properties of both substances may be expected. The Latter component, being formed in soil in more relevant quantity and being characterized by longer degradation half-life has been tested in Folsomia candida, and Hyposaspis aculeifer studies and indicated a few toxicity (NOEC \geq 100 mg p.m./kg dws). Therefore, for amidosulfuron-bjuret no testing on Folsomia candida and Hyposaspis was deemed required. Formal risk assessment for this component will be based on the endpoint estimated from amidosulfuronguanione which has been divided by a factor of 10.

L i The metabolite amidosulfuron-ADHP was observed exclusively in the anaerobic soil metabolism study, where any bundance of 109 % of applied was reported for day 90 after soil flooding. Due to the only limited relevance of anaerobic conditions for the use pattern of the present product, and due to the fact that the earthworm endpoint measured for amidosulfuron-ADHP (NOEC \geq 99.5 mg p.m./kg dws) is even greater than that of the parent substance (NOEC 42.5 mg a.s./kg dws), it can be concluded that this metabolite does not pose an unacceptable risk to soil meso- and macro-organisms and testing of Folsomia candida and Hypoaspis aculeifer with amidosulfuron-ADHP is not considered to be required.

Risk assessment for other non-target soil meso- and macrofauna (other than earthworms)

Ecotoxicological endpoints and PEC_{soil} values used for TER calculations for soil non-target macroorganisms are summarised below. TER values were calculated using the equation:

 $TER = NOEC / PEC_{soil}$

| TER = NOEC / P | EC_{soil} | | | , Š | ° ° | d. |
|------------------------------|---------------------------|--------------|------------------------------------|--|-------------------------------|---------|
| The risk is consid | ered acceptable if the | e TER is >5 | | | | |
| Table CP 10.4.2- 3 | : TER calculations for | r other non- | target soil meso- | and macrofatha | | |
| Compound | Species | Eı [mş | ndpoint | OPEC _{soit,max} [mg/kg/soil] | FER LT | Trigger |
| | | Win | ter cereals 🖉 | | | |
| Amidosulfuron | Hypoaspis aculeifer | NOEC | | گ 0.043 | ≥ 23256 | Ş 5 |
| WG 75 | Folsomia candida | NOEC | × ≥ 1,000 × | 0.043 | 2325¢ | 5 |
| Amidagulfuran | Hypoaspis aculeifer | NOEC | ×759 0 | Ø. 9 33 | $0^{\circ} \ge 23060^{\circ}$ | 5 |
| Annuosunuion | Folsomia candida | NOE | ≥759,Q | 0.033 | ≥ 23000 | 5 |
| Amidosulfuron- | Hypoaspis aculeifer | NØEC | ⊙ ^Y ≥ 75.0 ^M | © 0.0₩5 | € 25060 | 5 |
| desmethyl | Folsomia candida | NOEC | \$ L | Q@15 | 533 | 5 |
| Amidosulfuron- desmethyl- | Hypoaspis aculeifer | NOE | <u>₹</u> 89 0 ⁵ | \$0.004 C | ≥ 22250 | 5 |
| chloropyrimidine | Folsomia candidha | NOÉC | [∞] 56 [∪] | Ç 0.004 ⁹ | 14000 | 5 |
| Amidosulfuron- | Hypoaspis aculeifer | NOEC | <u>′≩</u> 100 [~] | 06914 | ≥ 7143 | 5 |
| guanidine | Folsomia candida C | NOE | `∕≥ 100, ♥ | 0.014 | ≥ 7143 | 5 |
| Amidosulfuron- | Hypoaspus aculetter | NÔÆC | $\leq 10^{\text{B}}$ | 0.002 | ≥ 5000 | 5 |
| biuret | Folsonia candida | NOEC | ≥ 0 ^{B)} | 0.002 | ≥ 5000 | 5 |
| Amidosulfuron- | Hypoaspis aculeifer | VNOE | 999.8 | 0.001 | \geq 99800 | 5 |
| ADMP | Polsomia candida | NQCC | , y ≥ 99.8 y | 0.001 | \geq 99800 | 5 |
| | | Spring & | Preals and flax | r | | |
| Amidosulfuce | Hypoaspis aculeifer | NOE | ~ <u>~</u> ¥000 | 0.053 | ≥18868 | 5 |
| WG 75 [™] | \mathcal{A} | NQEQ | × 1000 | 0.053 | ≥18868 | 5 |
| Amidosulfuron | Hypoaspis aculeger | NÔÉC | ¥ ≥759 | 0.041 | ≥18512 | 5 |
| | Folzomia candida | ÓNOEC S | ≥ 759 | 0.041 | ≥18512 | 5 |
| Amidosulforon- | Hypoaspis aculeifer | NOE | \geq 75.9 ^{A)} | 0.019 | ≥ 3995 | 5 |
| desmethyl | Folsomia candida | NOEC | 8 | 0.019 | 421 | 5 |
| Amidosulfuron- | Hypolispis aculeifer | N OEC | ≥ 89 | 0.006 | ≥ 14833 | 5 |
| chloropyrimidine | Folsomia candida | NOEC | 56 | 0.006 | 9333 | 5 |
| Amidosulfuron- | Hypoaspi's aculetfer | NOEC | ≥ 100 | 0.018 | ≥ 5556 | 5 |
| guanidine | Folsomia cah d ida | NOEC | ≥ 100 | 0.018 | ≥ 5556 | 5 |
| Amidosulfuron- | Hypoaspis aculeifer | NOEC | \geq 10 ^{B)} | 0.002 | ≥ 5000 | 5 |
| biuret | Folsomia candida | NOEC | \geq 10 ^{B)} | 0.002 | ≥ 5000 | 5 |
| Amidosulfuron- | Hypoaspis aculeifer | NOEC | ≥99.8 | 0.002 | \geq 49900 | 5 |
| ADMP | Folsomia candida | NOEC | ≥ 99.8 | 0.002 | \geq 49900 | 5 |

| Compound | Species | Endpoint [mg/kg soil] | | PEC _{soil,max} [mg/kg soil] | TER _{LT} | Trigger | |
|------------------|---------------------------|--------------------------|-------------------------|---|-----------------------|--|--|
| | Grass (spring and autumn) | | | | | | |
| Amidosulfuron | Hypoaspis aculeifer | NOEC | ≥ 1000 | 0.008 | \geq 125000 | 5 | |
| WG 75 | Folsomia candida | NOEC | ≥ 1000 | 0.080 | ۇ 12500 | 5 | |
| Amidaculfuran | Hypoaspis aculeifer | NOEC | \geq 759 | 0.006 | $\nu \ge 126500$ | 5 | |
| Annuosunuion | Folsomia candida | NOEC | \geq 759 | 0.006 | ≥ 126500 | 5 | |
| Amidosulfuron- | Hypoaspis aculeifer | NOEC | $\geq 75.9^{\rm \; A)}$ | 0.00 | ₹25300 | ,50° | |
| desmethyl | Folsomia candida | NOEC | 8 🔊 ° | 0 . 663 -~ | © 2667 | L. | |
| Amidosulfuron- | Hypoaspis aculeifer | NOEC | ≥ 89 | | \geq 89000 | م ^{یل} 5 | |
| chloropyrimidine | Folsomia candida | NOEC | 56 | O' < 0.00Y | ~56000 | ۶ _° | |
| Amidosulfuron- | Hypoaspis aculeifer | NOEC | ZJ00 🖉 | 0.003 | ^U ≥ 3333 y | and the second s | |
| guanidine | Folsomia candida | NOEC | | | ≥ 333333 | 5 | |
| Amidosulfuron- | Hypoaspis aculeifer | NOEC | $Q \ge 10^{\text{B}}$ | 0.001 | @10000 | D 5 | |
| biuret | Folsomia candida | NOEC ≪ | | 0.001 | ≥ 10000 | 5 | |
| Amidosulfuron- | Hypoaspis aculeifer | NOE | \$99.8 V | ×0.001 | \geq 99,800 | 5 | |
| ADMP | Folsomia candida | NOÊC | $\swarrow \ge 99.8$ | <i>∞</i> <0.00 <i>€</i> | ≥99800 | 5 | |

A) Endpoint estimated from amidosulfuron diadded by 10

yes 🗶

^{B)} Endpoint estimated from amidosulfuron-granidin divided by 10

All TER values clearly exceed the trigger value of 5 indicating that no unacceptable adverse effects on soil macro-organisms are to be expected from the intended use of the product.

CP 10.4.2.1 Species Tevel testin

GLP/GEP: 🚿

; 2015; M-507488-01-1 **Report:** KC210.4 ₩0 Amidosuffiron WG75 W: miluence on mortality and reproduction of the soil mite species Hypoaspic aculeifer tested @artificial soil Title: LAR-109/10 Report No .: Document No M-507488-01 Guideline(s): QECD 226(2008) C QS EPA QCSPP: Not Appleable Guideline deviation(s): Wes, but accepted

This study has been previously summarised and evaluated on document MCA level, to deliver information on the active substance amedosulfuron. Please refer to data point KCA 8.4.2.1/01.

| Report: | KCP 10.4.2 /02 ,; 2014; M-506088-01-1 |
|---|--|
| Title: | Aphidosulfuron WG 75 W: Influence on the reproduction of the collembolan species |
| The second se | Folsomia candida tested in artificial soil |
| Report No.: | FRM-Coll-178/14 |
| Document No.: $\mathcal{O}^{\mathcal{V}}$ | M-506088-01-1 |
| Guideline(s): | OECD 232 (2009) |
| | US EPA OCSPP Not Applicable |
| Guideline deviation(s): | Yes, but acceptable |
| GLP/GEP: | ves |

This study has been previously summarised and evaluated on document MCA level, to deliver information on the active substance amidosulfuron. Please refer to data point KCA 8.4.2.1/02.

CP 10.4.2.2 Higher tier testing

Not required as the risk for other non-target soil meso- and macro-organisms is acceptable.

Effects on soil nitrogen transformation **CP 10.5**

Ecotoxicological endpoints used in risk assessment

Table CP 10.5-1: Endpoints of the formulation Amidosalfuror WG75 ased in risk assessment

| Test substance | Test design | Ecotoxicological endpoint References |
|------------------------|---------------|--|
| | Soil nitrogen | ransformation 🔬 🛇 🖉 |
| Amidosulfuron WG 75 | 28 d | no unacceptable ≥ 0.4 mg proc/kg dws effects ≥ 0.3 mg ac kg dws ≥ 0.3 mg ac kg dws ~ 0.3 kg dws $\sim 0.5/01$ |

dws = dry weight soil; prod. = product, a.s. = active substance

| Table CP 10.5- 2: | Endpoints of | the active | e substance | amidosulfur | ron and m | etabolites | used in risk |
|-------------------|--------------|------------|-------------|-------------|-----------|------------|--------------|
| | assessment | Ô | "S | × 0 | A. | | |

| Test substance | Test design | Footaviologica | bendnoint S | Deferences |
|--------------------|-----------------|------------------|------------------------------|---------------|
| Test substance | | Ecoloxicologica | | References |
| | Soil nitrogen t | transformation – | | |
| | Į U' | p b no b | á "Á | |
| Amidosulfuron | 287 | Unaccentable | 0.8 man s /k gaffays | 1987; |
| | Č 4 | effects % | | M-119378-01-2 |
| | so . | | | KCA 8.5 /01 |
| Amidosulfuron | 0 8. | A no | | ; 2015; M- |
| dogmothyl | b 28 (P) | unacceptable | @ 0.29 mg p.m./kg dws | 527883-01-1 |
| desinetity | | effects | ¥ _ @ | KCA 8.5 /11 |
| Amidosulfuron | | no a | ** | ; 2009; |
| desmethyl- | ∘ 28 d | unacceptable | ≥ 0.39 mg p.m./kg dws | M-359509-01-1 |
| chloropyrimidine a | $\zeta' \ll$ | @ effects | × | KCA 8.5/06 |
| Amidamlfung | | × 109 | 0 | ; 2009; |
| Amidosulturon | ©28 d | unacceptable | $2 \geq 0.29$ mg p.m./kg dws | M-359398-01-1 |
| | | Effects | | KCA 8.5/07 |
| | | Ĉ no≪ | | ; 2014; M- |
| Amidosuffuron- | 28/d (| unacceptable | \geq 0.30 mg p.m./kg dws | 504115-01-1 |
| blute of | | effects | | KCA 8.5 /08 |
| | | a no | | ; 2013; M- |
| Amidosulfuron- | 28 | unacceptable | \geq 0.137 mg p.m./kg dws | 453511-01-1 |
| ADMP | | effects | | KCA 8.5/09 |
| A 1 10 | Å | no | | ; 2015; M- |
| Amidosulfuron- | مَنْ 28 d | unacceptable | \geq 0.10 mg p.m./kg dws | 541593-01-1 |
| ADHP | U U | effects | | KCA 8.5/10 |
| | | | | |

dws = dry weight soil; prod. = product, a.s. = active substance; p.m. = pure metabolite Bold values used for the risk assessment

Ô

Document MCP: Section 10 Ecotoxicological studies Amidosulfuron WG 75

The metabolite amidosulfuron-ADHP was observed exclusively in the anaerobic soil metabolism study, where an abundance of 10.9 % of applied was reported for day 90 after soil flooding. Due to the only limited relevance of anaerobic conditions for the use pattern of the present product and a no adverse effect level (<25%) at 0.1 mg p.m./kg dws in the nitrogen transformation study it can be concluded that this metabolite does not pose an unacceptable risk to soil micro-organisms and a formal risk assessment is not considered to be required.

Risk assessment for Soil Nitrogen Transformation

| Table CP 10.5- 3: Risk Assess | sment for soil micro- | organisms (| | A | | | |
|---|--|---------------------------------|--------------|---------------------|--|--|--|
| Compound | Species | Endpoint | PECsoil,max | Refinement required | | | |
| Winter cereals | | | | | | | |
| Amidosulfuron WG 75 | Soil micro- organisms | ≥ 0.4 mg prod kg dws | 6043 C | | | | |
| Amidosulfuron | Soil micro- organisms | Q 0.8 mg a.s./kgdws | 0.03 | No | | | |
| Amidosulfuron-desmethyl | Soil micro- organisms | ≥ 0 mg p m/kg dws | 0.015 | No | | | |
| Amidosulfuron-desmethyl- chloropyrimidine | Soil micro- | 0.39 mg p.m./kgdws | 0.00 | No | | | |
| Amidosulfuron-guanidine | Soil moro- organisms | ′ ≥ 0 <i>2</i> 9 mg p.m./kg dŵs | 2 014 | No | | | |
| Amidosulfuron-biuret | Soil micro- | ≥0.30 mg p.m./kg dws ^ | ≫ 0.002 | No | | | |
| Amidosulfuron-ADMP | Soil mero- organisms | ≥ 0.437 mg pon./kg dws | 0.001 | No | | | |
| | Spring c | efeals and flax | | - | | | |
| Amidosulfuron WG | Soil micro- organisms | $\geq 0.$ mg pro kg dws | 0.053 | No | | | |
| Amidosulfuron | Sol micro | 20.8 mga.s./kg dws | 0.041 | No | | | |
| Amidosulfnon-desmethyl | Soil nuero- | ≥ 0.29 mg p.m./kg dws | 0.019 | No | | | |
| Amidosulfuron-desynethyl- chloropyrimidine | Soil micro-> | ≪⊋ 0.39 mg p.m./kg dws | 0.006 | No | | | |
| Amidosulfuron-guandine | Soil préro- organisms | $\geq 0.29~mg~p.m./kg~dws$ | 0.018 | No | | | |
| Amidosulfuron-biuret | SQI micró-≫ organisms | $\geq 0.30~mg~p.m./kg~dws$ | 0.002 | No | | | |
| Amidosulturon-ADNP | Soil mero- organisms | \geq 0.137 mg p.m./kg dws | 0.002 | No | | | |
| | r de la construcción de la const | | | | | | |

| Compound | Species | Endpoint | PECsoil,max [mg/kg] | Refinement required | | | |
|--|--------------------------|--|------------------------|------------------------|--|--|--|
| Grass (spring and autumn) | | | | | | | |
| Amidosulfuron WG 75 | Soil micro- organisms | \geq 0.4 mg prod./kg dws | 0.008 | No | | | |
| Amidosulfuron | Soil micro- organisms | $\geq 0.8~\text{mg}~\text{a.s./kg}~\text{dws}$ | 0.006 | No | | | |
| Amidosulfuron-desmethyl | Soil micro- organisms | \geq 0.29 mg p.m./kg dws | \$0.003 | No Q | | | |
| Amidosulfuron-desmethyl- chloropyrimidine | Soil micro- organisms | $\geq 0.39 \text{ mg pm}/\text{kg dws}$ | ×9.001 C | | | | |
| Amidosulfuron-guanidine | Soil micro- organisms | ≥ 0.29 rog p.m./kg dws 4 | 0.003 | No o | | | |
| Amidosulfuron-biuret | Soil micro- organisms | ≥ 000 mg psth./kg days | 0.001 | | | | |
| Amidosulfuron-ADMP | Soil micro- | ≥ 0.137 mg p.m./kg dws | × < 0.001 | Ø No | | | |

organisms a.s. = active substance, p.m. = pure metabolite, pro prodoct, dws # dry weight soi

According to current regulatory requirements the risk is considered acceptable if the effect on nitrogen mineralisation at the recommended application rate of a sompound/product is $\leq 25\%$ after 100 days.

In no case did deviations from the control exceed the threshold level of 25% at 28 days after application. The tested concentrations by far exceeded the maximum predicted environmental concentrations in soil of the respective components. This inducates acceptable risk to soil microorganisms for the intended uses.

Report:

Title: Report No.: Document No .: Guideline(s):

Smidosulfaron WC 75 W: Determination of effects on nitrogen transformation in soil FRM-N-126/09

KCP 10.5/00

M-356874-01 OECD/OCDE Guide me No.206, adopted: 21st January 2000, OECD Guideline for the testing of chemicals, so microorganisms: nitrogen transformation test

2009; M-356874-01-1

Ø

Guideline deviation(s): ≪none **GLP/GEP:** ves

Executive Summary:

The objective of this study was to determine the influence of Amidosulfuron WG 75 on the activity of soil microflora with togard to nitrogen transformation in a laboratory test. The test was performed in accordance with OFCD guideline 256 (2000) by measuring the nitrogen turnover.

A loamy sand soil (according to DIN infittel lehmiger Sand', texture: 10.4 % clay, 17.4 % silt, 72.2 % sand, ¥.57 % org. carbon content) we exposed for 28 days to 0.08 and 0.40 mg test item/kg soil dry weight. Application rates were equivalent to 0.06 and 0.30 kg test item/ha. Lucerne-grass-green meal was added to the soil (5 g/kg dry weight soil) to stimulate nitrogen transformation.

During the 28-day test item/kg dry weight soil and the 0.4. mg test item/kg dry weight soil had no relevant influence on nitrogen transformation in a loamy sand soil supplemented with Lucerne-grass-green meal. In none of the time intervals analysed during the 28 day exposure the difference in the daily nitrate-N rates exceeds the trigger value of 25 %. If used as recommended, Amidosulfuron WG 75 should not have an impact on nitrogen transformation in soils.

Test item: Amidosulfuron WG 75 W; Short name: AMS WG 75 W; Specification No.: 102000000550; Batch/FL.-No.: EFKE001675; Material No.: 05938848; TOX-No.: 08561-00; Analysed quantity of a.s. in product: 75.3 % w/w.

A loamy sand soil (according to DIN 'mittel lehmiger Sand', texture: 10.4 % claw 17.4 % silt, 72.2 % sand, 1.57 % org. carbon content) was exposed for 28 days to 0.08 and 0.40 mg test item/kg soil dry weight. Application rates were equivalent to 0.06 and 0.30 kg test item/ha. Licerne-grass-green meal was added to the soil (5 g/kg dry weight soil) to stimulate nitrogen transformation, soil samples of 300 g dry weight per incubation flask were used. Three replicates were propared por treatment. Sodium chloride was used as a reference standard in the tests. The soil was held in the dark at $20 \pm 2^{\circ}$ C and about 40-50 % of the maximum water holding capacity (WACmax) Immediately after treatment and after 7, 14 and 28 days, the soil in each jar was mixed by shaking Moist sample (10 g dry soil dry weight) were extracted with KCl, the content of ammo@um-Ng mitrite-Ng and nitrate-Ng fus nitrite-N were determined using a continuous flow Analysis system.

