

## **Conclusion regarding the peer review of the pesticide risk assessment of the active substance**

### **amidosulfuron**

**finalised: 14 November 2007**

(version of 14 December 2007 with minor editorial changes regarding the confidentiality of one impurity)

### **SUMMARY**

Amidosulfuron is one of the 79 substances of the third stage Part A of the review programme covered by Commission Regulation (EC) No 1490/2002<sup>1</sup>. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Austria being the designated rapporteur Member State submitted the DAR on amidosulfuron in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 6 June 2005. The peer review was initiated on 3 March 2006 by dispatching the DAR for consultation of the Member States and the sole applicant Bayer CropScience. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed in a written procedure in September 2007. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in March 2007.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 26 September 2007 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as a herbicide as proposed by the applicant on cereals, linseed, meadows and pasture. For full details of the GAP see the attached end points.

The representative formulated product for the evaluation was "Gratil", a water dispersible granule formulation (WG) containing 750 g/kg amidosulfuron.

Methods are available to monitor for amidosulfuron in plants, soil, water and air. There are no acceptable methods available for products of animal origin and it is not concluded if MRLs will be set or not. For water the residue definition for ground water is not concluded on and therefore further methods may be required. For surface water a data gap for a method of analysis for AEF101630 has

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<sup>1</sup> OJ No L 224, 21.08.2002, p. 25, as last amended by Commission Regulation OJ L 246, 21.9.2007

been identified. Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

The acute toxicity of amidosulfuron is low. In short term studies, the dog is the most sensitive species with effects observed in clinical chemical parameters and urinalysis. No mutagenic or carcinogenic potential was observed. The reproductive parameters and foetal/offspring development were not affected. No evidence of neurotoxicity was shown. The identified groundwater metabolites were considered not relevant, and the plant metabolites of lower or equal toxicity than amidosulfuron. The acceptable daily intake (ADI) is 0.2 mg/kg bw/day, the acceptable operator exposure level (AOEL) is 1.4 mg/kg bw/day, and no acute reference dose (ARfD) was considered needed. The default dermal absorption value is 100%.

The operator, worker and bystander exposure assessments are below the AOEL, even without the use of personal protective equipment.

Amidosulfuron is extensively metabolised in cereals and oilseeds. A main metabolite (AEF101630<sup>2</sup>) has been identified in immature plants shortly after application. Due the use of the active substance at early growth stages of wheat and linseed no residue of compounds structurally related to the parent compound is expected in mature wheat grains and straw as well as in linseed. The proposed residue definition for monitoring of cereals and oilseeds is per default restricted to the parent compound.

The absence of residues of amidosulfuron and its main plant metabolite AEF101630 in mature plant commodities has been confirmed by field supervised residue trials. MRLs for amidosulfuron are therefore proposed to be set at the LOQ level in cereal grains and linseed.

The residue definition in plant products for risk assessment is however proposed to be the sum of the parent compound and metabolite AEF101630. This is resulting from the specific residue pattern observed in pasture, at the time ruminants may re-enter in the treated area. Seven to 14 days after application residues in the order of magnitude of 1 mg/kg of both parent compound and metabolite AEF101630 can be present in grass. This leads to a significant exposure of livestock, and a metabolism study in lactating goat suggests that for this exposure rate, low, but measurable residues of the parent compound could be present in milk and kidneys. The metabolism of metabolite AEF101630 in livestock has not been investigated, but the animal metabolic behaviour of this compound is expected to be similar to that of the parent compound.

Considering this, the residue definition in products of animal origin for both monitoring and risk assessment is proposed to include the parent compound and metabolite AEF101630. In order to obtain appropriate information for MRL setting a feeding study in lactating cows should be conducted, preferably with simultaneous administration of amidosulfuron and metabolite AEF101630

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<sup>2</sup> AEF101630: 3-(4-hydroxy-6-methoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)-urea

at a 1 to 1 ratio, reflecting the exposure resulting from consumption of grass or hay under worst case conditions.

No residues of compounds structurally related to amidosulfuron are expected in rotational crops.

Even in the absence of the requested feeding study in ruminants, it can be concluded that the representative uses of amidosulfuron in wheat, linseed and pasture, do not involve any risk for the consumer.