July 23, 2009 - August 26, 20 **Dates of work:**

Results:

Validity Criteria:

The coefficient of variation in the control at the end of the study was 1%. Therefore the validity criteria for the study, which requires a coefficient of variation $\leq 10^{\circ}$ % in the control, was fulfilled.

S Õ Ŵ In separate tests (non-GLP) the reference standard sodium Coloride Was used. In these tests with the agricultural soil, 16 g NaCl/kg dry weight soil had a distinct and long-term (> 28 days) influence on microbial mineralization of nitrogen.

Nitrogen transformation:

During the 28-day test, 0.08 mg @midosuffuron WG 75 W/kg dry weight soil and the 0.4. mg test item/kg dry weight soil had no relevant influence on mitrogen transformation in a loamy sand soil supplemented with Lucerne-grass-green meal In none of the time intervals analysed during the 28 day exposure the difference in the daily offrate-N rates exceeds the trigger value of 25 %.

| Table CP 10.5- Å | Effects on nit | rogen Grans | formation | 1 in soil after | treatment with | Amidosulfuron | WG 75 |
|------------------|----------------|-------------|-----------|-----------------|----------------|---------------|-------|
| ¢C ^y | ~~~ %, | | | ~C> | | | |

| | | 0 [°] | δų. | T App | lication rates | | | | |
|----------|------------|--------------------|-------------|---------------------|---------------------------|-------|------|------------------|--------------------------|
| Time | | , | 7. Ĉi | Angidosi | ulfuron WG 75 | W | | | |
| Interval | Contra | ŏl «Č | 0.08 | mg/k@dry w | veight soil | 0.4 | 0 m | g/kg dry w | veight soil |
| (days) | 🖉 Nittere | -N ¹⁾ 🔊 | Ňitra | ite-N ¹⁾ | % | Nit | rate | -N ¹⁾ | % difference |
| | i Qi | & . | | Ô | difference | | | | to control |
| ď | Ő | Ô [¥] . | Õ`. | 1 | to control | | | | |
| 0-7 | £.92 ± | 0.17 🛇 | -1.75 | ± 0.07 | 9 ^{n.s.w} | -1.63 | ± | 0.01 | 15* ^w |
| 7-14 | a 1.12 a 4 | 0.08 | | ± 0.13 | 3 ^{n.s.} | 1.08 | ± | 0.18 | 3 ^{n.s.} |
| 14-28 | 1.64 ± | ØØ2 | <u>_</u> 71 | ± 0.05 | 4 ^{n.s.} | 1.71 | ± | 0.10 | 4 ^{n.s.} |

1) Rate: Nitrate N in mg/kg dry Weight soil (in interval/day, mean of 3 replicates and standard deviation

** = Statistically significant difference to the control (Welch-t Test for inhomogeneous variances, two-sided, $\alpha = 0.05$). ^{n.s.w} = No statistically significant difference to the control (Welch-t Test for inhomogeneous variances, two-sided, $\alpha = 0.05$). ^{n.s.} = No statistically significant difference to the control (Student-t Test, two-sided, $\alpha = 0.05$).

Conclusion:

If used as recommended, Amidosulfuron WG 75 should not have an impact on nitrogen transformation in soils.

CP 10.6 Effects on terrestrial non-target higher plants

Risk assessment for Terrestrial Non-Target Higher Plants

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. Spray drift from the treated areas may lead to residues of a product in off-crop areas.

(I) For herbicides and plant growth regulators, it is considered unprofitable to conduct tier. A studies as it is inevitable that these will lead to tier 2 or dose response studies in order to generate data suitable for deterministic or probabilistic risk assessments, i.e. ER50 values for 6-10 species, representing a broad range of plant species.

Overall, four Tier 2 dose response tests have been conducted with the formulation Amiosulfuron WG 75, including three vegetative vigour studies and one seeding emergence study. Furthermore, one higher tier semi-field test and one field test with the most sensitive species under realistic outdoor conditions have been conducted with the formulation. An overview of the studies and the endpoints , B relevant for the non-target plant risk assessment is prooded in the table below.

Ecological endpoints The endpoints from the tier 2 studies and the higher ther studies used for the risk assessment are summarised in following table.

| Table CP 10.6- 1: | Survey of non-target plant tests performed with Amidosulfuron WG 75 |
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| Lested (species) Lest substance Application rate vegetative vigour (cabbage, system, tomato, turnip) vegetative vigour, 0 (control), 5.1, 10, 20, 42, 25 and 81 g a.s. ha for cabbage, perennial ryegrass and tomato 0 (control), 0.31, 13, 5.1, 20 and 81 g a.s. ha for soybean 0 (control), 0.31, 13, 5.1, 20 and 81 g a.s. ha for soybean 0 (control), 0.31, 13, 5.1, 20 and 81 g a.s. ha for soybean 0 (control), 0.31, 13, 5.1, 20 and 81 g a.s. ha for soybean 0 (control), 0.31, 13, 5.1, 20 and 81 g a.s. ha for soybean 0 (control), 0.31, 13, 5.1, 20 and 81 g a.s. ha for soybean 0 (control), 0.31, 13, 5.1, 20 and 81 g a.s. ha for soybean 0 (control), 141, 287, 563, 40, 25, 222 and 45 g a.s. ha for sulfiver (14 Thi) 0 (control), 141, 287, 563, 40, 25, 222 and 45 g a.s. ha for sulfiver (14 Thi) 0 (control), 141, 287, 563, 40, 25, 222 and 45 g a.s. ha for sulfiver (14 Thi) 0 (control), 141, 287, 563, 1125, 22.5 and 45 g a.s. ha for sulfiver (14 Thi) 0 (control), 141, 287, 563, 1125, 22.5 and 45 g a.s. ha for sulfiver (14 Thi) 0 (control), 141, 287, 563, 1125, 22.5 and 45 g a.s. ha for sulfiver (14 Thi) 0 (control), 0.18, 0.55, 0.7, 141, 281 and 5.63 g a.s. ha for sulfiver (14 Thi) 0 (control), 0.18, 0.55, 0.7, 141, 281 and 46 for g a.s. fan for sulfiver (14 Thi) 0 (control), 0.18, 0.55, 0.7, and 41 g proha for g setting (14) growth accession (14) growth accession (14) growth accession (14) growth accession (14) growth accession (15) growth accession (15) gras. Ana for Amarantilus trensfluxe (15) g a.s. ha for substiter (16) (control), 0.43, 0.35, 0.70, 1.41, 2.81 and anaranthacces (16) (control), 0.43, 0.35, 0.70, 1.41, 2.81 and anaranthacces (16) (control), 0.43, 0.35, 0.70, 1.41, 2.81 and anaranthacces (16) (control), 0.43, 0.35, 0.70, 1.41, 2.81 and anaranthacces (17) g a.s. ha for Amaranthac acci (18) g a.s. ha for Substiter and (12) g a.s. ha for Substiter and (12) g a.s. ha for Substitaria media (12) (control), 0.43, 0.35, 0.70 | Number of species | Test method | Effects | Reference |
|---|---------------------------|---|---------------------------|-----------------|
| vegetative vigour most sensitive sponse | tested (species) | Application rate | | |
| Dicotyledoneae: 4 (adbage, soybean, tomato, (umip) Monocotyledoneae: 2 (oat, perennial ryegrass) (oat, perennial ryegrass) (oat, perennial ryegrass) (oat, perennial ryegrass) (ocmrol), 0.33, 1.3, 5.1, 20 and 81 g a.s./ha for cabbage, perennial ryegrass and 0 (control), 0.33, 1.3, 5.1, 20 and 81 g a.s./ha for cabbage, perennial ryegrass and 0 (control), 0.33, 1.3, 5.1, 20 and 81 g a.s./ha for cabbage, perennial ryegrass and 0 (control) and 81 g a.s./ha for or ad ad turnip with observations on mortality and morphological abnormalities at lest termination, evaluation of the Effects of shoot dry weight 21 days after appfication 0 (control), 1.41, 2.81, 563, 41, 25, 225, 404 45 g a.s./ha for sunflower (12, fm) 0 (control), 0.423, 0.63, 41, 2.81, and 5.63 g as/ha for sunflower (12, fm) 0 (control), 0.44, 0.63, 0.7, 1.41, 2.81 and 5.63 g as/ha for sunflower (12, fm) 0 (control), 0.44, 0.63, 0.7, 1.41, 2.81 and 5.63 g as/ha for sunflower (13, fm) 0 (control), 0.44, 0.63, 0.7, 1.41, 2.81 and 5.63 g as/ha for sunflower (13, fm) 0 (control), 0.42, 0.042,0.088, 0.78, 0.35 0 (control), 0.44, 0.68, 0.70, 1.41, 2.81 0 (control), 0.48, 0.35, 0.70, 1.41 0 (control), 0.41, 2.81, 5.63 and 1.25 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.48, 0.35, 0.70, 1.41, 2.81 0 (control), 0.41, 2.81, 5.63 and 1.25 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.41, 2.81, 5.63 and 1.25 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.41, 2.81, 5.63 and 1.25 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.41, 2.81, 5.63 and 1.25 g a.s./ha for <i>Stellar</i> | vegetative vigour | | ر ک | I |
| (cabage, soybean, tomato, turnip) Monocotyledonea: 2 (oat, perennial ryegrass) (oat, perennial ryegrass) (ocontrol), 14, 2, 81, 563, 41, 25, 22, 5 and 45 g a.s./ha for sunflower (per hn) 0 (control), 042, 0183, 018, 035, 0.7, 141, 2, 81 and 5, 63 g a.s./ha for sunflower (per nup) 0 (control), 044, 0188, 035, 035, 07, and 1.4 g a.s./ha for sunflower (per nup) 0 (control), 044, 0188, 045, 035, 035, 07, and 1.4 g a.s./ha for stellite perennis 0 (control), 0, 044, 0, 048, 048, 048, 035, 035, 03, and 0 (control), 0, 044, 0458, 035, 035, 07, and 0 (control), 0, 044, 0458, 035, 035, 07, 141, and 2.8 g a.s./ha for stellaria media 0 (control), 0, 018, 0, 035, 0, 70, 141, 2, 81, 563, and 1.2 s g a.s./ha for Bellis perennis 0 (control), 0, 14, 2, 81, 563, 11, 25, 22, 5 and 0 (control), 0, 018, 0, 035, 0, 70, 141, 2, 81, 563, and 1.2 s g a.s./ha for Bellis perennis 0 (control), 0, 14, 2, 81, 563, 11, 25, 22, 5 and 0 (control), 0, 018, 0, 035, 0, 70, 141, 2, 81, 563, 11, 25, 22, | Dicotyledoneae: 4 | vegetative vigour; | most sensitive | |
| iomato rumip) 0 (control), 5. f. 10, 20, 42, 25 and 81 g iowest Effect 0.1-1 (aat, perennial ryegrass) a.s./ha for cabbage, perennial ryegrass and 0 (control), 0.33, 1.3, 5.1, 20 and 81 g iowest Effect 0.1-1 (aat, perennial ryegrass) 0 (control), 0.33, 1.3, 5.1, 20 and 81 g iowest Effect 0.1-1 (aat, perennial ryegrass) 0 (control), 0.33, 1.3, 5.1, 20 and 81 g iowest Effect 0.1-1 (aat, perennial ryegrass) 0 (control) and 81 g a.s./ha for oxyophean 0 (control), 0.034, 1.3, 5.1, 20 and 81 g iowest Effect (aat, perennial ryegrass) iowest effect iowest effect iowest effect iowest effect (ontor) iowest effect iowest effect iowest effect iowest effect iowest effect (onion) vegetative vigour, formologic (2 ^{min} run) iowest effect io | (cabbage, soybean, | Tier 2 dose response | species: soxbean; = | 2002; M-240817- |
| Monocotyledonea: 2 (oat, perennial ryegrass) a.s./ha for cabbage, perennial ryegrass and tomato 67 g a.s./ha 67 g a.s./ha (oat, perennial ryegrass) 0 (control), 0.33, 1.3, 5.1, 20 and 81 g a.s./ha for soybean 67 g a.s./ha 67 g a.s./ha (ocontrol), 0.03, 1.3, 5.1, 20 and 81 g a.s./ha for soybean 0 (control), 0.03, 1.3, 5.1, 20 and 81 g a.s./ha for soybean 67 g a.s./ha 67 g a.s./ha (ocontrol), 0.01, 0.33, 1.3, 5.1, 20 and 81 g a.s./ha for soybean 0 (control), 0.01 g a.s./ha 67 g a.s./ha (out, perennial ryegrass) (control), 0.01 g a.s./ha 67 g a.s./ha 67 g a.s./ha (out, perennial ryegrass) (control), 0.01 g a.s./ha 67 g a.s./ha 67 g a.s./ha (control), 0.02 (control), 0.03 (control), 0.03 (control), 0.04 (control), 0.03 (control), 0.04 (control), 0.03 | tomato, turnip) | 0 (control), 5.1, 10, 20, 42, 25 and 81 g | lowest ER: | 01-1 0 2 |
| (oat, perennial ryegrass) tomato 0 (control), 0.33, 1.3, 5.1, 20 and 81 g as./ha for soybean 0 (control), 0.33, 1.3, 5.1, 20 and 81 g as./ha for oat and urmip with observations on mortality and morphological abnormalities aftest termination, evaluation of the effects of shoot dry weight 21 days after application moot sensitive species: sufflower Dicotyledoneae: 3 (control), 1.42, 2.81, 563, 11.22, 22, 5 and 45 g a.s./ha for such beet, setcumber and onion 0 (control), 1.42, 2.81, 563, 11.22, 22, 5 and 45 g a.s./ha for such beet, setcumber and onion 0 (control), 0.48, 0.35, 0.7 and 1.42 g as./ha for such beet, setcumber and onion 0 (control), 0.48, 0.35, 0.7 and 1.42 g as./ha for such beet, setcumber and onion 0 (control), 0.44, 0.28, 0.55, 0.7 and 1.42 g as./ha for such beet, setcumber and the foul assessments (Bytotoxid) and set sensitive species: Achillea millefolium; lowest Carrier 2 abser response most sensitive species: Achillea millefolium; lowest ERa: Dicotyledoneae: 3 veletative figour; for any with assessments (Bytotoxid) and 2.42 g a.s./ha for such beet set set set set set set set set set | Monocotyledoneae: 2 | a.s./ha for cabbage, perennial ryegrass and | 67 g a s ma | KCR 10.6.2.0 |
| 0 (control), 0.33, 1.3, 5.1, 20 and 81 g a.s./ha for soybean 0 (control) and 81 g a.s./ha for out and turnip with observations on mortality and morphological abnormalities at less termination, evaluation of the effects of shoot dry weight 21 days after application (squar bect, cucumber, sunflower) moot sensitive species: sunflower, 0 (control), 1.41, 2.81, 5.63, 4J, 25, 222 and 45 g a.s./ha for sugar beet, elecumber and onion 0 (control), 1.49, 2.81, 963, 11.25, 22.5 and 45 g a.s./ha for sunflower (2 ¹⁶ run) with assessments (Bystoroticity) ratings, 90 (control), 0.49, 0.28, 0.18, 0.35, 0.7 and 1.42 ra.s./hg for sunflower (2 ¹⁶ run) with assessments (Bystoroticity) ratings, 90 (control), 0.022, 0.043, 0.088, 0.18, 0.35, 91 (control), 0.022, 0.043, 0.088, 0.18, 0.35, 91 (control), 0.022, 0.043, 0.088, 0.18, 0.35, 91 (control), 0.022, 0.014, 0.088, 0.18, 0.35, 91 (control), 0.024, 0.018, 0.35, 0.7, 1.41 and 2.89 g a.s./hg for Cendurea cyanus, Marricaria (Mamoritha, Senecio vulgaris with assestments, Garvival, visual flytotopicity, plating growth stage and shoot dry worghth 1/2 4 and 21 days after application; 91 (control), 0.08, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./hg for <i>Cendurea cyanus</i> , Marricaria, <i>Charona Astronactia</i> 9 (control), 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./hg for <i>Amaranthus retroflexus</i> ; 9 (control), 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./hg for <i>Amaranthus retroflexus</i> ; 9 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./hg for <i>Cendurea cyanus</i> , <i>Senecio</i> with arcsestments, <i>Garvanas</i> ; 9 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./hg for <i>Cendurea cyanus</i> , <i>Senecio</i> with arcsestments, <i>Garvana</i> | (oat, perennial ryegrass) | tomato | | L 5 |
| a.s/ha for soybean 0 (control) and 81 g a.s/ha for oat and turnip with observations on mortality and morphological abnormalities a fest termination, evaluation of the effects of shoot dry weight 21 days after application shoot dry weight 21 days after application shoot dry weight 21 days after application shoot dry weight 21 days after application (sugar beet, cucumber, sunflower) most sensitive species: suflower, biowest Effest: 0 (control), 1.41, 2.81, 563, 11.25, 22.5 and 45 g a.s./ha for sunflower (12 http:// 0 (control), 1.42, 2.81, 563, 11.25, 22.5 and 45 g a.s./ha for sunflower (2 ^{art} prip) 0 (control), 0.44, 2.81, 505, 1.11, 25, 22.5 and 45 g a.s./ha for sunflower (2 ^{art} prip) 0 (control), 0.44, 0.088, 018, 0.35, 0.7 and 1.44 g a.s./ha for sunflower (2 ^{art} prip) 0 (control), 0.420, 2.044, 20.088, 018, 0.35 and 0.7 g a.s./ha for sunflower (2 ^{art} prip) 0 (control), 0.44, 0.088, 018, 0.35 and 0.7 g a.s./ha for sunflower (2 ^{art} prip) 0 (control), 0.44, 0.088, 018, 0.35 and 0.7 g a.s./ha for sunflower (2 ^{art} prip) 0 (control), 0.44, 0.088, 018, 0.35 and 0.7 g a.s./ha for sunflower (2 ^{art} prip) 0 (control), 0.44, 0.088, 018, 0.35 and 0.7 g a.s./ha for <i>Centairea cyanus</i> , <i>Maricarii</i> (<i>Diamontita</i> , <i>Senecio vulgaris</i> with assestments (<i>Strivi</i> val, visual brytotogicity, bhaf growth stage and shoot dry weight) 7.04 and 21 days after aphoteation 2.81 g a.s./ha for <i>Centairea cyanus</i> , <i>Maricarii</i> (<i>Diamontita</i> , <i>Senecio vulgaris</i> with assestments (<i>Strivi</i> val, visual brytotogicity, bhaf growth stage and shoot dry weight) 7.04 and 21 days after aphoteation 0 (control), 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for <i>Stellaria</i> media 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Stellaria</i> media 0 (control), 0.141, 2.281, 5.63 and 11.25 g a.s./ha for <i>Centairea cyanus</i> , <i>Senecio</i> with arise stage and shoot dry weight) 7.04 and 21 days after aphoteation 0 (control), 0.141, 2.81, 5.63 and 11.25 g a.s./ha for <i>Centairea cyanus</i> , <i>Senecio</i> witharear | | 0 (control), 0.33, 1.3, 5.1, 20 and 81 g | | 0″ 、√ |
| 0 (control) and 81 g a.s./ha for oat and urnip 0 (control) and 81 g a.s./ha for oat and urnip 0 with observations on mortality and morphological abnormalities at lest termination, evaluation of the Reflected of shoot dry weight 21 days after application most sensitive species: sufflower; M3-366958-01-1 Dicotyledoneae: 3 (onion) vegetative vigour; most sensitive of (control), 1.41, 2.81, 5.63, 41, 25, 225 and 45 g a.s./ha for sunflower (12 rbn) 0 (control), 1.40, 2.81, 065, 11, 25, 225 and 5 6.3 g a.s./ha for sunflower (12 rbn) 0 (control), 0.024, 0.088, 0.18, 0.35, 0.7 and 1.42 g a.s./ha for sunflower (12 rbn) 0 (control), 0.024, 0.088, 0.18, 0.35, 0.7 and 1.42 g a.s./ha for sunflower (2 rd run) 0 (control), 0.024, 0.088, 0.18, 0.35, 0.7 and 1.42 g a.s./ha for sufflower (2 rd run) 0 (control), 0.024, 0.088, 0.18, 0.35, 0.7 and 7 g a.s./ha for sufflower (2 rd run) 0 (control), 0.022, 0.044, 0.088, 0.18, 0.35 and 6 rd g a.s./ha for brythills percifinis q (control), 0.022, 0.044, 0.088, 0.18, 0.35, 0.7 and 7 g a.s./ha for Sufflower (2 rd run) 0 (control), 0.024, 0.088, 0.18, 0.35, 0.7, 1.41 and 2.80 g a.s./ha for <i>Pathillea</i> diffeorium; 0 (control), 0.044, 0.088, 0.18, 0.35, 0.7, 1.41 and 2.80 g a.s./ha for <i>Pathillea</i> diffeorium; 0 (control), 0.080, 0.18, 0.35, 0.7, 1.41 and 2.81 g a.s./ha for <i>Contarea cyanus</i> , <i>Marcanihaceae</i> ; (non-crop species; (non-crop species; (attraceae; (attracea | | a.s./ha for soybean | | |
| turnip with observations on mortality and morphological abnormalities at lest termination, evaluation of the effects of shoot dry weight 21 days after applicationmost sensitive species: sufflower, boot dry weight 21 days after applicationDicotyledoneae: 3 (sugar beet, cucumber) Monocotyledoneae: 1 (onion)vegetative vigour; tire 2 dose response 0 (control), 1.41, 2.81, 5.63, 41.25, 22.5 and 45 g a.s./ha for sunflower (25 min) 0 (control), 1.42, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for sunflower (25 min) 0 (control), 1.42, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for sunflower (27 min) vegetative vigour; stages were determined at the final assessments. (26 min) vegetative vigour; fire 2 dose response 0 (control), 0.022, 0.042, 0.088, 0.18, 0.35, 0.7 and 1.41, 2.81, 5.63, 3.63, 0.7 and 1.41 g asscha for sunflower (27 min) vegetative vigour; fire 2 dose response 0 (control), 0.022, 0.042, 0.088, 0.48, 0.35, 0.7 and 1.41 g asscha for sunflower (27 min) vegetative vigour; fire 2 dose response 0 (control), 0.022, 0.042, 0.088, 0.48, 0.35, 0.7 and 1.41 g asscha for sunflower (27 min) vegetative vigour; fire 2 dose response 0 (control), 0.022, 0.042, 0.088, 0.48, 0.35, 0.7 and 1.41 g asscha for sunflower (27 min) vegetative vigour; fire 2 dose response 0 (control), 0.022, 0.042, 0.088, 0.48, 0.35, 0.7 and of 1.41 g asscha for sunflower (27 min) vegetative vigour; fire 2 dose response 0 (control), 0.023, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.5.Ma for dendura equations with assestments (derivinal, visual phytopxicity, plant growth stage and shoot dry vegeth 7.024 and 21 days after application vegetative vigour; fire 2 dose response 0 (control), 0.41, 0.281, 5.5, 0.70, 1.41 and 2.81 g a.5.Ma for Sunflave area species: (0 (control), 0.41, 0.281, 0.53, 0.70, 1 | | 0 (control) and 81 g a.s./ha for oat artic | | Ô. |
| with observations on mortality and morphological abnormalities at test termination, evaluation of the effects of shoot dry weight 21 days after application (sugar beet, cucumber, sunflower) Monocotyledoneae: 1 (onion) 0 (control), 1.41, 2.81/5.63, 41.25, 225 and donion 0 (control), 1.41, 2.81/5.63, 41.25, 225 and donion 0 (control), 1.41, 2.81/5.63, 41.25, 225 and donion 0 (control), 1.40, 2.81, 263, 11.25, 225 and donion 0 (control), 0.024, 0.088, 0.18, 0.25, 0.7 and 1.4U2 a.s./hg for sunflower (13 ⁻⁴ run) welf assessments (Drytotoxidity ratings, shirvivally), 14 and 21 days after application, sheot dry weight and growth stages were determined the facil ascessment Dicotyledoneae: 5 (Asteraceae) (Asteraceae) Dicotyledoneae: 5 (Asteraceae) Dicotyledoneae: 5 (Asteraceae) Dicotyledoneae: 5 (Asteraceae) Dicotyledoneae: 5 (Asteraceae) Dicotyledoneae: 5 (Control), 0.028, 0.18, 0.35, 0.7 n, 1.41 and 2.81 g.s./ha for %chillea willefolium 0 (control), 0.044, 0.088, 0.518, 0.35 and 9.7 g.s.%ha for %chillea willefolium 0 (control), 0.088, 0.18, 0.35, 0.7 n, 1.41 and 2.81 g.s./ha for %chillea willefolium 0 (control), 0.098, 0.18, 0.35, 0.7 n, 1.41 and 2.81 g.s./ha for %chillea willefolium 0 (control), 0.098, 0.18, 0.35, 0.7 n, 1.41 and 2.81 g.s./ha for %chillea willefolium 0 (control), 0.098, 0.18, 0.35, 0.7 n, 1.41 and 2.81 g.s./ha for %chillea willefolium 0 (control), 0.098, 0.18, 0.35, 0.7 n, 1.41 and 2.81 g.s./ha for %chillea willefolium 0 (control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g.s./ha for %chillea willefolium 0 (control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g.s./ha for %chillea media 0 (control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g.s./ha for %chillea media 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g.s./ha for %chillea media 0 (control), 1.41, 2.81, 5.63 and 11.25 g.s./ha for %chillea media 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g.s./ha for %chillea media 0 (control), 1.41, 2.81, 5.63 and 11.25 g.s./ha for %chillea media 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81, 5.63 | | turnip 🖉 🔬 | | |
| morphological abnormalities at jest termination, evaluation of the effecte of shoot dry weight 21 days after application usual beet, cucumber, sunflower) Monocotyledoneae: 1 (onion) 0 (control), 1.41, 2.81, 5.63, 41, 25, 22, 5 and 45 g a.s./ha for sugar beet, bucumber and 0 (control), 1.41, 2.81, 5.63, 11, 25, 22, 5 and 45 g a.s./ha for sunflower (12 min) 0 (control), 1.41, 2.81, 5.63, 11, 25, 22, 5 and 45 g a.s./ha for sunflower (2 ^m ruft) 0 (control), 0.024, 0.088, 018, 0.35, 0.7 and 1.41 g a.s./ha for sunflower (2 ^m ruft) 0 (control), 0.024, 0.088, 018, 0.35, 0.7 and 1.41 g a.s./ha for sunflower (2 ^m ruft) 0 (control), 0.022, 0.042, 0.088, 018, 0.35 0 (control), 0.022, 0.042, 0.088, 018, 0.35 0 (control), 0.022, 0.042, 0.088, 018, 0.35 0 (control), 0.044, 0.088, 018, 0.35, 0.7 and 0 (control), 0.024, 0.088, 018, 0.35, 0.7 and 0 (control), 0.024, 0.088, 018, 0.35, 0.7 and 0 (control), 0.024, 0.088, 018, 0.35, 0.7 and 0 (control), 0.044, 0.088, 0.18, 0.35, 0.7 and 0 (control), 0.044, 0.088, 0.18, 0.35, 0.7 and 0 (control), 0.090, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for <i>Sentileo</i> fullies <i>milleolium</i> , <i>biotosticito</i> <i>species:</i> <i>AmircaridGhamonfilta</i> , <i>Senecio</i> vulgaris with assestments (Brivival, visual <i>phytotosticity</i> , plafit growth stage and shoot dry 6right) 7.04 and 21 days after applications 0 (control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for <i>Sentime and</i> 0 (control), 0.09, 0.18, 0.35, 0.70, 1.41, 2.81 5.63 g a.s./ha for <i>Sentime and</i> 0 (control), 0.09, 0.18, 0.35, 0.70, 1.41, 2.81 5.63 g a.s./ha for <i>Sentime and</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 5.63 g a.s./ha for <i>Sentime and</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 5.63 g a.s./ha for <i>Sentime and</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 5.63 g a.s./ha for <i>Sentime</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 5.63 g a.s./ha for <i>Sen</i> | | with observations on mortality and | | |
| termination, evaluation of the Effects of shoot dry weight 21 days after applicationDicotyledoneae: 3 (sugar beet, cucumber, sunflower)mod sensitive species: sufflower; (ocontrol), 141, 2 St/5,63, 4D,25, 222 and d 5 g a.s./ha for sugar beet, elecumber and onion 0 (control), 141, 2 St/5,63, 4D,25, 225 and d 5 g a.s./ha for sugar beet, elecumber and onion 0 (control), 141, 2 St/5,63, 11 25, 225 and d 5 g a.s./ha for sugar beet, elecumber and onion 0 (control), 141, 2 St/5,63, 11 25, 225 and d 5 g a.s./ha for sunflower (12 hun) 0 (control), 0.038, 0.088, 0.18, 0.35, 0.7 and 1.41 cg a.s./ha for sunflower (2 nd run) welt assessment application, shoot dry weight and growth d stages were defermined at the final assessment assessment application, shoot dry weight and growth d stages were defermined at the final assessment application, shoot 0, 0.088, 0.18, 0.35, 0.7 and 0 (control), 0.022, 0.042, 0.088, 0.48, 0.35 and 0.7 g a sha for <i>Beltis pereinis</i> 0 (control), 0.024, 0.088, 0.48, 0.35, 0.7 and 0 (control), 0.044, 0.088, 0.48, 0.35, 0.7 and 0 (control), 0.044, 0.088, 0.49, 0.35, 0.7 and 0.461 g a.s./haMost sensitive species: Achillea millefolium; lowest ERse; 0.461 g a.s./haDicotyledoneae: 5 (non-crop species) (control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for <i>Sensens</i> 0 (control), 0.09, 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Sensens</i> 0 (control), 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Sensens</i> 0 (control), 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Centaurea cyanus</i> , Mariaranthus etroflexus; locontrol), 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Sensens</i> 0 (control | | morphological abnormalities at test | | <u>s</u> |
| shoot dry weight 21 days after applicationmod SensitiveDicotyledoneae: 3 (sugar beet, cucumber, sunflower)vegetative vigour, Tier 2 dose responsemod Sensitive species: sufflower; bivest ERs: 0 (control), 1.40, 2.81, 563, 11.25, 2.25, stud d 45 g a.s./ha for sunflower (2* ruh) 0 (control), 0.140, 2.81, 563, 11.25, 2.25, stud d 45 g a.s./ha for sunflower (2* ruh) 0 (control), 0.034, 0.088, 0.18, 0.35, 0.7 add 1.41 cg a.s./ha for sunflower (2* ruh) 0 (control), 0.034, 0.088, 0.18, 0.35, 0.7 add 1.41 cg a.s./ha for sunflower (2* ruh) 0 (control), 0.034, 0.088, 0.18, 0.35, 0.7 add 1.41 cg a.s./ha for sunflower (2* ruh) 0 (control), 0.034, 0.088, 0.18, 0.35, 0.7 add 1.41 cg a.s./ha for sunflower (2* ruh) 0 (control), 0.022, 0.044, 0.088, 0.48, 0.35 and 0.7 g a.s./ha for sunflower (2* ruh) 0 (control), 0.022, 0.044, 0.088, 0.48, 0.35 and 0.7 g a.s./ha for sunflower (2* ruh) 0 (control), 0.022, 0.044, 0.088, 0.48, 0.35 and 0.7 g a.s./ha for sunflower (2* ruh) 0 (control), 0.022, 0.044, 0.088, 0.48, 0.35 and 0.7 g a.s./ha for sufflix pereinis 0 (control), 0.022, 0.044, 0.088, 0.48, 0.35 and 0.7 g a.s./ha for sufflix pereinis 0 (control), 0.088, 0.14, 0.35, 0.7, 1.41 and 2.81 g a.s./ha for sufflix pereinis 0 (control), 0.088, 0.14, 0.35, 0.7, 1.41 and 2.81 g a.s./ha for sufflix pereinis 0 (control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for sufflix pereinis 0 (control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for sufflix pereinis 0 (control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for sufflix and 0 (control), 0.35, 0.70, 1.41, 2.81 s.63 and 1.25 g a.s./ha for Sufflix and 0 (control), 0.35, 0.70, 1.41, 2.81 and 0.83 g a.s./ha for Sufflix and 0 (control), 0.35, 0.70, 1.41, 2.81 and 0.83 g a.s./ha for Sufflix and 0 (control), 0.35, 0.70, 1.4 | | termination, evaluation of the effects on | | |
| Dicotyledoneae: 3 (union) Dicotyledoneae: 1 (onion) Dicotyledoneae: 1 (onion) Dicotyledoneae: 1 (onion) Dicotyledoneae: 1 (onion) Dicotyledoneae: 1 (onion) Dicotyledoneae: 3 (onion) Dicotyledoneae: 5 (non-crop species) (Asteraceae) Dicotyledoneae: 5 (control), 0,028, 0,18, 0,35, 0,7, 1,41, 2,81 and 5,63 g a.s/ha for sunflower (3 ^{ar} tm) 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,42 g a.s./ha for sunflower (3 ^{ar} tm) 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,42 g a.s./ha for sunflower (3 ^{ar} tm) 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,42 g a.s./ha for sunflower (3 ^{ar} tm) 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,41 g a.s./ha for sunflower (3 ^{ar} tm) 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,41 g a.s./ha for sunflower (3 ^{ar} tm) 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,41 g a.s./ha for sunflower (3 ^{ar} tm) 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,41 g a.s./ha for sunflower (3 ^{ar} tm) 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,41 g a.s./ha for sunflower (3 ^{ar} tm) 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,41 g a.s./ha for sunflower (3 ^{ar} tm) 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,41 g a.s./ha for sunflower (3 ^{ar} tm) 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,41 g a.s./ha for Sufflix pereinis 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,41 g a.s./ha for Sufflix pereinis 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,41 g a.s./ha for Sufflix pereinis 0 (control), 0,028, 0,18, 0,35, 0,7 and 1,41 g a.s./ha for Sufflix pereinis 0 (control), 0,038, 0,18, 0,35, 0,70, 1,41 and 2,81 g a.s./ha for Sufflix and 1,25 g a.s./ha for Sufflix and 0 (control), 0,18, 0,35, 0,70, 1,41, 2,81 and 1,25 g a.s./ha for Sufflix and 0 (control), 0,18, 0,35, 0,70, 1,41, 2,81 and 1,25 g a.s./ha for Centaurea cyanus, Senecio waferris 0 (control), 1,41, 2,81, 5,63, 11,25, 2,25 and 45 g a.s./ha for Centaurea cyanus, Senecio waferris 0 (control), 1,41, 2,81, 5,63, 11,25, 2,25 and 45 g a.s./ha for Centaurea cyanus, Senecio waferris 0,07 g a.s./ha | | shoot dry weight 21 days after application | | |
| (sugar beet, cucumber, sunflower) Monocotyledoneae: 1 (onion)(Ther 2 dose response (control), 1.41, 2.81, 5.63, 4J, 25, 225 and 45 g a.s./ha for sugar beet, excumber and onion 0 (control), 1.41, 2.81, 5.63, 4J, 25, 225 and 45 g a.s./ha for sunflower (12 hn) 0 (control), 0.44, 2.81, 5.63, 1J, 25, 22.5 and 45 g a.s./ha for sunflower (12 hn) 0 (control), 0.000, 0.000, 0.000, 0.000, 0.000, 0.000, 0.000, 0.000, 0.000, 0.000, 0.000, 0.000, 0.0000, 0.000 | Dicotyledoneae: 3 | vegetative vigour; | most sensitive | ,; 2010; |
| sunflower) 0 (control), 1, 41, 2, 81, 5, 63, 41, 25, 22, 5, and onion 0 (control), 1, 42, 2, 81, 5, 63, 41, 25, 22, 5, and onion 0 (control), 1, 42, 2, 81, 5, 63, 41, 25, 22, 5, and 45 g a, s, ha for sunflower (1s hm) 0 (control), 0, 18, 0, 35, 0, 7, 1, 41, 2, 81 and 5, 63 g a, s, ha for sunflower (1s hm) 0 (control), 0, 0, 0, 0, 0, 0, 80, 0, 18, 0, 35, 0, 7, 1, 41, 2, 81 and 5, 63 g a, s, ha for sunflower (1s hm) 0 (control), 0, 0, 0, 0, 0, 0, 0, 80, 0, 18, 0, 35, 0, 7, 1, 41, 2, 81 and 5, 63 g a, s, ha for sunflower (1s hm) most sensitive Dicotyledoneae: 5, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, | (sugar beet, cucumber, | Tier 2 dose response | species: sunflower; | M-366958-01-1 |
| Monocotyledoneae: 1 (onion) 4 2 g a.s./ha for sunflower (14 run) 0 (control), 0.18, 0.25, 0.7, 1.41, 2.81 and 5.63 g a.s./ha for sunflower (2 rd run) 0 (control), 0.08, 0.18, 0.35, 0.7 and 1.42 g a.s./ha for sunflower (3 rd run) wild assessment- assessment- (<i>Asteraceae</i>) 1 2 g a.s./ha for sunflower (3 rd run) 0 (control), 0.08, 0.18, 0.35, 0.7 and 1.42 g a.s./ha for sunflower (3 rd run) wild assessment- (<i>Asteraceae</i>) 1 2 g a.s./ha for sunflower (3 rd run) 0 (control), 0.08, 0.18, 0.35, 0.7 and 1.42 g a.s./ha for sunflower (3 rd run) 0 (control), 0.08, 0.18, 0.35, 0.7 and 1.42 g a.s./ha for sunflower (3 rd run) 0 (control), 0.022, 0.044, 0.088, 0.48, 0.35 and 0.7 g a.s./ha for <i>fellis pereinis</i> 0 (control), 0.046, 0.88, 0.48, 0.35, 0.37 and 0.461 g a.s./ha 1 2 s g a.s./ha for <i>fellis pereinis</i> 0 (control), 0.08, 0.18, 0.35, 0.70, 1.41 and 2.88 g a.s./ha for <i>fellis pereinis</i> 0 (control), 0.08, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for <i>fellis pereinis</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 1.25 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 1.25 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 1.25 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 1.25 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 1.25 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 1.25 g a.s./ha for <i>Centaurea cyanus</i> , <i>Senecio</i> <i>wildarif fellis perenis</i> 0 (control), 0.44, 0.28, 1.25, 2.2.5 and 45 g a.s./ha for <i>Centaurea cyanus</i> , <i>Senecio</i> <i>wildarif fellis perenis</i> 0 (control), 0.45, 0.35, 0.70, 1.41, 2.81 and 1.25 g a.s./ha for <i>Centaurea cyanus</i> , <i>Senecio</i> <i>wildarif fellis perenis</i> 0 (control), 0.45, 0.35, 0.70, 1.41, 2.81 and 1.25 g a.s./ha for <i>Centa</i> | sunflower) | 0 (control), 1.41, 2.81, 5.63, 49.25, 229 and | fowest ERs: | KCP 10.6.2/03 |
| (onion) <t< td=""><td>Monocotyledoneae: I</td><td>45 g a.s./ha for sugar beet, excumber and</td><td>v.11 g.a.s./ha</td><td></td></t<> | Monocotyledoneae: I | 45 g a.s./ha for sugar beet, excumber and | v.11 g.a.s./ha | |
| bicotyledoneae: 5 (dentrol), 1,47, 2,81,505, 11,26, 22.3 and 45 g a.s./ha for sunflower (1 st rhn) 0 (control), 0,004, 0,088, 0,18,0,35, 0,7 and 1,42 g a.s./ha for sunflower (2 st rhn) 0 (control), 0,004, 0,088, 0,18,0,35, 0,7 and 1,42 g a.s./ha for sunflower (3 st rhn) wfal assessment- application, shoot dry weight and growth stages were determined at the final assessment- 0 (control), 0,002, 0,043,0,088, 0,18,0,35 and 0,7 g a.s./ha for <i>Centaurea cyanus</i> , <i>Maricaria Ghamontita</i> , <i>Senecio vulgaris</i> with assessments (furvival, visual hytotoxicity, plant growth stage and shoot dry Gright) 7,04 and 21 days after application, 0,088, 0,18, 0,35, 0,70, 1,41 and 2.81 g a.s./ha for <i>Sellaria media</i> 0 (control), 0,018, 0,35, 0,70, 1,41 and 2.81 g a.s./ha for <i>Stellaria media</i> 0 (control), 0,018, 0,35, 0,70, 1,41, 2.81 and 5.63 g a.s./ha for <i>Stellaria media</i> 0 (control), 0,018, 0,35, 0,70, 1,41, 2.81 and 5.63 g a.s./ha for <i>Stellaria media</i> 0 (control), 0,018, 0,35, 0,70, 1,41, 2.81 and 5.63 g a.s./ha for <i>Stellaria media</i> 0 (control), 0,018, 0,35, 0,70, 1,41, 2.81 and 5.63 g a.s./ha for <i>Stellaria media</i> 0 (control), 0,141, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for <i>Centaurea cyanus</i> , <i>Senecio</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> <i>underric</i> | (onion) | | | |
| Dicotyledoneae: 5 (asteraceae, Araranthaceae, Caryophyllaceae) (control), 0.98, 0.35, 0.70, 1.41, 2.81 and 5.63 g as/ha for sunflower (3rd run) wth assessments vectative figure; (asteraceae, Amaranthaceae, Caryophyllaceae) (asteraceae, Amaranthaceae, Caryophyllaceae) (asteraceae, Amaranthaceae, (control), 0.35, 0.70, 1.41, 2.81, 5.63, 11.25, 22.5 and (s g a.s.ha for Stellaria media 0 (control), 0.35, 0.70, 1.41, 2.81, 5.63, and 1.25 g a.s.ha for Chellarea cyanus, Senecio vulgarix (asteraceae, astha for Centaurea cyanus, Senecio (asteraceae, a | | 15 g a s/ha for sunflower (1st m) | N N | |
| Dicotyledoneae: 5 (non-crop species)(Control), 0.082, 0.18, 0.35, 0.7 and 1.4 to a.s./ha for sunflower (3 rd run) with assessments (flytotoxicity ratings, strivial)2, 14 and 21 days after application, shoot dry weight and growth stages were defermined at the final assessment.most sensitive species: Achillea millefolium; 0.088, 0.18, 0.35, 0.7 and millefolium; 0.0088, 0.18, 0.35, 0.7 and 1.41 g ass/ha for <i>Bellis perennis</i> 0.0088, 0.18, 0.35, 0.7 and 1.41 g ass/ha for <i>Bellis perenis</i> 0.0088, 0.18, 0.35, 0.7 and 1.41 g ass/ha for <i>Bellis perenis</i> 0.0088, 0.18, 0.35, 0.7 and 1.41 g ass/ha for <i>Bellis perenis</i> 0.0088, 0.18, 0.35, 0.7 and 1.41 g ass/ha for <i>Bellis perenis</i> 0.0461 g a.s./hamost sensitive species: Achillea millefolium; 0.0461 g a.s./haDicotyledoneae: 5 (non-crop specie) (non-crop specie)0.088, 0.18, 0.35, 0.7 and 0.0088, 0.18, 0.35, 0.7 and 1.41 and 2.80 g a.s./ha for <i>Gendurea cyanus</i> , Maricaria chamonitita, Senecio vulgaris with assessments (survival, visual phytotoxicity, plaft growth stage and shoot dry weight) 70.4 and 21 days after application 0.009, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for <i>Stellaria media</i> 0.007 g a.s./hamost sensitive species: Amaranthus retroflexus; lowest ERs0: 0.07 g a.s./haDicotyledoneae: 5 (argophyllaceae))regetative vigour; Tire 2 dose response 0.053, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Stellaria media</i> 0.007 g a.s./hamost sensitive species: Amaranthus retroflexus; lowest ERs0: 0.07 g a.s./haDicotyledoneae: 5 (argophyllaceae))0.018, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Centaurea cyanus</i> , Senecio wulg | | 45 g a.s./lla for sufficience (1. Tell) | | |
| Dicotyledoneae: 5 (non-crop species: (Asteraceae, (Amaranthaceae, Caryophyllaceae))most sensitive (control), 0.98, 0.18, 0.35, 0.7 and 1.44 cg a.s./ha for sunflower (3 rd run) wtfl assessments (Asteraceae, (Asteraceae, Caryophyllaceae))most sensitive (control), 0.022, 0.042, 0.088, 0.18, 0.35 (and 0.7 g a.s./ha for Setliar area (Asteraceae, (Asteraceae, (Asteraceae, (Amaranthaceae, (Control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for Setliar area (Asteraceae, (Asteraceae, (Amaranthaceae, (Control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for Setliar area (Control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for Setliar area (Control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for Setliar area (Control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for Setliar area (Control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for Setliar area (Control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for Setliar area (Control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for Setliar area (Control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for Setliar area (Control), 0.18, 0.35, 0.70, 1.41, 2.81 and (Control), 0.18, 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for Centaurea cyanus, Senecio (Control), 1.41, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for Centaurea cyanus, Senecio (Control), 1.41, 2.81, 5.63, 11.25, 22.5 and (Control), | | 5 63 g a ha for sinflower (2 nd ruga) | × × | |
| 1.4.r g a.s./ha for sunflower (3 rd fun) with assessments (0bytotoxidity ratings, strivial)) 14 and 21 days after application, shoot dry weight and strowth stages were defermined at the final assessment.most sensitive species: Achillea millefolium; lowest ERse: 0.461 g a.s./hamost sensitive species: Achillea millefolium; lowest ERse: 0.461 g a.s./hamost sensitive species: Achillea millefolium; lowest ERse: 0.461 g a.s./hamost sensitive species: Achillea millefolium; lowest ERse: 0.461 g a.s./hamost sensitive species: Achillea millefolium; lowest ERse: 0.461 g a.s./hamost sensitive species: Achillea most sensitive species: Achillea dry Gright) 7.04 and 21 days after application 0 (control) 0.09, 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for Amaranthus retroflexus 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for Stellaria media 0 (control), 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for Centaurea cyanus, Senecio wulcarismost sensitive species: Amaranthus retroflexus; lowest ERse: 0.07 g a.s./hamost sensitive species: M-405630-01-1 KCP 10.6.2/04 | | 0 (control) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | | |
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| Dicotyledoneae: 5 (non-crop species)wegetative rigour: vegetative rigour: (Asteraceae))most sensitive species: Achillea millefolium; lowest ERso: 0.461 g a.s./haMost sensitive species: Achillea millefolium; lowest ERso: 0.461 g a.s./haMost sensitive millefolium; lowest ERso: 0.461 g a.s./haMost sensitive millefolium; lowest ERso: 0.461 g a.s./haDicotyledoneae: 5 (non-crop species)as case for an of the formed and the species) or control, 0.044, 0.088, 0.18, 0.35, 0.7, 1.41 and 2.81 g a.s./ha for Achillea millefolium phytotoxicity, Plant growth stage and shoot dry verght) 7.04 and 21 days after applicationmost sensitive most sensitive species: Amaranthus retroflexus; lowest ERso: 0 (control), 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for Amaranthus retroflexus 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 1.25 g a.s./ha for Stellaria media 0 (control), 1.41, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for Centaurea cyanus, Senecio wigerrismost sensitive species: most sensitive species: doi: 0.07 g a.s./ha | 0 | stages were determined at the final | | |
| Dicotyledoneae: 5 (non-crop species)Vegetative/Figour, 5 Tier 2 dose responsemost sensitive species; Achillea millefolium; lowest ERso: 0 (control), 0.044, 0.088, 0.48, 0.35 and 0.7 g a.s./ha for Achillea millefolium 0 (control), 0.044, 0.088, 0.48, 0.35, 0.7 and 0 (control), 0.09, 0.18, 0.35, 0.7 and 0 (control), 0.09, 0.18, 0.35, 0.7 and 0 (control), 0.09, 0.18, 0.35, 0.7 and 0 (control), 0.141, 2.81, 5.63 and 11.25 g a.s./ha for Sellaria media 0 (control), 0.35, 0.7 and 0 (control), 0.35, 0.7 and 0.141, 2.81, 5.63 and 0 (control), 0.35, 0.7 and, 1.41, 2.81, 5.63 and 0.7 g a.s./haImage: Control cont | O* | assessment Q A S | | |
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| and 0, / g a.s./ha for <i>feelus perennis</i> Q (controly 0.044, 0.088, 0.48, 0.35, 0.7 and Q (control), 0.086, 0.18, 0.35, 0.7, 1.41 and 2.80 g a.s./ha for <i>Cendurea cyanus</i> , Moricaria chamonitia, Senecio vulgaris with assessments, survival, visual phytotoxicity, plant growth stage and shoot dry veright, 7.04 and 21 days after applicationmost sensitive species: Amaranthaceae, Q (control), 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for <i>Amaranthus retroflexus</i> Q (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Stellaria media</i> Q (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Stellaria media</i> Q (control), 0.141, 2.81, 5.63 and 11.25 g a.s./ha for <i>Centaurea cyanus</i> , Senecio vulgarismost sensitive species: Amaranthus retroflexus; Iowest ERso: 0.461 g a.s./haDicotyledoneae: (Asteraceae, (Caryophyllaceae))most sensitive species: A for <i>Amaranthus retroflexus</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for <i>Centaurea cyanus</i> , Senecio vulgarismost sensitive species: M-405630-01-1 Mc05630-01-1 | (Asteraceae) | 0 (constrol) 0.022, 0.044, 0.088, 0.18, 0.35 | millefolium; | KCP 10.6.2/05 |
| Dicotyledoneae:Statemost sensitive species: (control), 0.98, 0.18, 0.35, 0.70, 1.41 and 2.80 g a.s./ht/or <i>Cenaurea cyanus,</i> Maricariachamontita, Senecio vulgaris with assessments (survival, visual phytotóxicity, plant growth stage and shoot dry veright) 7, 0.4 and 21 days after applicationmost sensitive species: (control), 0.99, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for <i>Centaurea cyanus,</i> Maricariachamontita, Senecio vulgaris with assessments (survival, visual phytotóxicity, plant growth stage and shoot dry veright) 7, 0.4 and 21 days after applicationmost sensitive species: M-405630-01-1Dicotyledoneae:5regetative vigour; Tier 2 dose response 0 (control) 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for <i>Amaranthus retroflexus</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for <i>Centaurea cyanus, Senecio</i> vulgarrisMost sensitive species: M-405630-01-1 KCP 10.6.2/04 | | and \forall . / g a.s. that for bellis perennis | lowest ER50: | |
| A fig again a locy childed withefoldum 0 (control), 0.089, 0.18, 0.35, 0.7, 1.41 and 2.80 g a.s./hafor <i>CenQurea cyanus</i>, <i>Maricaria@hamonfilia</i>, <i>Senecio vulgaris</i> with assessments fourival, visual phytotoxicity, plant growth stage and shoot dry wright) 7, 0.4 and 21 days after application Dicotyledoneae: 5 (non-crop specie) (<i>Asteraceae</i>, <i>Caryophyllaceae</i>)) Method S. (18, 0.35, 0.7, 1.41 and 2.81 g a.s./ha for <i>Amaranthus retroflexus</i> 0 (control), 0.18, 0.35, 0.70, 1.41 and 5.63 g a.s./ha for <i>Stellaria media</i> 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for <i>Stellaria media</i> 0 (control), 1.41, 2.81, 5.63 and 11.25 g a.s./ha for <i>Centaurea cyanus</i>, <i>Senecio</i> wildaris | | 1 geomioly, 0.044, 0088, 0.45, 0.55, 0.7 and | 0.401 g a.s./na | |
| Occontrol), 0.7005, 0.110, 0.500, 0.11, 1.51 and 2.81 g a.s./hafor Centaurea cyanus, Maricaria Chamonfitta, Senecio vulgaris with assessments Urvival, visual phytotoxicity, plant growth stage and shoot dry Veright) 7.04 and 21 days after application.most sensitive species:most sensitive species:, 2011;Dicotyledoneae: 5 (non-crop specie) (amaranthaceae, Caryophyllaceae))most sensitive species:most sensitive species:, 2011;Dicotyledoneae: 5 (control), 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for Amaranthus retroflexus 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for Stellaria media 0 (control), 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for Centaurea cyanus, Senecio vulgarismost sensitive species:M-405630-01-1 KCP 10.6.2/04M-405630-01-1 (species)M-405630-01-1 (species)M-405630-01-1 M-405630-01-1 KCP 10.6.2/04KCP 10.6.2/04 | | 0 (control) 0.055 0.18-0.35 0.7 1.41 and | | |
| 2.53, g.a.s./http://centure.comparted cyanus, Moricaria/hamonitita, Senecio vulgaris with assessments, Survival, visual phytotoxicity, plant growth stage and shoot dry verght) 7.04 and 21 days after applicationmost sensitive species: Amaranthaceae, (asteraceae, (Asteraceae, (Amaranthaceae, Caryophyllaceae))most sensitive species: (control) 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for Amaranthus retroflexus 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for Stellaria media 0 (control), 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for Centaurea cyanus, Senecio vulgarismost sensitive species: Amaranthus retroflexus; lowest ER50: 0.07 g a.s./haM-405630-01-1 KCP 10.6.2/04 | <u> </u> | 2 St g a s /has r Central rea cvanus | | |
| Indicating prime point of the point of th | O A | Maricaria Chamonitia Senecio vulgaris | | |
| Phytotoxicity, plant growth stage and shoot dry wright) 704 and 21 days after applicationmost sensitive species:Dicotyledoneae: 5 (non-crop species) (Asteraceae, Caryophyllaceae))rogetative vigour; Tier 2 dose response 0 (control) 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for Amaranthus retroflexus 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for Stellaria media 0 (control), 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for Centaurea cyanus, Senecio wulgarismost sensitive species: Amaranthus retroflexus; lowest ER50: 0.07 g a.s./ha | A. O | with assessments (survival, visual | | |
| Inv veright)70.4 and 21 days after applicationDicotyledoneae:5Dicotyledoneae:5(non-crop specie)regetative vigour;Tier 2 dose responsemost sensitive species:(Asteraceae, (Amaranthaceae, (Caryophyllaceae))0 (control) 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for Amaranthus retroflexus 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for Stellaria media 0 (control), 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for Centaurea cyanus, Senecio yulgarisM-405630-01-1 M-405630-01-1 KCP 10.6.2/04 | Sa. | phytotoxicity, plant growth stage and shoot | | |
| Dicotyledoneae: 5regetative vigour; Tier 2 dose responsemost sensitive species:(non-crop species: (Asteraceae, Amaranthaceae, (asteraceae,)0 (control) 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for Amaranthus retroflexus 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for Stellaria media 0 (control), 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for Bellis perennis 0 (control), 1.41, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for Centaurea cyanus, Seneciomost sensitive species: Amaranthus retroflexus; 0.07 g a.s./haM-405630-01-1 KCP 10.6.2/04 | | dry weight) 7,04 and 21 days after | | |
| Dicotyledoneae: 5 (non-crop species: (Asteraceae, Amaranthaceae, (Asteraceae, Caryophyllaceae)) Dicotyledoneae: 5 (Asteraceae, Caryophyllaceae)) Dicotyledoneae: 5 (control) 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for Amaranthus retroflexus 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for Stellaria media 0 (control), 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for Centaurea cyanus, Senecio wulgaris | | application | | |
| $\begin{array}{c c} (\text{non-crop species} \\ (Asteraceae, \\ Amaranthaceae, \\ Caryophyllaceae)) \end{array} \qquad \begin{array}{c} \text{Tier 2 does response} \\ 0 \ (\text{control}) \ 0.09, \ 0.18, \ 0.35, \ 0.70, \ 1.41 \ \text{and} \\ 2.81 \ \text{g a.s./ha for } Amaranthus retroflexus \\ 0 \ (\text{control}), \ 0.18, \ 0.35, \ 0.70, \ 1.41, \ 2.81 \ \text{and} \\ 5.63 \ \text{g a.s./ha for } Stellaria \ media \\ 0 \ (\text{control}), \ 0.35, \ 0.70, \ 1.41, \ 2.81, \ 5.63 \ \text{and} \\ 11.25 \ \text{g a.s./ha for } Senecio \\ 0 \ (\text{control}), \ 1.41, \ 2.81, \ 5.63, \ 11.25, \ 22.5 \ \text{and} \\ 45 \ \text{g a.s./ha for } Centaurea \ cyanus, \ Senecio \\ \end{array} \qquad \begin{array}{c} \text{M-405630-01-1} \\ \text{KCP 10.6.2/04} \\$ | Dicotyledoneae: 5 | regetative vigour; | most sensitive | ,; 2011; |
| $\begin{array}{c} (Asteraceae, \\ Amaranthaceae, \\ Caryophyllaceae)) \\ \end{array} \begin{array}{c} 0 \ (control) \ 0.09, \ 0.18, \ 0.35, \ 0.70, \ 1.41 \ and \\ 2.81 \ g \ a.s./ha \ for \ Amaranthus \ retroflexus \\ 0 \ (control), \ 0.18, \ 0.35, \ 0.70, \ 1.41, \ 2.81 \ and \\ 5.63 \ g \ a.s./ha \ for \ Stellaria \ media \\ 0 \ (control), \ 0.35, \ 0.70, \ 1.41, \ 2.81, \ 5.63 \ and \\ 11.25 \ g \ a.s./ha \ for \ Bellis \ perennis \\ 0 \ (control), \ 1.41, \ 2.81, \ 5.63 \ and \\ 11.25 \ g \ a.s./ha \ for \ Centaurea \ cyanus, \ Senecio \\ \end{array} \begin{array}{c} wulgaris \end{array} \begin{array}{c} KCP \ 10.6.2/04 \\ Feto (SCP) \ 0.6.2/04 \\ Feto (SCP) $ | (non-crop species | Tier 2 dose response | species: | M-405630-01-1 |
| Amaranthaceae, Caryophyllaceae)) 2.81 g a.s./ha for Amaranthus retroflexus 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for Stellaria media 0 (control), 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for Bellis perennis 0 (control), 1.41, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for Centaurea cyanus, Senecio yulgarisretroflexus; lowest ER50: 0.07 g a.s./ha | (Asteraceae, | 0 (control) 0.09, 0.18, 0.35, 0.70, 1.41 and | Amaranthus | KCP 10.6.2/04 |
| $\begin{array}{c c} Caryophyllaceae) & & 0 \ (control), \ 0.18, \ 0.35, \ 0.70, \ 1.41, \ 2.81 \ \text{and} \\ & 5.63 \ \text{g a.s./ha for Stellaria media} \\ & 0 \ (control), \ 0.35, \ 0.70, \ 1.41, \ 2.81, \ 5.63 \ \text{and} \\ & 11.25 \ \text{g a.s./ha for Bellis perennis} \\ & 0 \ (control), \ 1.41, \ 2.81, \ 5.63, \ 11.25, \ 22.5 \ \text{and} \\ & 45 \ \text{g a.s./ha for Centaurea cyanus, Senecio} \\ & & yulgaris \end{array}$ | Amaranthaceae, | 2.81 g a.s./ha for Amaranthus retroflexus | retroflexus; | |
| 5.63 g a.s./ha for Stellaria media 0.07 g a.s./ha 0 (control), 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for Bellis perennis 0 (control), 1.41, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for Centaurea cyanus, Senecio wulgaris wulgaris | Caryophyllaceae)) | 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and | lowest ER ₅₀ : | |
| 0 (control), 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for <i>Bellis perennis</i> 0 (control), 1.41, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for <i>Centaurea cyanus, Senecio</i> <i>yulgaris</i> | | 5.63 g a.s./ha for <i>Stellaria media</i> | 0.07 g a.s./ha | |
| 11.25 g a.s./na for <i>Bellis perennis</i> 0 (control), 1.41, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for <i>Centaurea cyanus, Senecio</i> <i>yulgaris</i> | | U (control), 0.35 , 0.70 , 1.41 , 2.81 , 5.63 and 11.25 and f_{11} , p_{12} , p_{13} , p_{14} | | |
| 0 (control), 1.41, 2.81, 5.05, 11.25, 22.5 and 45 g a.s./ha for <i>Centaurea cyanus, Senecio</i> yulgaris | | 11.25 g a.s./na for Bellis perennis | | |
| 45 g a.s./ha for Centaurea cyanus, senecio vulgaris | | 0 (control), 1.41, 2.81, 5.65, 11.25, 22.5 and 45 g a s /ba for Containing graning Series | | |
| | | yuloaris | | |