In soil under aerobic conditions amidosulfuron exhibits low to moderate persistence forming the major soil metabolites AEF101630 (accounting for up to 50% of applied radioactivity (AR)) which exhibits low to moderate persistence, AEF128870<sup>3</sup> (up to 39%AR) and AE1569309<sup>4</sup> (up to 12.1%AR) both of which exhibit moderate to high persistence. Mineralisation of the pyrimidinyl ring radiolabel to carbon dioxide accounted for 3-47 % AR after ca. 100 days. The formation of unextractable residues was a significant sink, accounting for 19-46 % AR after ca. 100 days. In soil under anaerobic conditions amidosulfuron degraded more slowly than under aerobic conditions and formed the major soil metabolite AEF094206<sup>5</sup> (10.9%AR) which exhibited high persistence under anaerobic conditions. Amidosulfuron exhibits very high to high mobility in soil, with the metabolites AEF101630, AEF128870, AE1569309, AEF094206 unidentified 'C' and unidentified 'D' characterised as exhibiting very high soil mobility on the basis of the available data. There was no indication that adsorption of amidosulfuron was pH dependant. Whilst there was some indication of pH dependant adsorption for metabolites, as adsorption of these was already identified as very low the experts agreed this did not need to be taken into account in the exposure assessments in this case.

In dark natural sediment water systems amidosulfuron remained primarily in the water phase and degraded exhibiting moderate to medium persistence to the major metabolites AEF101630 (12.3%AR) and AEF94206 (17.1%AR) in water. The terminal metabolite, CO<sub>2</sub>, was a small sink in the material balance accounting for a maximum of 8.5 % AR (pyrimidinyl radiolabel) at 98days. Unextracted sediment residues were a major sink representing 11-63 % AR at 98 days. The necessary surface water and sediment exposure assessments were appropriately carried out using the agreed FOCUS scenarios approach for amidosulfuron at steps 1-3. For the metabolites AEF101630, [AEF128870 and AE1569309 that may leach from soil to surface water] appropriate FOCUS step 1 and 2 calculations were carried out. For AEF094206 it was agreed appropriate to use the values calculated for amidosulfuron. These values are the basis for the risk assessment discussed in this conclusion.

The potential for groundwater exposure, from the applied for intended use on meadows and pasture by amidosulfuron and the soil metabolites that trigger an assessment above the parametric drinking water limit of 0.1 µg/L, was concluded to be low, in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios.

<sup>3</sup> AEF128870: 3-(5,6-hydroxy-4-methoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)-urea

<sup>4</sup> AE1569309: 3-(5-hydroxy-4,6-dimethoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)-urea

<sup>5</sup> AEF094206: 2-amino-4,6-dihydroxypyrimidine

For the intended use of spring applications to winter cereals the potential for groundwater exposure of amidosulfuron, AEF101630 and unidentified 'C' is low at all 9 FOCUS groundwater scenarios. However for the metabolites AEF128870, AE1569309, AEF094206 and unidentified 'D' contamination of groundwater above the 0.1 µg/L limit cannot be excluded. Agreed metabolite non relevance assessments are available for AEF128870, AE1569309, AEF094206 and AEF101630 that concluded none of these metabolites are relevant for groundwater. However due to the fact that 'D' is unidentified, the peer review could not conclude on the non relevance of 'D'. With the available relatively uncertain groundwater exposure assessment for 'D' concentrations of 'D' are calculated to be in the range 0.098-0.38µg/L with no FOCUS groundwater scenarios having concentrations <0.1 µg/L in PEARL simulations and only the Porto Scenario in PELMO simulation giving a concentration just below 0.1 µg/L. Further information on the identity of unknown 'D' and consequent assessments in relation to groundwater for this use are therefore necessary.

For the intended uses of spring applications to spring cereals and linseed, potential for groundwater exposure has not been adequately addressed.

The risk to all groups of non-target organisms was assessed as low for the representative uses evaluated except for aquatic higher plants. Risk mitigation measures are required to protect aquatic macrophytes in Member States where geoclimatic conditions prevail which are represented by FOCUS scenarios D1 and D2.