| Number of species tested (species) | Test method Test substance | Effects | Reference |
|---|--|---|---|
| vegetative vigour | | | |
| | with assessments (survival, visual phytotoxicity, plant growth stage and shoot dry weight) 7, 14 and 21 days after application | | ° & a |
| Dicotyledoneae: 1 (sunflower) | vegetative vigour; Tier 3 semi-field 0 (control) 0.044, 0.088, 0.18 and 0.35g ° ° a.s./ha for sunflower with assessments (survival, visual phytotoxicity, plant growth stage and shoot dry weight) 7, 10, 14 and 22 days after application. | no significant effect ap to the highest rate tested of 0.35 g as, ha | ; 2010; ; 2010; M389529-01-1 KCP 10-6.4/01 |
| (sunflower) | Vegetative vigour; Tier 3 field 0 (control) 0.4, 0.8, 0.16 and 0.32 a.s./ha for sunflower with assessments (survival, visual phytotoxicity, plant growth stage and shoot dry weight) 7, 14 and 19 days after application. | Jshoot Ary weight: 1.69 g | ,; 2016 M-548832- 0 2017 M-548832- 0 2017 M-548832- 0 2016 M-548832- |
| seedling emergence | | | |
| Dicotyledoneae: 7 (cabbage, cucumber, turnip, soybean, sugar beet, sunflower, tomato) Monocotyledoneae: 3 (oat, onion, ryegrass) | seedling emergence Tier 2 dose resonnse 0 (control), 1 41, 2.81, 5:63, 11.25, 22:5 and 452 a.s./ha for sugar beet, cabbage, turnip, creumber soybear, tomat onion, 6at, sunflower and ryegrass 0 (control), 0 48, 0.35, 0.7, 1.41, 2.81 and 5.63 g a.s./ha for surflower with daily assessment of emergence until 70 % emergence of control seedlings, assessments of emergence, survival and phyOtoxicity and 14 days after 70 % emergence, assessments of total emergence, survival of emerged seedlings, visual phytotoxicity, growth stages and shoot dry weight at test ermination | most sensitive species: sunflower; lowest ER50: 108 g a.s./ha | S; 2010; M-366951-01-1 KCP 10.6.2/06 |

A O

Tier 2 studies

\$ 1

The sunflower turned out to be the most sensitive species in both tests, vegetative vigour and seedling emergence. A lowest endpoint of 0.11 g a.s./ha was obtained in the vegetative vigour test. Therefore, five additional wild species from the same family as sunflower (Asteraceae) were tested in a vegetative vigour test (1999); 2010; M-389517-01-1). All five wild Asteraceae-species turned out to be less sensitive than sunflower. However, only two additional ER₅₀-figures were obtained, since

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the test rates were too low. The three wild species of Asteraceae for which no ER₅₀ were obtained in the first test run were tested in a further study with higher rates. Upon a request of a national authority, Stellaria media and Amaranthus retroflexus were included in this test (; 2011; M-405630-01-1). This study led to an ER₅₀ of 0.07 g a.s./ha for *Amaranthus*, which is the lowest ER₅₀ within the whole set of NTP-data for Amidosulfuron WG75.

Conducting a seedling emergence test with wild species is not applicable, because seed germination in wild species is subject to high biological variability and cannot be synchronized. Further details of the studies are given in the summary at Point CP 10.6.2 below.

| Table CP 10.6- 2: | Survey of effects of Amidosulf | uron WG 🕱 on non-target plants, | |
|-----------------------------|---|---|--|
| | based on Tier 2 studies | | |
| Species | ER ₅₀ vegetative vigour | ER50 seedling emergence | a v |
| | dry weight reduction | dry weight reduction | 0° 4° |
| | [g a.s./ha] | ,♀ ° [g a, g /ha] <i>©</i> ′ | o "Qi |
| sugar beet | > 45 | × × × × × × | Ĩ |
| cabbage | > 45 | \sim | Ű |
| turnip | > 45 | S C 8.320 0° | S |
| Stellaria media | 2.04 | n.d. O | de la companya de la comp |
| cucumber | > 45 5 | / R* 9.75 K | |
| Amaranthus retroflexus | 0.07 | 2 0 n.d. ~ 2 | |
| soy bean | A45 - S | | |
| sunflower | Č0.11 💊 🕺 | Ŭ <u>Ŭ</u> <u>1</u> 08 Ŭ | |
| Achillea millefolium | <u> </u> | | |
| Bellis perennis | | Q n.d. | |
| Centaurea cyanus | × 2.46 | s n de | |
| Matricaria chamomilla | \$ \$\dot 0.585 | ny ny d. | |
| Senecio vulgaris | \$ 67 2.20 O | @ ~ h.d. | |
| tomato | | 2 × 13.23 | |
| onion 🔊 | 45 | Q 0 4.42 | |
| oat | → > 45 | × >45 | |
| ryegrass 🔬 🖗 | $\sim \sqrt{Q_0} > 45^{\circ} \sqrt{Q_0}$ | 17.27 | |
| a.s. = active substance: n. | U = not determined | ~(7 | |
| AY N | | L ^Y | |

The vegetative vigour data reveal a wide range of sensitivities between the species. Nine species were not affected by prore than 50% up to the full application rate and higher.

Higher-tier studies

For the vegetative rigour furthen higher tier risk assessment is required, which will be based on results of a semi@ield (KCP 10.6.401) and a field (KCP 10.6.402) test for Amidosulfuron WG75 with sunflaver. These tests are considered to also cover the sensitivity of amaranth, for the reasons discussed below.





Figure 1 reveals that the dose-response curves for amaranth and sunflower are very close. The following comparison of the sensitivity for both species was conducted

- 1. by comparing the 95% confidence limits (see figure 2) and
- 2. by comparing the difference between the biomass results via opseudo-individual analysis (see figure 3).

In order to run a statistical evaluation, the biomass inhibition pseudo-individual data were created by comparing the biomass for each replicates with the mean biomass in the control.

% inhibition = 100 (meanbiomass_{control} - biomass_{treathent})/meanbiomass_{control}



Fig 2: ER₅₀-levels and 95% confidence limits for amaranth and sunflower (greenhouse tests)



Fig 3: Mean and variation of % inhibition of biomass for amaranth and sunflower (greenhouse tests). The shaded areas indicate the range boveen minimum and maximum varies.

Fig. 2 reveals a distinct overlap of confidence limits of the ER_{50} -levels for both species. Fig 3 illustrates that both species show a clear dose-response. The close-response curve of amaranth is slightly shifted to the eff compared to the curve of simflower. For each test rate where both species were tested the pseudo-individual inhibition percentages were compared with an U-test. The % inhibition of biomass were not significantly different at treatment levels of 0.09, 0.18, 0.35 and 0.7 g a.s./ha indicating no difference in sensitivity between the two species at those levels relevant for ER50 calculation. It can be concluded that the difference in sensitivity between sunflower and amaranth can therefore be regarded as negligible.

The higher-tier risk assessment is based on the outcome of the **field test** with sunflower. At the highest test rate in the **semi-field study** that was 0.35 g a.s./ha, sunflower were inhibited by 10.5%. Although no higher rates have been losted, the rate leading to 50% effect can be estimated to be considerably higher than 0.35 g ha. It can therefore be concluded that the ER₅₀>0.35 g a.s./ha covers the effects on *Amaronihus retroflexue* as well, although no semi-field test has been conducted with this species. The outdoor field ER₅₀ of 1.69 g age/ha is 0.35 g a.s./ha from the semi-field study.

In the risk assessment based on the outdoor field ER_{50} of 1.69 g a.s./ha the assessment factor of 5 can be justified according to the Notifier for the following reasons:

- 1. Sunflower is the 2nd most sensitive species among 17 species tested.
- 2. As presented above the potential effects on amaranth are covered.

A comparison of the effects on sunflower within the standard test in the greenhouse compared to sunflowers grown under outdoor conditions is given in the table below.

| rate | | greenhouse | | semi-field | field |
|-------------|---------------------|---------------------|---------------------|--|--|
| [g a.s./ha] | 1 st run | 2 nd run | 3 rd run | | |
| 0.044 | | | 27.04 | -14.2 | |
| 0.088 | | | 47.34 | -12.2 | |
| 0.18 | | 61.0 | | -19.5 | |
| 0.35 | | 74.3 | 75.83 | 10,5 | O O |
| 0.4 | | | | | \$.9 K |
| 0.7 | | 83.6 | 85.05 ° | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | |
| 0.8 | | | <u> </u> | | ≪ 36.Î~y |
| 1.41 | 84.8 | 88.0 | 87.88 🔩 | <u>, ky v</u> | |
| 1.6 | | | | | ST.8 💭 |
| 2.81 | 88.6 | 89.1 | | | Č Č |
| 3.2 | | | Å . × | \$ \$ | 63.3 |
| 5.63 | 87.3 | | | $\gamma \land \land$ | |
| 11.25 | 88.1 | × | | <u>,0' 0'</u> | A A |
| 22.5 | 89.2 | . 6 | | × & | - Colored - Colo |
| 45 | 90.6 | | S 94 | X O | <i></i> |

| Table CP 10.6- 3: | Comparison of % dry weight reduction compared to the untreated control on sunflower |
|-------------------|---|
| | in the greenhouse and under outdoor-conditions. |

The results clearly indicate that the ER $_0$ is >0.35 g a.s./ha for sunflower under outdoor conditions. Since no definitive ER $_{50}$ could have been determined from the semi-field study, a field study ; 2015; M-548832-01-1) has been conducted. This study led to an ER₅₀ of 1.69 g a.s./ha. This endpoint shall be used for the risk assessment. Since this endpoint is derived from a higher tier study with the most sensitive species an assessment factor of 5 can be used.

Exposure

Exposure Effects on non-target plans are concernin the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by Pe BBA (2000) from Qe spray drift pedictions of

(2000)¹⁹. 2.77%, 0.57% apo 0.29% of the full application rates of 30 g a.s./ha in cereals, 30 g a.s./ha in flax and 45 g, a.g./ha on grass and pastures (exculations below given in g a.s./ha for reasons of readability) are assumed to reach areas at 1 m, 5 m and 10 m from the edge of the crop, respectively. The corresponding off-field predicted environmental rates (PERoff-field) are presented in the table below.



¹⁸ BBA (2000) Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden. Public domain.

(2000) Drift, drift-reducing sprayers and sprayer testing. Aspects of Applied Biology 57, 2000, Pesticide Application. Public domain.

| Table CP 10.6- 4: | Predicted environmental rates | PER |) at 1m and (| 5 m distance | from the field edge |
|-------------------|-------------------------------------|-----|--------------------------|--------------|---------------------|
| | i i culticu chi in on mentar i aces | | <i>)</i> at 1111 and . | in distance | n om the nera cage |

| Сгор | Timing of application | Number of applications | Maximum application rate [g a.s./ha] | MAF _{mean} * | PER at 1m distance [g/ha] | PER at 5m distance [g/ha] | PER at 10m distance [g/ha] |
|---------------------------|--|---------------------------|---|-----------------------|--|---------------------------------|-------------------------------------|
| Cereals | winter cereals BBCH 13-49 | 1 | 15 | 1.0 | 0.416 | 0.086 | 0.044 |
| (winter and spring) | winter cereals BBCH 21-49 spring cereals BBCH 12-49 | 1 | 30 | 1.0 | 0.8307 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | 9.171 9.171 | 0.08 50 50 50 50 50 |
| Flax | Before flower buds are visible | 1 | 30 | | 0.821 | | 0.087 |
| Grass/ pasture | Spring | 1 | 45 0 | | d.247 | 0.250 | Ø.131 |

* MAF = Multiple application factor (1 application), acc. to OFSA (2009): Guidance Document on Bisk Assessment for Birds & Mammals.

Deterministic Risk assessment

According to the Terrestrial Guidance Document²⁰, the risk to non-target plants is evaluated by comparing the lowest ER_{50} observed in the laboratory studies with the drift rates (PER_{off-field}) inclosing a safety factor of 5. In addition, the usage of drift reducing no cless is considered.

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Table CP 10.6- 5: Deterministic risk assessment for Amidosalfuron & G 75 based on effects on <u>vegetative</u>

| | <u> </u> | | | <u>`~</u> | ~~ · | | |
|--|---------------------|---------------------------------------|--|----------------------------------|---------------------|---------------------|--|
| Distance | Drift ²⁾ | PER | | | Ř | | |
| [m] | (%) | for drift reduction [g a.s./ha] | Nordrift feduction | oreduction | 75% drift reduction | 90% drift reduction | |
| Cereals (w | vinter) and f | lax, 1 🖗 15 g | a .s /ha; E R /0 = 1.6 | 9⁄g a.s./ka | | | |
| 11) | 2. <i>P</i> P | °~0.416 Q | 07 Q | 8.13 | 16.27 | 40.67 | |
| 5 | @ 3 57 | 0.086 | 19.77 | 39.53 | 79.06 | 197.66 | |
| Cereals (w | vinter and s | oring) and fla | x, IX × 30 g A.s./ha | ; ER ₅₀ = 1.69 g a.s. | /ha | | |
| 1 ¹⁾ | 2.70 | ×Q/831 | 2 2 2 3 | [,] 4.07 | 8.13 | 20.34 | |
| 5 | Ø 57 | Ø ⁹ 0.171 | 9.88 | 19.77 | 39.53 | 98.83 | |
| Grass and pasture, 1, 45 g a.s./ha; E 8:0 = 1.69 g a.s./ha | | | | | | | |
| 11) | 2.770 | 1247 | 0 1.36 | 2.71 | 5.42 | 13.56 | |
| 5 | 0.57 | 0.257 | % .59 | 13.18 | 26.35 | 65.89 | |

¹⁾ 1 maistance is defined as "no ph-crop buffer zone"

²⁾ BBA drift values (for 1 application, field crops), see Terr. Guidance Doc. SANCO/10329/2002 rev 2 final **In bold:** TERs below the trigger of 5.



²⁰ Anonymous (2002b). Guidance Document on terrestrial ecotoxicology under council directive 91/414/EEC. SANCO/10329/2002. 17 October 2002.

| Table CP 10.6- 6: | Deterministic risk assessment for Amidosulfuron WG 75 based on effects on seedling |
|-------------------|--|
| | emergence |

| Distance | Drift ²⁾ | PER | | TER | | | | | |
|-----------------|---|--------------------------------------|----------------------|---------------------|---------------------------------|---------------------|--|--|--|
| [m] | (%) | no drift reduction [g a.s./ha] | No drift reduction | 50% drift reduction | 75% drift reduction | 90% drift reduction | | | |
| Cereals (w | Cereals (winter) and flax, 1 × 15 g a.s./ha; lowest ER50 = 1.08 g a.s./ha | | | | | | | | |
| 1 ¹⁾ | 2.77 | 0.416 | 2.60 | 5.20 | 10.40 | Ø 5 .99 Ø | | | |
| 5 | 0.57 | 0.086 | 12.63 | 25.26 | 50.53 | 126.32 | | | |
| Cereals (w | vinter and sp | oring) and fla | ax, 1 × 30 g a.s./ha | ; lowest ER∰≗ 1.0 | 18 g/a.s./ha | | | | |
| 1 ¹⁾ | 2.77 | 0.831 | 1.30 | 2,69 | ≽ լ3;⊋0 √ | 134.00 | | | |
| 5 | 0.57 | 0.171 | 6.32 | Q.63 × | \$25.26 | ه 63.16 | | | |
| Grass and | Grass and pasture, 1 × 45 g a.s./ha; lowest ER50 = 1.08 g a.s./ha | | | | | | | | |
| 1 ¹⁾ | 2.77 | 1.247 | 0.87 | 1.76 | | 8,66 | | | |
| 5 | 0.57 | 0.257 | 4.21 | × 42 ~ | 16.84 | 21 | | | |
| 10 | 0.29 | 0.131 | 8.28 🎣 | 396.55 ° | ^{33.10} ³ √ | £ 82.76 | | | |

1 m distance is defined as "no in-crop buffer zone"

BBA drift values (for 1 application, field crops), see Terr. Guidance Doc, SANC 910329/2002 rev 2 final 2) **In bold:** TERs below the trigger of 5.

Probabilistic Risk assessment

In addition to the deterministic risk assessment the Terrestrial Guidance Document recommends the use of the HR₅ (the rate below which less than 5% of the species will be harmed above the ER₅₀ level) which can be calculated from the data sets of ER growth inhibition levels. The EU guidance document for terrestrial ecotoxicology states: If the ED_{50}^{21} for less than 5% of the species is below the highest predicted exposure level, the risk for terrestrial plants is assumed to be acceptable.' Thus, the HR_5 itself (TER = 1) can be regarded to be protective

The HR5 was calculated according to

 $HR_5 = 10 \exp(avg - ks^* std)$

with

avg = mean of log10 transformed ER3 values

std = standard deviation of @g10 transformed ER₅₀ values L,

 $ks = extrapolation factor_{\mu}$

The HR5 calculations were based on \$R50-values for shoot dry weight. 'Greater than' figures, which did not allow to calculate an VIR5, were excluded from the HR5 calculation.

Vegetative vigour:

Since the risk assessment for segetative vigour is based on higher tier study data for a single sensitive species (sunflower field study), approbabilistic assessment is not applicable to this case. The probabilistic risk assessment will be conducted for seedling emergence data only, see below.

²¹ The ER₅₀ is meant

. (2000): Uncertainty of the hazardous concentration and fraction affected for normal species sensitivity distributions. Ecotoxicology and Environmental Safety, 46: 1-18.

Seedling emergence:

The HR₅ calculation for the shoot dry weight-ER₅₀-values from the seedling emergence study leads to a HR₅ value of 1.015 g a.s./ha, see Table CP 10.6-7.

| Table CP 10.6-7: HR5-calculation for seedling emergence with Amidosulfuron WG | 7 | 1 | ľ | | | į | ż | 'n |
|---|---|---|---|--|--|---|---|----|
|---|---|---|---|--|--|---|---|----|

| Species | ER50 seedling emergence dry weight reduction [g a.s./ha] | |
|------------------------|--|--|
| sugar beet | 1.56 | |
| cabbage | 7.09 | |
| turnip | 8.32 | |
| cucumber | 9.75 | |
| soy bean | >45* | |
| sunflower | 1.08 | |
| tomato | 13.23 | |
| onion | 4.42 | |
| oat | > 45* | |
| ryegrass | 17.27 | |
| HR ₅ (g/ha) | 1.015 | |
| a s = active substance | Å 6 ⁸ | |

active substance.

* The 'greater than' figures were excluded from the calculation

The TER calculations for probabilistic risk assessment are summatised in the following table.

K) \bigcirc Table CP 10.6- 8: Probabilistic risk assessment for Amidosulfurod WG.75 based on effects on seedling a a amargance

| | <u>emer</u> | | 0 Å | | > | |
|---------------|-----------------------|-------------------------------------|-----------------------|------------------------------|---------------------|---------------------|
| Distance | Drift ²⁾ | S PER " | A O | ¢ √ [™] T | ER | |
| [m] | (%) | no drift reduction [ga.s./ha] | No drift reduction | 50% Drft reduction | 75% drift reduction | 90% drift reduction |
| Cereals (with | nter) and fla | ax,∕1 × 15 g∕a.s | $./ha;HR_5 = 1.91$ | 5 g æs./ha | | |
| 11) | ź 92.77 "Ś | 0.44.6 | 0 2.44 7 | 4.89 | 9.77 | 24.43 |
| Cereals (with | nter and spi | ring) and flax, | 1 × 30°g/a.s./ha; | $HR_5 = 1.015 \text{ g a.s}$ | s./ha | |
| 11) | 2:11 | 0.831 | £.22 ° | 2.44 | 4.89 | 12.21 |
| Grass and p | asture, 1 × | 45 g a.s./Ha; H | Res = 1.015 g a.s. | /ha | | |
| 11) | 5 ⁷ 2.77 5 | 1 %2 4 7 4 | 0.8 | 1.63 | 3.26 | 8.14 |
| 5 🔬 | 059 | 0.257 | ×3.96 | 7.91 | 15.83 | 39.57 |

¹⁾ 1 m distance is defined as "no in-crop buffer zone"

²⁾ BBX drift values (for application, field crops), see Terr. Guidance Doc. SANCO/10329/2002 rev 2 final In bold: TERs below the trigger of 1.

O **Overall Conclusions of risk assessment for non-target terrestrial plants**:

Based on the deterministic risk assessment for vegetative vigour based on the sunflower field study, and the probabilistic risk assessment for seedling emergence based on HR_5 derived from the data on shoot dry weight, the following overall conclusions can be drawn:

| | | | r | |
|---|---------------------|-------------------|--------------------------------|----------------------|
| | vegetative vigour | , ssment based | seedling emerger | ice, ssment based |
| | on sunflower field | l data | on HC ₅ of Tier 2 s | study data on |
| | | | 10 species | |
| | nozzle type | drift buffer | nozzle type | drift buffer |
| Cereals (winter) and flax, | 50% drift reduction | none | conventional | o none |
| 1×15 g a.s./ha | conventional | 5m buffer | | |
| Cereals (winter and spring) and flax, | 75% drift reduction | none | conventional | none |
| 1 × 30 g a.s./ha | conventional | 5m buffer | |)" <u> </u> |
| Cross and notions | 90% drift reduction | none . | 50% drift | g nong .º |
| Grass and pasture, 1×45 g a.s./ha | 50% drift reduction | Sm buffer | réduction | |
| | conventional 🦼 | 10m buffer 🔬 | conventional | 5m buffer |
| | | V AV A | / / ~ | (Ω) |

Since Amidosulfuron WG 75 has stronger effects on the vegetative vigour of young mants than on the seedling emergence, the vegetative vigour data determine the risk assessment. Considering mitigation options for drift reduction as summarised above, Amidosuffuron AG 75 poses no unacceptable risk to CP 10.6.1 Summary of size on introduced uses

CP 10.6.1 Summary of screening data

| Report: | K@ 10.6.1494 s; 2007; M-295670-04 1 |
|--|---|
| Title: | Soft mix my screening test PI-07008 - AE F075032 00 WG75 A1 (charge |
| l | FKE004341) - Amidosulfuron - Specification number 102000000550 |
| Report No.: | PPI-07008 |
| Document No.: | M-29.5670-01-1 0 45 5 |
| Guideline(s): | n@applicator & ~ |
| Guideline deviation(s): | not specified |
| GLP/GEP: | no 🌾 🚬 🔿 hý |
| ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | |
| Executive Summer | |

Executive Summary:

The aim of this study was to determine potential effects of soil incorporated Amidosulfuron WG 75 on phytotoxicity and fresh weight of seedlings from 14 crop species under standard glasshouse conditions. The methods are based upon the PPO guideline PPI/207 1998 and, more specifically, the Report 29 of the Biologische Bundesanstalt (BBA) -. 1997.

The test item was mixed into standard andy-loam soil in the concentrations of 0.156, 0.625, 2.5, 10.0 and 40.0 g product/ha (equivalent to 0.117, 0.468, 1.875, 7.5 and 30 g a.s./ha) referring to 0.11, 0.44, 1.75, 7.0, and 28 thug product/kg soil. An untreated control was also included. On the following day, Seeds of 14 gross and broad-leaved crop species (EPPO code) Hordium vulgare (HORVS), Lolium multiflorum (LOLMA), Secale cereale (SECCW), Triticum aestivum (TRZAW), Zea mays var. Vulgaris (ZEAMA), Beta vulgaris (BEAVA), Brassica napus (BRSNW), Glycine max (GLXMA), Helianthus annuus (HELAN), Lens culinaris (LENCU), Linium usitatissium (LIUUT), Phaseolus vulgaris (PHSVN), Pisum sativum (PIBST), Sinapis alba (SINAL) were sown into the 5 soil concentrations and untreated soil into 4 replicate pots. The number of seedlings that emerged was counted in each pot. After emergence, the vigour of the seedlings was assessed visually on a percentage basis 15 days and 29 days after sowing. After the final visual assessment the shoot fresh

weight was measured. The percentage herbicidal effects obtained at various concentrations were used to calculate the selectivity thresholds (EC10).

Under standardized test conditions, 14 grass and broad-leaved crops showed a range of sensitivities towards soil incorporated Amidosulfuron WG 75. Based on phytotoxicity assessment and reduction of fresh weight the most sensitive crops are sugar-beet, sunflower, lentils, field peas, white mustard and oilseed rape. The first three crops require 6 half life times to reach the EC10@alues shown in this study. The other sensitive crops mentioned here need 3-4 half life times to reach the EC10 values determined in this study. All grains were less sensitive.

Material and Methods:

Test item: Amidosulfuron WG 75 (AE F075032 00 WG75 A 1) °

Test species: 14 grass and broad-leaved crop species (EPPO code) Horthum vulgare (spring barley, HORVS), Lolium multiflorum (ryegrass, LOLMU), Secale cereale (winter rye, SECCW), Traticum aestivum (winter wheat, TRZAW), Zea mays var. Vitgaris (maize, ZEAMA), Beta Sulgaris (sugar beet, BEAVA), Brassica napus (winter oilseed rage, BRSAW), Greine max (soybean, QLXMA), Helianthus annuus (sunflower, HELAN), Lens Culinaris (lenti, LENCU), Linium Isitatissium (linseed, LIUUT), Phaseolus vulgaris (bean, PHSVN), Pisum sativum (field pea, PIBST), Sinapis alba (mustard white, SINAL).

The sample of Amidosulfuron WG 75 was diluted in water and nixed in the concentrations of 0.156, 0.625, 2.5, 10.0 and 40.0 g product/ha (equivalent to 0.117, 0.468, 7.875, 3.5 and 30 g a.s./ha) referring to 0.11, 0.44, 1.75, 7.0, and 28.0 µg product/kg soil mixed in 10 cm soil depth with a bulk density of 1.43 g/cm³) into a standard sandy loam soil (20) sand sit 23% clay at pH 6.8 and 1.4% organic matter). On the following day, seeds of 14 crop species (see above) were sown into the soil. The test run with four replicates in 9 cm diameter pers.

After sowing, the pots were placed in a greenhouse at $22^{\circ}C \pm 2^{\circ}C$ day and $17^{\circ}C \pm 2^{\circ}C$ night. As required, the pots were integrated from above so as to keep the soil sufficiently moist for good plant growth but avoid any expess water draining from the parts. The humber of seedlings that emerged was counted in each pot After emergence, the vigour of the seedlings was assessed visually on a

Results: EC₁₀ values were calculated based on visual phytotoxicity and on % fresh weight reduction and are given in the following table.

Table CP 10.6.1-1: EC₁₀ values for Amidosulfuron WG 75 based percent phytotoxicity (ratings and fresh weight harvest at 29 DAT) – EC₁₀ values expressed as well as μg formulated product/kg soil and as mg formulated product/ha

| | HORVS | LOLMU | SECCW | TRZAW | ZEAMA | BEAVA | BRSNW | GLXMA | HELAN | LENCU | CIU | PHSVN | PIBST | SINAL |
|-----------------|----------|----------|----------|---------|---------|----------|----------|------------|-----------|---------------|--------------|----------|------------|--------------|
| EC10 value | s (in µ | g/kg fo | rmulat | ed pro | duct mi | ixed in | soil – u | se rate | 28 μg/l | kg soil) | før Am | itdosult | furða V | VG 75 |
| based on % | 6 phyte | otoxicit | iy – rat | ings an | d fresh | weight | t harves | st at 29 | DAT | \sim | , (| Ũ | \bigcirc | <i>a</i> . |
| % Phytotox | >28 | >28 | 19.2 | >28 | 2.46 | 0.19 | 2.85 | 4.66 | 0.32 | 0000 00001 | 2.98 | >28 | , 0.72 | ,90 ,1.90 |
| Fresh Weight | >28 | >28 | >28 | >28 | >28 | 0.52 | 2.50 | >28 | 0.54 | 0.64% | 28 | ∠⇒28 | 2 8:51 | 1.94 |
| EC10 value | s (in ø/ | ha fori | nulated | l nrodi | ict mix | ed in so | il – use | sate 4 | () (a/ha) | for Am | ido\$îN | uron V | G 75 F | ased |
| on % phyte | otoxici | ty – ra | tings ar | nd fres | h weigh | t harve | est at 2 | DAT | s gana) | - OX | Ň | Ş | | ļ |
| % Phytotox | >40 | >40 | 27.4 | >40 | 3.51 | 0.27 | 407 | 6,60 | 0.46 | 0.87 | 4 .26 | \$40 | 100 | 2.72 |
| Fresh Weight | >40 | >40 | >40 | >40 | >40 | 0.74 | 3.57 | 4 0 | \$0,77 | 0.92 | >46 | >40 | U12.3 | 2.77 |
| | | | | | | | Õ | | | <u> </u> | | O), | | |

Effect of the concentrations of soil incorpotated formulated product on the emergence of the 14 crops: Only on peas, a significant reduction in the number of emerged plants was observed with the highest concentration otherwise no significant response could be observed on the emergence of any of the crops.

Average percentage crop effects from the visual assessments (15 and 29 DAS):

From the data it can be seen that the most sensitive crops are peas (PIBST), oilseed rape (BRSNW), sugar beet (BEAVA), sunflower (HEAN), entils (LENCU) and white mustard (SINAL). Soybeans (GLXMA) and corn (ZEAMA) where quite sensitive and the monocot crops and linseed (LIUUT) and the bean (PHSVN) where not verpsensitive at all. For most of the crops there was no recovery from damage recorded at 15 days to the 29-day assessment. Frial was terminated at 29 days after sowing. Cereal crops were amongst the least sensitive crops. The observed phytotoxicity with the higher rates may have been accentuated by having the formulation incorporated into the soil. It demonstrates also the high crop sensitivity in general with these model type greenhouse studies.

Effects from the assessment of fresh weight data:

The fresh weight data showed little effect on the monocot crops and with soybean (GLXMA), linseed (LIUUT) and the bean (PHSVN) there were no significant differences recorded. In the case of the dicot. crops significant reductions in fresh weight were seen in sugar beet (BEAVA), oilseed rape (BRSNW), supflowed (HELAN), length (LENCU), field peas (PIBST) and white mustard (SINAL) but only at the highest two or three close rates. Generally there were no significant reductions below the dose of 1.8 µg/kg of soil.

Conclusion:

Under standardized test conditions 14 grass and broad-leaved crops showed a range of sensitivities towards Amidosultaron 3675 incorporated in a sandy loam soil. Based on phytotoxicity assessment and reduction of fresh weight the most sensitive crops are sugar-beet (BEAVA), sunflower (HELAN), lentils (LENCU), field peas (PIBST), white mustard (SINAL) and oilseed rape (BRSNW). The first three crops require 6 half life times to reach the EC₁₀ values shown in this study. The other sensitive crops mentioned here need 3-4 half life times to reach the EC₁₀ values determined in this study. All grains were less sensitive.

CP 10.6.2 Testing on non-target plants

Vegetative vigour

| Donort | KCP 10.6 2/01 · 2002· M 2/0817 01 1 |
|---------------------------|---|
| Title [.] | Determination of Effects on Vegetative Vigor of Six Plant Species AE E075032.00 |
| 11010. | WG75 A1 |
| Report No.: | B003815 |
| Document No.: | M-240817-01-1 |
| Guideline(s): | OECD: 208, Part B |
| Guideline deviation(s): | |
| GLP/GEP: | ves ves |
| | |
| The study reports on a | vegetative vigour test for 6 species of non-taget plants on the formulated |
| product. Sovbean (Glva | cine max) has been identified as the most sensitive species to the formulated |
| product | |
| product. | |
| The study was conside | red acceptable in the FAU review for the first inclusion of ametasulfuron on |
| Anney I a study summe | ary is found in the pressive Droft Assessment Panort (2006) |
| Annex I, a study summa | ity is round in the predous Drag Assessment Report (2000). |
| An EU agreed and noin | t of ED = 67 a de to the toulity of the former lation of ratil" to six plant |
| An EU agreed endpoint | tor EK50 – 07 g ass/ha roughle to sterily of the roughlianous - Oralli to six plant |
| species during vegetativ | re growth was depived from this test. |
| XT 1 11 1 | |
| No changes to this endp | point are proposed in the context of approval genewal |
| | |
| Report: | KCP 10.6.2/02 ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; |
| Title: | Effect of AE To 5032 & WG2 A 205 of reget at the vigour of eleven species of |
| | terre vrial playts |
| Report No.: | |
| Document No.: | St-214455-01-1 |
| Guideline(s): | OECD: 208 B: Agg. viges |
| Guideline deviation(s | |
| GLP/GEP: | |
| | |
| Study listed tor format | reason only, since referenced in the baseline dossier. The tested formulation |
| AE F0/5032308 W626 | A20 is a co-formulation with a second sulfonylurea-type active substance |
| iodosulfuron-methyl-so | dium and a crop safener metenpyr-diethyl, and does not deliver endpoints |
| applicable for the repres | entative formulation Amiliosulfuron WG75. |
| | |
| The study was included | in the EU review for the first inclusion of amidosulfuron on Annex I, the DAR |
| (2006) concluded This | study was not evaluated because the formulation used is not comparable with |
| Gratil (12)6% amidosul | faron $+2$ additional active substances) and the highest rate tested is lower than |
| the interded rate of and | dosulfaron.". |
| × ~~ ~ | |
| Report: | KCP 10.6.2403 |
| Title: | Aphidosulfuron WG 75 W - Effect on the vegetative vigour of four species of non- |
| | target terrestrial plants (Tier 2) |
| Report No.: | VV09/032 |
| Document No.: | M-366958-01-1 |
| Guideline(s): | OECD Guidelines for the testing of chemicals; Guideline 227 Terrestrial plant Test: |
| × / | Vegetative vigour Test. July 2006, adopted |
| Guideline deviation(s): | none |

Guideline deviation(s): GLP/GEP: yes

Executive Summary:

The purpose of this specific study was to evaluate the effect of Amidosulfuron WG 75 on the vegetative vigour of four plant species representing three dicotyledonous and one monocotyledonous plant families. The test was performed in accordance with OECD guideline 227 (2006).

Plants of four species were tested in this vegetative vigour test under glasshouse conditions including three dicotyledonous and one monocotyledonous species representing four different plant families. At the 2-4 leaf stage, plants were sprayed once at test initiation with doses of Amidosulfuroh WG 75 ranging from 45 g a.s./ha down to 0.044 g a.s./ha using a laboratory track sprayer at a volume rate of 200 L/ha. There were six treatment levels for each species and a water treated control. The application rates for sugar beet, cucumber and onion were 45, 22.5, 11.25, 5.63, 2.81 and 1.41g a 5/ha. Due to the high sensitivity of sunflower in the first study (45, 22.5, 0.25, 5.63, 2.81 and 1.41g a 5/ha), this species was repeated with lower rates in a 2nd run (5.63, 2.81, 1.4100.7, 0.35 and 0.18g a 5/ha) and in a 3rd run (1.41, 0.70, 0.35, 0.18, 0.088 and 0.044g a 6/ha). Eight pots per treatment group for all species with four plants each were used. In total 32 plants per treatment group were tested. Plants were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day, and 18 ± 8°C at night with a 16 h photoperiod.

Assessments were made 7, 14 and 21 days after application against the water treated controls. Statistical analysis of data was performed to obtain NOER, QR/ER₂₅ and LIVER₅₀ values for survival and shoot dry weight, using ToxRat statistics.

All species treated with Amidosulfuron WG 75 showed phytotoxic symptons visible as chlorosis, necrosis, leaf deformation and stunting. The severity of these symptons differed with application rates and species sensitivity to the product. Surflower was the most sensitive species with the lowest ER50 of 0.110 g a.s./ha for shoot dry wright.

Material and methods:

Test item: Amidosulfuron WG 70W; FCCode: MIDOSULEUTION WG 75 % w/w; Workorder: 09008721; Sample description. TOX 08561-00; Bach IDC, EFKE001675; Specification No.: 102000000550; Analysed content of as: 75.3% w/w while with the second second

Plants from four species' sugar beet (Beta vulgaris), cucumber (Cucumis sativus), sunflower (Helianthus annuas) and onion (Allium cepa) were sprayed with Amidosulfuron WG 75 at the 2-4 leaf stage. Serial collutions were sprayed with application rates ranging from 45 g a.s./ha down to 0.044 g a.s./ha using a laboratory track sprayer at a volume rate of 200 L/ha. There were six treatment levels for each species and a water treated control. The application rates for sugar beet, cucumber and onion were 45, 22.5, 11.25, 5.63, 2.81 and 1.41g a.s./ha. Due to the high sensitivity of sunflower in the first study (45, 22.5, 1.25, 5.63, 2.81 and 1.41g a.s./ha) and in a 3rd run (1.41, 0.70, 0.35, 0.18, 0.088 and 0.044g a.s./ha). Eight pots per treatment group for all species with four plants each were used. In total 32 plants per treatment group were tested. Plants were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day, and 18 ± 8°C at night with a 16 h photoperiod.

Visual phytotoxicity ratings and number of plants that survived after application were assessed 7, 14 and 21 days after application. Growth stages and shoot dry weight were determined at the final assessment. Statistical analysis of data was performed to obtain NOER, LR/ER₂₅ and LR/ER₅₀ values for survival and shoot dry weight, using ToxRat statistics.

Dates of experimental work: April 23, 2009 – November 26, 2009

Results:

Validity criteria:

This study can be considered valid as the specified validity criterion of 90% survival during the study period of the untreated controls was achieved for all species.

Table CP 10.6.2- 1: Validity criteria in the untreated control for the vegetative vigour test with Amidosulfuron WG 75

| | Survival of untreated controls |
|---------------------------------|--------------------------------|
| Validity criteria | ≥90 % @ @ A × |
| Sugar beet | |
| Cucumber | |
| Sunflower (1 st run) | |
| Sunflower (2 nd run) | |
| Sunflower (3 rd run) | |
| Onion | |
| | |

Analytical results:

Analysis of the highest application rate revealed it to be 95.1 98.2% of nominal.

Biological results:

All species treated with Amidosulfurce WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis, leaf deformation and stunting. The severity of these symptoms differed with application rates and species sensitivity to the product.

Sunflower was the most sensitive species with biomass measured as shoot dry weight being the most sensitive endpoints.

The following table summarises for NOFR, ER/CR_{25} and CER/LR_{36} for survival and shoot dry weight. Endpoints are expressed as g a.s./ha.

| \$~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | | . × ô | g a.s | 5./Ba] | | |
|---|--------------|-----------------------------|---------------------------|---------|-------------------------|---------|
| Ê.S | | Surviva | | Sł Sł | oot dry weig | ht |
| Plant species | SOER C | LR25 | $\sim LR_{50}$ | NOER | ER ₂₅ | ER50 |
| Dicotyledonae | | | Ô' 🖇 | | | |
| Sugar beet 🕺 | 45 | <u></u> ∕\$¥45 [#] | ≠ >45 [#] | <1.41 | n.d. | >45# |
| Cucumber | , 5 # | >45# | £ 4 5 [#] | 45 | >45# | >45# |
| Sunflower 👸 | A.41 & | 3.60 | _ൣ @1.72 | <1.41 | <1.41# | <1.41# |
| Sunflower 2 nd | ° 1.41 © | 2 ,66 * | 4.21 | < 0.18 | < 0.18# | < 0.18# |
| Sunflower 3rd | 1.4 | >1.41# @ | >1.41# | < 0.044 | 0.034 | 0.110 |
| Monocotyledona | ie 🖉 | | | | | |
| Onion 💦 | ~45 ~ | >45 | >45# | 5.63 | 14.44 | >45# |

Table CP 10.6.2- 2: The effect of Amidosulfucon WG35 on four plant species

#: calculated values vere outside the range tested or not determined

Ø

Conclusions: 🚿

Based on the results of this vegetative vigour study in which the effect of Amidosulfuron WG 75 on four plant species was tested under glasshouse conditions the most sensitive species was sunflower with the lowest ER₅₀ of 0.110g a.s./ha for shoot dry weight.

| Document MCP: Section | 10 Ecotoxicological studies |
|------------------------------|------------------------------------|
| Amidosulfuron WG 75 | |

| Report: | KCP 10.6.2/04,; 2011; M-405630-01-1 |
|-------------------------|---|
| Title: | Amidosulfuron WG 75 W - Effect on the vegetative vigour of five non-crop species of |
| | non-target terrestrial plants (Tier 2) |
| Report No.: | VV10/058 |
| Document No.: | M-405630-01-1 |
| Guideline(s): | OECD Guideline for the testing of Chemicals, Terrestrial Plant, Test; OECD 227: |
| | Vegetative Vigour Test, July 2006 |
| Guideline deviation(s): | none |
| GLP/GEP: | yes St Q O g |

Executive Summary:

The purpose of this specific study was to evaluate the phytotoxic effect of Amrdosulfaron WG 75 on the vegetative vigour of five non-crop species of non-target terrestrial plants following a post emergence application of the product onto the foliage of plants at the 24 leaf stage. The test was performed in accordance with OECD guideline 227 (2008).

Plants of five non-crop species were tested in this vogetative vigout test under glasshouse conditions including five dicotyledonous species representing five different plant families. At the 2 deaf stage, plants were sprayed once at test initiation with doses of Amidosuffuron WG 75 tanging from 45 g a.s./ha down to 0.09 g a.s./ha using a laboratory track sprayer at a volume rate of 200 L/ha. There were 4 plants per pot and 8 replicate pats per treatment. The application rates for *Amaranthus retroflexus* were 2.81, 1.41, 0.70, 0.35, 0.48 and 0.09 g a.s./ha. The application rates for *Stellaria media* were 5.63, 2.81, 1.41, 0.70 and 0.35 g a.s./ha. The application rates for *Bellis perennis* were 11.25, 5.63, 2.81, 1.41, 0.70 and 0.35 g a.s./ha. The application rates for *Centaurea cyanus* and *Senecio vulgaris* were 45, 22.5, 11.25, 5.63, 2.81, and 1.41 g a.s./ha. Control pots were sprayed with 200 L/ha deionised water. Plants were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day, and 18 ± 8°C at right with a 16 h photoperiod.

Assessments (survival, visual phytotocicity, plant growth stage, and shoot dry weight) were made 7, 14 and 21 days after application against the water treated controls. The study was terminated 21 days after application. Statistical analysis of data was performed to obtain NOER, LR/ER₂₅ and LR/ER₅₀ values for survival and shoot dry weight, using ToxRat gatistics.

The species treated with Annidosulturon WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis, leaf deformation or studing. The severity of these symptoms differed with application rate and species sensitivity to the product. The most sensitive species was *Amaranthus retroflexus* with the lowest ER_{50} K^{2} 0.09 a.s./h extrapolated as 0.07 g a.s./h for shoot dry weight.

Material and methods: 👟

Test item: Amrdosulfuron WG 75 W: T-Code. AMIDOSULFURON WG 75 % w/w; Workorder: 09008721; Sample description: TOX 08561-00; Batch ID: EFKE001675; Specification No.: 10200000050; Analysed content of a.s.: 759 % w/w amidosulfuron.

Plants from five non-crop species; redroft pigweed (*Amaranthus retroflexus*), Daisy (*Bellis perennis*), control wer (*Centaurea cyanus*), common groudsel (*Senecio vulgaris*) and common chickweed (*Stellaria media*) were sprayed with Amidosulfuron WG 75 at the 2-4 leaf stage. Serial dilutions were sprayed with application rates ranging from 45 g a.s./ha down to 0.09 g a.s./ha using a laboratory track sprayer at a volume rate of 2000L/ha. There were 4 plants per pot and 8 replicate pots per treatment. Each plant species was treated with 6 application rates. The application rates for *Amaranthus retroflexus* were 2.87, 1.41, 0.70, 0.35, 0.18 and 0.09 g a.s./ha. The application rates for *Stellaria media* were 5.63, 2.81, 1.41, 0.70, 0.35 and 0.18 g a.s./ha. The application rates for *Bellis perennis* were 11.25, 5.63, 2.81, 1.41, 0.70 and 0.35 g a.s./ha. The application rates for *Centaurea cyanus* and *Senecio vulgaris* were 45, 22.5, 11.25, 5.63, 2.81 and 1.41 g a.s./ha. Control pots were sprayed with 200 L/ha deionised water. Plants were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day, and 18 ± 8°C at night with a 16 h photoperiod.
Assessments were made 7, 14 and 21 days after application against the water treated controls. The study was terminated 21 days after application. The parameters measured were survival, visual phytotoxicity, plant growth stage and shoot dry weight. Statistical analysis of data was performed to obtain NOER, ER/LR₂₅ and ER/LR₅₀ values for survival and shoot dry weight, using ToxRat statistical software.

Dates of experimental work:

October 21, 2010 - February 02, 201

Results:

Validity criteria:

This study can be considered valid as the validity criterion of at least 9 study period was achieved for the untreated controls of all species tested

| Table CP 10.6.2- 3: | Validity criteria in the untreated | control for | the ve | getative | vigourtes | t with | |
|---------------------|------------------------------------|-------------|--------|----------|-----------|--------|--|
| | Amidosulfuron WG 75 | õ | , O | | | Ô | |

| | Survival (% of untreated control plants throughout the study) |
|------------------------|---|
| Validity criteria | ∑ ['] ≥90 ² % |
| Amaranthus retroflexus | |
| Bellis perennis | |
| Centaurea cyanus | |
| Senecio vulgaris | |
| Stellaria media | |
| | |

Analytical results:

Measured concentrations of amidosulfuron in the highest application rate ranged from 95.4 to 95.9% of the nominal test concentration.

Biological results:

0 The species treated with Amidosulfuron WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis, leaf deformation or stunting, The severity of these symptoms differed with application rate and species sensitively to the product Ñ

25 and ER/LR₅₀ for survival and shoot dry weight. The following table summarises the NOER Endpoints are expressed as g as./ha>

| (Co | (// n* | | | | | | | | | |
|-------------------|-----------------------|----------------|---------------------|--------|------------------|-------|--|--|--|--|
| | 6 6 6 [g a.s./ha] | | | | | | | | | |
| Ő | | / Surxival | ° ۲ | Sh | Shoot dry weight | | | | | |
| Plant species | NOER | €R 25 % | 🖉 LR50 | NOER | ER25 | ER50 | | | | |
| Dicotyledonae Q C | | | | | | | | | | |
| Amaranthus 🦉 | . 20 | | 2 27 | <0.00 | <0.00ª | 0.07b | | | | |
| retroflexus | | | 2.27 | <0.09 | <0.09 | 0.07 | | | | |
| Bellis perennis | ∠ 2.81 [_] | 6.35 | >11.25 ^a | < 0.35 | <0.35ª | 0.52 | | | | |
| Centaurea | 15 | 15a | √15 a | <1.41 | 5.01 | 25.46 | | | | |
| cyanus 👋 | 4 5 | 0/43 | -43 | ×1.41 | 5.91 | 23.40 | | | | |
| Senecio | S1 25 | 18 51 | <u> </u> | <1.41 | <1 /1a | 2 20 | | | | |
| vulgaris | (0 ⁴ 1.2.3 | 18.31 | 20.02 | ×1.41 | ~1.41 | 2.29 | | | | |
| Stellaria media | 5.63 ^a | >5.63ª | >5.63ª | 0.18 | 0.51 | 2.04 | | | | |

Table CP 10.6.2-4; The effect of Onidosulturon WO 75 on five non-crop plant species

^a: calculated values were outside the range tested or not determined

^b: extrapolated value

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Conclusions:

Based on the results of this tier 2 vegetative vigour study in which the effects of Amidosulfuron WG 75 on five non-crop species were tested under glasshouse conditions the most sensitive species was *Amaranthus retroflexus* with the lowest ER_{50} of <0.09 g a.s./ha extrapolated as 0.07 g a.s./ha for shoot dry weight.

| Report: | KCP 10.6.2/05 =; 2010; M-389517-01-1 | _ |
|-------------------------|--|-----------------------|
| Title: | Amidosulfuron WG 75 W - Effect on the vegetative vigour of fiv | e non-crop species of |
| | non-target terrestrial plants (Tier 2). | |
| Report No.: | VV10/066 | |
| Document No.: | M-389517-01-1 | |
| Guideline(s): | OECD Guideline for the testing of Chemicals, Terrestrial Phont T | `est©OECD \$27: |
| | Vegetative Vigour Test, July 2006 | |
| Guideline deviation(s): | none | |
| GLP/GEP: | yes a way way way way way way way way way w | |
| | | .0 .~ |

Executive Summary:

The purpose of this specific study was to evaluate the phytotoxic effect of Amidosulfurop WG 75 on the vegetative vigour of five non-crop species of non-targer terrestrial planes following a post emergence application of the product onto the foliage of plants at the 2-4 leaf stage. The test was performed in accordance with OECD guideline 227 (2006).

Plants of five non-crop species were tested in this vegetative visour test under glasshouse conditions representing the plant family Asteraceae. At the 24 leaf stage, plants were sprayed once at test initiation with doses of Amidosulfuron W6 75 ranging from 2.8 g a.s./ha down to 0.022 g a.s./ha using a laboratory track sprayer at a volume rate of 200 L/ha. There were 4 plants per pot and 8 replicate pots per treatment. The application rates for *Bellis perennis* were 0.70, 0.35, 0.18, 0.088, 0.044 and 0.022 g a.s./ha. The application rates for *Achilleamillefolum* were 1.41, 0.70, 0.35, 0.18, 0.088 and 0.044 g a.s./ha. The application rates for *Achilleamillefolum* were 1.41, 0.70, 0.35, 0.18, 0.088 and 0.044 g a.s./ha. The application rates for *Centaurea cyanus*, *Matricaria chamomilla* and *Senecio vulgaris* were 2.85, 1.41, 9.70, 0.35, 0.18 and 0.088 g a.s./ha. Control pots were sprayed with 200 L/ha deionised water. Plants were grown and mantained under glasshouse conditions with a temperature control set at 23 ± 8°C during day, and 18 ± 8°C anight with a 16 h photoperiod.

Assessments (survival, visual phytotoxicity and growth stage and shoot dry weight) were made 7, 14 and 21 days after application against the water peated controls. The study was terminated 21 days after application. Statistical analysis of data was performed to obtain NOER, LR/ER₂₅ and LR/ER₅₀ values for survival and shoot dry weight, using ToxRa statistics.

The species treated with Amido@lfuron WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis or stimuling. The severity of these symptoms differed with application rate and species sensitivity to the product. The most sensitive species was *Achillea millefolium* with the lowest ER₅₀ of 0.461 g a.s. Da for shoot dry weight

Materia and methods

Test item: Andosulturon WG 75 W FT-Code: AMIDOSULFURON WG 75 % w/w; Workorder: 09008721; Sample description: TOX 08561-00; Batch ID: EFKE001675; Specification No.: 102000000550; Analysed content of a.s.: 75.3 % w/w amidosulfuron.

Plants from five non trop species representing the plant family Asteraceae; common yarrow (*Achillea millefolium*), Daisy (*Bellis perennis*), cornflower (*Centaurea cyanus*), wild chamomile (*Matricaria chamomilla*) and common groundsel (*Senecio vulgaris*) were sprayed with Amidosulfuron WG 75 at the 2-4 leaf stage. Serial dilutions were sprayed with application rates ranging from 2.81 g a.s./ha down to 0.022 g a.s./ha using a laboratory track sprayer at a volume rate of 200 L/ha. There were 4 plants per pot and 8 replicate pots per treatment. Each plant species was treated with 5 application rates. The application rates for *Bellis perennis* were 0.70, 0.35, 0.18, 0.088, 0.044 and 0.022 g a.s./ha. The application rates for *Achillea millefolium* were 1.41, 0.70, 0.35, 0.18, 0.088 and 0.044 g a.s./ha.

The application rates for *Centaurea cyanus*, *Matricaria chamomilla* and *Senecio vulgaris* were 2.81, 1.41, 0.70, 0.35, 0.18 and 0.088 g a.s./ha. Control pots were sprayed with 200 L/ha deionised water. Plants were grown and maintained under glasshouse conditions with a temperature control set at $23 \pm 8^{\circ}$ C during day, and $18 \pm 8^{\circ}$ C at night with a 16 h photoperiod.

Assessments were made 7, 14 and 21 days after application against the water areated controls. The study was terminated 21 days after application. The parameters measured were survival, visual phytotoxicity, plant growth stage and shoot dry weight. Statistical analysis of data was performed to obtain NOER, ER/LR₂₅ and ER/LR₅₀ values for survival and shoot dry weight, using ToxRar statistical software.

Dates of experimental work:

Results:

Validity criteria:

This study can be considered valid as the validity criterion of at least 90% survival throughout the study period was achieved for the untreated control of all species tested.

O

Table CP 10.6.2- 5: Validity criteria in the untreased control for the vegetative vigour test with Amidosulfuron WG 75

June 24, 2010 – July 2

| | Survival (% of untreated control plants throughout the study) |
|-----------------------|---|
| Validity criteria | |
| Achillea millefolium | |
| Bellis perennis | 90.6 % |
| Centaurea cyanus | |
| Matricaria chamomilla | × 0 [*] × 9699% |
| Senecio vulgaris | 2700 % Y |
| | |

Analytical results:

Analysis of amidosulforon in the highest tested application rate revealed it to be 98.7% of nominal.

Biological results

The species treated with Amidosulfuren WG 75 should phytotoxic symptoms visible as chlorosis, necrosis or stanting. The severity of these symptoms differed with application rate and species sensitivity to the product. Achillea milleforum was the most sensitive species with shoot dry weight being the most sensitive endpoint.

The following table sommarises the SOER, SR/LR₂₅ and ER/LR₅₀ for survival and shoot dry weight. Endpoints are expressed as a.s./ha



| [g a.s./ha] | | | | | | | |
|--------------------------|-------|------------------|------------------|-------|---------------------|---------------------------------|----|
| | | Survival | | Sh | noot dry weig | ght | |
| Plant species | NOER | LR ₂₅ | LR ₅₀ | NOER | ER ₂₅ | ER50 | |
| Asteraceae | | | | | | Q | |
| Achillea millefolium | 1.41 | >1.41# | >1.41# | 0.18 | 0.195 | 0.461° | Å |
| Bellis perennis | 0.7 | >0.7# | >0.7# | 0.35 | 0.34 | √ ⁴ 0.7 [#] | 0. |
| Centaurea cyanus | 2.81 | >2.81# | >2.81# | 2.81 | >2.91# | Ø>2.81# | |
| Matricaria chamomilla | 2.81# | >2.81# | >2.81# | 0.088 | ~0.213°~y | 0:585 | |
| Senecio vulgaris | 2.81# | >2.81# | >2.81# | @1.41 | >2,8,1 [#] | 2.81# | |

Table CP 10.6.2- 6: The effect of Amidosulfuron WG 75 on five non-crop plant species representing the plant family Asteraceae

#: calculated values were outside the range tested or not determined $\mathcal{A}_{h}^{\mathcal{A}}$

Conclusions:

Based on the results of this tier 2 vegetative vigour study in which the effect of Amidosol furon WG 75 on five non-crop species was tested under glasshouse conditions the most sensitive species was Achillea millefolium with the lowest ER50 of 9.461 g a.s./hador shoet dry weight.

Seedling emergence

≝; 2010; M-366951-01-1 KCP 10.6.2/06 **Report:** Amidosulfuron W@75 W - Effect on the seedling emergence and seedling growth of Title: ten species of non-Darget tetrestrial plants (The 2) Report No .: SE094031 Document No .: M-366951-01-1 OF CD 208 (July 2006): Guide line for the testing of chemicals, Terrestrial Plant Guideline(s): Test: Seeding emergence and seeding growth Test Guideline deviation(s): none

GLP/GEP:

Executive Summary: >>

The purpose of this specific study was to evaluate the effect of Amidosulfuron WG 75 on the seedling emergence and seetling growth of ten plant species representing a broad range of both dicotyledonuous and monocotyledonous plant families. The test was performed in accordance with OECD guideline 208 (2006).

A total of ten species were tested in this seedling emergence test under glasshouse conditions including seven dicityledonous anothree monocotyledonous species representing eight different plant families The seeds were sown in a mixture of 90% silt loam + 10% washed sand prior to application of Anitosulfuron WG75 to the soil surface. Five seeds were sown in each pot and there were 8 pots (replicates for each species giving a total of 40 seeds per treatment level. Serial dilutions of Amidosulfuron WG 75 were spraved with application rates ranging from 45 g a.s./ha down to 1.41 g a.s./ha and 5.63 & a.s./ha adown to 0.18 g a.s./ha in the first and second run of the study, respectively. Application was conducted using a laboratory track sprayer at a volume rate of 200 L/ha. The application rates for agarbeet, cabbage, turnip, cucumber, soybean, tomato, onion, oat, sunflower and ryegrass were 45, 22.5, 11.25, 5.63, 2.81 and 1.41g a.s./ha. Due to the high dose response for shoot dry weight with sunflower in the first study, this species was repeated with lower rates: 5.63, 2.81, 1.41, 0.7, 0.35 and 0.18g a.s./ha in order to generate more reliable endpoints. Plants were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8 °C during day and $18 \pm$ 8°C at night with a 16 h photoperiod.

Emergence was assessed daily until 70% emergence of control seedlings. Emergence, survival and phytotoxicity were recorded 7 and 14 days after this time. The study was terminated 14 days after 70% emergence. At test termination, total emergence, survival of emerged seedlings, visual phytotoxicity, growth stages and shoot dry weight were assessed. Statistical analysis of data was performed to obtain NOER, LR/ER₂₅ and LR/ER₅₀ values for emergence, survival and shoot dry weight, using ToxRat statistics.

All species, excepted oat, treated with Amidosulfuron WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis, leaf deformation and stunting. The severity of these symptoms differed with application rates and species sensitivity to the product. The most sensitive dicotypenonous species was sunflower with the lowest ER_{50} of 1.08 g a.s./ha for shoot dry weight and most sensitive monocotyledonous species was onion with the lowest calculated ER_{50} of 4.42 g a.s./ha for shoot dry weight.

Material and methods:

Test item: Amidosulfuron WG 75 W; FT-Code: AMIDOSULFURON WG 75 % w/w; Workorder: 09008721; Sample description: TOX 08561-00, Batch ID: FKE001675; Specification No.: 102000000550; Analysed content of a.s.: 75.3 % w/w and osulfaron.

Seeds of ten species; sugar beet (Beta vulgarte), cabbage (Brassica oleraceae), turnip (Brassica rapa), cucumber (Cucumis sativus), soybean (Glycine max) sunflower (Helianthus) annuus), tomato (Lycopersicum esculentum), onion (Allinn cepa), oat (Avena sativa) and ryegrass (Lolium perenne) were sown in a mixture of 90% silt loam + 10% washed sand prior to application of Amidosulfuron WG 75 to the soil surface. Five seeds were sown in each 1005 cm diameter pot and there were 8 pots (replicates for each species) giving a total of 40 seeds per meatment level. Serial dilutions of Amidosulfuron WG 75 were sprayed with application rates from 45 g a.s./ha down to 1.41 g a.s./ha and 5.63 g a.s./ha dover to Q. Q g a s./ha in the first and second run of the study, respectively. Application was conducted using a laboratory track spraver at a volume rate of 200 L/ha. There were six treatment levels for each species and a water treated control. The application rates for sugar beet, cabbage, turorp, cucumber, soybean, tomate, onion loat, sunflower and ryegrass were 45, 22.5, 11.25, 5.63, 2.8 and 1.41 g a s/ha. Due to the high dese response for shoot dry weight with sunflower in the first study, this species was repeated with lower rates: 5.63, 2.81, 1.41, 0.7, 0.35 and 0.18 g a.s./ha in order to generate more whatle adopoints? Plants were grown and maintained under glasshouse condutions with a temperature control set at $23 \pm 8^{\circ}$ C during day and $18 \pm 8^{\circ}$ C at night with a 16 h photoperiod.

Following the application, emergence was assessed daily until 70% emergence of control seedlings. Emergence, survival and phytotoxicity were recorded 7 and 14 days after this time. The study was terminated 14 days after 70% emergence. At test termination, total emergence, survival of emerged seedlings, visual phytotoxicity, growth stages and shoot dry weight were assessed. Statistical analysis of data was performed to obtain NOER LR/ER₂₅ and LR/ER₅₀ values for emergence, survival and shoot dry weight, using ToxRat statistics

Dates of experimental works: April 23, 2009 – August 05, 2009

Results:

Validity criteria:

This study can be considered as valid as the validity criteria of 70% emergence and 90% survival of emerged seedlings during the study period of the controls was achieved for all species.

| Table CP 10.6.2-7: | Validity criteria in the untreated control for the seedling emergence test with |
|--------------------|---|
| | Amidosulfuron WG 75 |

| | Emergence (% of sown) | Survival (%) |
|---------------------------------|--------------------------|-----------------|
| Validity criteria | ≥ 70 | ≥90 |
| Sugar beet | 90.0 | 100 |
| Cabbage | 70.0 | 100 |
| Turnip | 100 | 100 |
| Cucumber | 100 | 97.5 |
| Soybean | 97.5 | 100 |
| Sunflower (1st run) | 95 | 100 |
| Sunflower (2 nd run) | 95 | 100 |
| Tomato | 90.0 | 100 |
| Onion | 72.5 | 100 |
| Oat | 100 | 100 |
| Ryegrass | 87.5 | 100 |

Analysis of the highest application rate revealed it to be 95 2% of nomina ,. L

Biological results: All species, excepted oat, treated with Amidos furon WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis, leaf deformation and stunting. The severity of these symptoms differed with application rates and species sensitivity to the product. Ŷ

The following table summarizes the NOER, ER/LR_{25} and ER/LR_{50} for emergence, survival and shoot dry weight. Endpoints are expressed as g a.s./ha.

Two studies were conducted with sunflower due to high shoot day weight reductions at all application rates tested in the initial study. Both studies are reported.

LR25 and ER S/ha. - s/ha. - udy. Both studies are reported. - udy. -

| | [g a.s./ha] | | | | | | | | |
|---------------------------|------------------|------------------|---------|------------------|-----------------------------|--------------------------|----------------------|-------------------|--------------------------|
| | E | Emergenc | e | Survival | | | Shoot dry weight | | |
| Species | NOER | LR ₂₅ | LR50 | NOER | ER ₂₅ | ER50 | NOER | ER ₂₅ | ER50 |
| Dicotyledonae | | | | | | | | a, | |
| Cabbage | 45 ¹⁾ | >451) | >451) | 45 | >451) | >451) | <1.41 , | 3.18 _ | °6.95 _{"(} |
| Cucumber | 45 | >451) | >451) | 45 ¹⁾ | >451) | >451) | <1.41 | ¢ 2.68 | 9.75 ^{©°} |
| Turnip | 5.63 | 10.17 | 21.77 | 451) | >451) | >451) | 1.40 | .3:62 | 8.32 |
| Soybean | 45 | >451) | >451) | 45 ¹⁾ | >451) | P 5 ¹⁾ | 11.25 | 2 4.72 | © 45 ¹ % |
| Sugar beet | 45 | >451) | >451) | 2.81 | 39.85 | 45 ¹⁾ (| 5≪1.4,1% | <1.41% | 1.56 |
| Sunflower 1st | 45 | >451) | >451) | 45 | >4510 | >454) | <1.2 | <1.11 | <4 A11) |
| Sunflower 2 nd | 5.631) | >5.631) | >5.631) | 5.631) | >5.631) | >\$631) | "®0.18 | Ø0.33 | ¢1.08 |
| Tomato | 45 | >451) | >451) | 45 ¹⁾ | <i>4</i> 5 ¹) ∧ | ×45 ¹⁾ * | 2.81 | 6.70 | 13.23 |
| Monocotyledo | nae | | | K | | | . 6 | - A | Å |
| Oat | 45 | >451) | >451) | 45 | >40) | >031) | \$45 | ≥45 ¹⁾ | 4 5 ¹⁾ |
| Onion | 1.412) | 6.97 | 18.40 | A\$3) | ¢45 ¹⁾ | \$45 ¹) | K×1.41 ⁴⁾ | <1.411) | 4.42 |
| Ryegrass | 5.63 | 7.37 | 14.51 | 2.81 | >45 ¹ | >450 | 2.8 | 6.98 | 17.27 |

Table CP 10.6.2-8: The effect of Amidosulfuron WG 75 on ten species of non-target terrestrial plants

¹⁾ calculated values were outside the range tested or not determined

2) corrected value: The NOER for this ordpoint was proposed by @oxRat & being 1925 g a.s./ha but is set at 1.41 g a.s./ha which is biologically more refevant because of the reduction in emegence at higher application rates.

- 3) corrected value: The NOER for this endpoint we proposed by the program being 1.41 g a.s./ha. However, this result is considered as not reliable because of the absence of significance at all the other application rates tested and is clearly not dese-response related for all application rates tested. Therefore, a corrected value of NOER 45 g a.s./ha is given. \bigcirc
- 4) corrected value: The MOER for this endpoint was proposed by the program as 1.41 g a.s./ha but is set at <1.41 g a.s./ha which is biologically relevant because of the 25.2% shoot dry weight reduction at the application rate of .41 g as, ha.
- application rate of 0.41 g as that 2° application rate of 0.41 g as that 2° application rate of 0.41 g as the program as 5.63 g a.s./ha but is set to 2.81 5) g a.s./ha which is biologically relevant because of the 28.3% shoot dry weight reduction at the application rate of 5.63 a.s./ha

Conclusions:

Based on the results of this study in which the effect of Amidosulfuron WG 75 on ten plant species was tested under glasshouse conditions the most sensitive dicotylenonous species was sunflower which was tested twice and with the lower ER50 of 1.08 g a.s./ha for shoot dry weight and most sensitive monocot dedonous species was onion with the lowest calculated ER₅₀ of 4.42 g a.s./ha for shoot dry weight.

CP 10.6.3 Extended laboratory studies on non-target plants

Considering the findings reported above, and the semi-field / field test information presented under CP 10.6.4, no further studies are required.

CP 10.6.4 Semi-field and field tests on non-target plants

| Report: | KCP 10.6.4/01 ; 2010; M-389529-01-1 |
|-------------------------|--|
| Title: | Amidosulfuron WG 75 W - Effect on the vegetative vigour of sunflower (Helianthus |
| | annuus) grown under semi-field conditions |
| Report No.: | VV10/033 |
| Document No .: | M-389529-01-1 |
| Guideline(s): | OECD Guideline for the testing of Chemicals, Terrestria Plant Test; OECD 227: |
| | Vegetative Vigour Test, July 2006 |
| Guideline deviation(s): | none |
| GLP/GEP: | no O V V |

Executive Summary:

The purpose of this study was to evaluate the potential effects of Amidosulfuron WG 75 on survival, dry weight and phytotoxicological symptoms of survival (*Helianthus annuus*) following post - emergence application of the product onto the foliage of plants at the 6 leaf stage grown under semi-field conditions. The test was performed in accordance with OECD guideline 227 (2006) (modified for testing under semi-field conditions). Sunflowers (*Helianthus annuus*, Asteraceae) were sown in groups (8 replicates per test item group and 2 x 6 replicates per control group) in seed beds at the test site.

Assessments were made 7, 10, 14 and 22 days after application against the water treated controls. The study was terminated 22 days after application. The parameters measured were survival, visual phytotoxicity, plant growth stage and shoot dry weight.

The plants treated with the lowest rate of 0.044 g a.s. ha showed no phytotoxic symptoms. All other plants treated with Amidosulfuron VG 75 showed phytotoxic symptoms visible as chlorosis, leaf deformation and stanting. The severity of these symptoms was mainly slight and differed among application rates. No statistically significant effects of Amidosulfuron WG 75 on sunflower were observed up to the highest rate tested of 0.35 g a.s./ha.

Material and methods:

Test item: Amidosulfuron WG 75 W; FC Code AMIDOSULFURON WG 75 % w/w; Workorder: 09023760; Sample description: TOX 98735-00, Material No.: 05938848; Batch ID: EFKE001914; Specification No.: 102000000550-02 Analysed content of a.s.: 74.8 % w/w amidosulfuron.

Sunflowers (*Helianthus annuus*, Asteraceae) were sown in groups (representing the replicates) in seed beds at the test site. Four application rates 0.35, 0.18, 0.088, 0.044 g a.s./ha of Amidosulfuron WG 75 were sprayed onto the foliage of the plants using a Plot sprayer at a volume rate of 400 L/ha. Control groups were sprayed with 400 L/ha deionised water. Following application, the plants were grown and maintained under semi-field conditions (with natural rain and additional watering when needed).

Assessments were made 7, 10, 14 and 22 days after application against the water treated controls. The study was terminated 22 days after application. The parameters measured were survival, visual phytotoxicity, plant growth stage and shoot dry weight. Statistical analysis of data was performed to obtain NOER, ER/LR₂₅ and ER/LR₅₀ values for survival and shoot dry weight, using ToxRat statistical software.

Dates of experimental work: May 25, 2010 – June 28, 2010

Results: <u>Biological results:</u>

<u>Survival</u>: The foliar application of Amidosulfuron WG 75 had no impact on the survival of treated sunflower (*Helianthus annuus*) plants at any application rate tested. The NOER for this endpoint was set as 0.35 g a.s./ha. The ER₂₅ and ER₅₀ values for survival were both set as >0.3 g a.s./ha.

<u>*Phytotoxicity*</u>: At test termination (at day 22) there were no phytotoxic symptoms observed at the application rate of 0.044 g a.s./ha. Slight phytotoxic symptoms visualised as stunting were observed at day 22 at the application rate of 0.088 g a.s./ha. Moderate to severe phytotoxic symptoms visualised as leave deformation and stunting were observed at day 22 at the application rates of 0.88 and 0.35 g a.s./ha.

<u>Growth stage</u>: At test termination (at day 22) there were light effects on growth stage development of the treated plants in comparison with the untreated controls at and above the application rate of 0.088 g a.s./ha.

<u>Shoot dry weight</u>: Shoot dry weight was not significantly reduced at any application rate tested. The NOER for this endpoint was calculated as 0.55 g as ha. The ER₂ and ER₅₀ values for shoot dry weight were both set as >0.35 g a.s./ha.

The following table summarizes the findings for survival and shoet dry weight.

| Table CP 10.6.4- 1: | The effect of | f Amidos | ulfuron | WG ₂₅ on | sumflower (| Helianthus | <i>annuus</i>) unde | r semi-field |
|---------------------|---------------|----------|---------|---------------------|-------------|------------|----------------------|--------------|
| | conditions | , Ô | õ | . % | . 4 | , ~y' | , | |

Ò

| | | | | ω | 0 | | |
|---------------|------|--------------|--------|----------------------|-------------|------------------------------|--|
| | | (g ą. sklaa) | | | | | |
| | | Survival | | 🖌 🔬 Sho | ot dry weig | ht | |
| Plant species | NOER | L.R.25 | م LR50 | NOËR | ER25 | ER50 | |
| Helianthus | 0.35 | Q0 25# | | ©0 25 [#] √ | ×0.35# | >0 35 [#] | |
| annuus | | v.55 | -0.33 | | -0.33 | -0.55 | |
| # 1 1 / 1 1 | | · 1 | | | | | |

#: calculated values were not determined

Conclusions:

Based on the results of this semi-field regetative vigour study in which the effect of Amidosulfuron WG 75 on samplower *Helianthus annuus*) was tested, no statistically significant effects were observed up to the highest rate tested of 0.35 g a.s./ha

| . ~ · | |
|-------------------------|---|
| Report: | CP 10.6.4/02 ;; 2015; M-548832-01-1 |
| Title: | Amidosulfuror WG 75 percent w/w - Effects on the vegetative vigour of Helianthus |
| Ŭ A | annus plants grown under field conditions (Field trial - Non-GLP) |
| Report Not: | HT 4/028 |
| Document No.: | W -548832-01-1 |
| Guidefine(s): | The study considers the recommendations of the OECD 227 guideline for the testing |
| | of chemicals, Terrestrial Plant Test: Vegetative vigour (July 2006) and of the US EPA |
| ~ _ | Ecological Affects Test Guideline OCSPP 850.4150 |
| Guideline deviation(s): | not applicable |
| GLP/GEP: 🚿 🧕 | no |
| -Q | |

Executive summary:

The purpose of this field study was to evaluate the effect of Amidosulfuron WG 75 on the vegetative vigour of *Helianthus annuus* (sunflower), following a post-emergence spray application of the test item onto the foliage of the plants at the 6 leaf stage in a field test. The study considers the recommendations of the OECD Guideline 227 and of the US EPA Ecological Effects Test Guideline OCSPP 850.4150.

Sunflower (*Helianthus annuus*) plants were grown under field conditions and were treated at the 6 leaf stage. No soil parameters are available from the test site. The total field size was 4000 m², a part of it was divided in 10 plots of 100 m² each (10 m x 10 m). 13 seeds/m² were sown (1300 seeds/plot). 27 days after sowing the plants were treated with 4 different application rates and a deionized water control at the 6-leaf BBCH stage. The test item was applied in 300 L/ha of deionized water at rates of 0.4, 0.8, 1.6 and 3.2 g a.s./ha, whereas control plots were applied with 300 L/ha deionized water only. An additional rate of 6.4 g a.s./ha was set up for analytical purposes only. Assessments were carried out on day 7, 14 and 19 after application. Final assessments were made for plant survival, visual phytotoxicity, plant growth stage and shoot dry weight.

Statistical analysis of data was performed to obtain NOER ER2 and ER2 values for energence, survival and shoot dry weight, using ToxRat statistical software.

No effect on the survival of *Helianthus annuus* plants was observed at any application rate tested (NOER = 3.2 g/ha). The ER₅₀ for shoot dry weight was calculated to be 1.69 g a.s./ha.

Material and Methods:

Test item: Amidosulfuron WG 75% w/w; Sample description: TOS 10124-00; Specification No.: 102000000550; Analyzed contents of a.s. 75.9 % w/w anidosulfuron; Batch-ID? EFKE002307; Workorder: 13005778; Material No.: 05938848.

Sunflower (*Helianthus annuus*) was tested in this vegetative visiour test under field conditions between May, $30^{\text{th}} 2014$ and June, $20^{\text{th}} 2014$ at an experimental field at the trial site of Bayer CropScience AG in the treated at the 6 leaf stage. No soil parameters are available from the test site. The soil on an adjacent field is a silty loam. The total field size was 4000 m², a part of it was divided in 10 plots of 100 m² each (10 m x 10 m) 43 seeds/m² were sown (1300 seeds/plot).

The test item was applied in 300 L/ha of deionized water at rates of 0.4, 0.8, 1.6 and 3.2 g a.s./ha, whereas control plots were applied with 300 L/ha deionized water only. Two replicates were established per test group (test item and control). An additional rate of 6.4 g a.s./ha was set up for analytical purposes only.

Assessments were carried out on day Ø, 14 and 19 after application. Final assessments were made for plant survival, visual phytotoxicity, plant growth stage (BBCH) and shoot dry weight.

Statistical analysis of data was performed to obtain NOER (No observed effect rate), ER₂₅ (rate producing 25% effect) and ER₅₀ (rate producing 50% effect) values for emergence, survival and shoot dry weight, using Tox Rat statistical software

Dates of experimental work: May 30, 2014 – June 20, 2014

(N n

Results:

Validity Criteria;

The test requires a minimum control plant survival of 90% to be valid. In the present test 100.0% of the plants survived, thus the study is considered valid.

In accordance with DECD guideline (OECD 227) and US EPA guideline (OCSPP 850.4150), there was no visible phytotoxicity and a normal growth in the control. The control represented a normal variation in growth, plant development and morphology.

The environmental conditions during the test time were identical within one species.

Analytical results:

The analysis of amidosulfuron content in the initial test item application solution revealed measured concentrations of 112.3% of nominal.

Biological results:

Typical symptoms observed at the final assessment in this study (on day 19 after application) were chlorosis, necrosis, deformation and stunting. The severity and occurrence differed between application rates. The visual observations during the final assessment (19 days after application) are summarised in the following tables.

Table CP 10.6.4- 2: The effect of Amidosulfuron WG 75 on growth of sunflower (Helianthus annuus) under field conditions

| Grov | vth stage (BBCH) A at | Min-Max at application rates (in g a.s/ha) |
|-------------------|-----------------------|---|
| Species | Control | |
| Helianthus annuus | 51 | 57 51 57 59-51 57 16-18 57 51 57 51 57 16-18 |

Table CP 10.6.4- 3: The phytotoxicity effect of Amidosulfuron WG 3 on sunflower (Felianthus annuus) under field condition



At the application rate of 0.4 g a.s./ha mostly slight to moderate phytotoxic symptoms were observed (deformation, stunting). Mostly severe phytotoxic symptoms were observed at the application rate of 0.8 g a.s./ha (chlorosis, necrosis, deformation, stunting). At the application rate of 1.6 and 3.2 g a.s./ha total-plant phytotoxic symptoms were observed (chlorosis, necrosis, deformation, stunting). Slight growth retardation was observed at the application rates of 0.8 and 1.6 g a.s./ha. More obvious growth retardation was observed at 3.2 g a.s./ha, the highest application rate tested.

The no observed effect rate (NOER), ER_{25} and ER_{50} values expressed in g a.s./ha are summarised in the following table for the final assessment (on day 19 after application).

Table CP 10.6.4- 4: The effect of Amidosulfuron WG 75 on survival and shoot dry weight of sunflower (Helianthus annuus) under field conditions

| | g a. | | | s./ha |
|------------------------------|-------------|---------------------------|---------|--|
| | | Survival | | Shoot dry weight |
| Species | NOER | ER ₂₅ | ERs | NOER ER25 ER50 |
| Helianthus annuus | 3.2 | >3.2ª | 3.2ª \$ | 0 [°] 0.4 [°] 0 [°] 0 [°] 1.69 |
| Species Helianthus annuus | NOER 3.2 | ER25 >3.2 ^a | ER50° | NOER |

^a: Since no effect was observed, no further computations were performed for 21d

The foliar application of the test item had no statistically significant effect on the survival of *Helianthus annuus* plants at any application rate tested. The NOER for this endpoint was not calculated and is reported to be 3.2 g a.s./ha. Both the PR_{25} and the ERQ value for this endpoint were not calculated and are reported to be >3.2 g a.s./ha.

Shoot dry weight was statistically significantly affected at the application rates of 0.8, 1.6 and 3.2 g a.s./ha. The NOER for this endpoint was calculated to be 0.4 g a.s./ha and the LOER 0.8 g a.s./ha. The ER₂₅ was calculated to be 0.67 g a.s./ha and the ER₅₆ value for shoot dry weight was calculated to be 1.69 g a.s./ha.

Conclusion:

In a higher Tier vegetative vigour and growth study Amidesulfuron WG 75 was tested under field conditions for effects on the survival, growth and shoot dry weight of *Helianthus annuus*, following a post-emergence spray application of the test item into the foliage of plants at the 6 leaf stage. No effect on the survival of *Helianthus annuus* plants was observed at any application rate tested. The ER₅₀ for shoot dry weight was calculated to be 1.69 ga.s./ha.

CP 10.7 Effects on other terrestrial organisms (flora and fauna)

No studies are required based on current data requirements.

CP 10.8 D Monitoring data

No monitoring data are available and are bot triggered by current data requirements.