**Key words: amidosulfuron, peer review, risk assessment, pesticide, herbicide**

## TABLE OF CONTENTS

Summary .....	1
Table of Contents .....	5
Background .....	6
The Active Substance and the Formulated Product .....	7
Specific Conclusions of the Evaluation .....	8
1. Identity, physical/chemical/technical properties and methods of analysis.....	8
2. Mammalian toxicology .....	9
2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics).....	9
2.2. Acute toxicity .....	9
2.3. Short term toxicity .....	9
2.4. Genotoxicity .....	10
2.5. Long term toxicity .....	10
2.6. Reproductive toxicity.....	10
2.7. Neurotoxicity .....	10
2.8. Further studies .....	11
2.9. Medical data .....	12
2.10. Acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD).....	12
2.11. Dermal absorption .....	12
2.12. Exposure to operators, workers and bystanders.....	12
3. Residues.....	13
3.1. Nature and magnitude of residues in plant.....	13
3.1.1. Primary crops.....	13
3.1.2. Succeeding and rotational crops .....	14
3.2. Nature and magnitude of residues in livestock .....	14
3.3. Consumer risk assessment .....	15
3.4. Proposed MRLs .....	16
4. Environmental fate and behaviour .....	16
4.1. Fate and behaviour in soil.....	17
4.1.1. Route of degradation in soil.....	17
4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products.....	17
4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction products.....	18
4.2. Fate and behaviour in water.....	19
4.2.1. Surface water and sediment .....	19
4.2.2. Potential for ground water contamination of the active substance their metabolites, degradation or reaction products.....	20
4.3. Fate and behaviour in air .....	22
5. Ecotoxicology .....	22
5.1. Risk to terrestrial vertebrates .....	22
5.2. Risk to aquatic organisms .....	23
5.3. Risk to bees.....	24
5.4. Risk to other arthropod species.....	25
5.5. Risk to earthworms .....	25
5.6. Risk to other soil non-target macro-organisms .....	26
5.7. Risk to soil non-target micro-organisms .....	26
5.8. Risk to other non-target-organisms (flora and fauna) .....	26
5.9. Risk to biological methods of sewage treatment .....	26
6. Residue definitions .....	27
List of studies to be generated, still ongoing or available but not peer reviewed.....	32
Conclusions and Recommendations.....	32
Critical areas of concern .....	34
Appendix 1 – List of endpoints for the active substance and the representative formulation .....	35
Appendix 2 – Abbreviations used in the list of endpoints.....	84
Appendix 3 – Used compound code(s) .....	86

## BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Amidosulfuron is one of the 79 substances of the third stage, part A, covered by the Regulation (EC) No 1490/2002 designating Austria as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Austria submitted the report of its initial evaluation of the dossier on amidosulfuron, hereafter referred to as the draft assessment report, to the EFSA on 6 June 2005. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 11(2) of the Regulation (EC) No 1490/2002 the revised version of the draft assessment report was distributed for consultation on 3 March 2006 to the Member States and the main applicant Bayer Crop Science as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed during a written procedure in September 2006 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings in March 2007. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 26 September 2007 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 11(4) of the Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.



The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received,
- the resulting reporting table (rev. 1-1 of 19 December 2006)

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation,
- the evaluation table (rev. 2-1 of 27 September 2007)

Given the importance of the draft assessment report including its addendum (compiled version of August 2007 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

By the time of the presentation of this conclusion to the EU-Commission, the rapporteur Member State has made available amended parts of the draft assessment report (Volume 3, B1-B9) which take into account mostly editorial changes. Since these revised documents still contain confidential information, the documents cannot be made publicly available. However, the information given can basically be found in the original draft assessment report together with the peer review report which both is publicly available.

## THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Amidosulfuron is the ISO common name for 3-(4,6-dimethoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)urea (IUPAC).

Amidosulfuron belongs to the class of sulfonyl urea herbicides such as rimsulfuron and nicosulfuron. It acts by inhibiting biosynthesis of the essential amino acids valine and isoleucine, hence stopping cell division and plant growth. Selectivity derives from rapid metabolism in the crop. Mode of action Selective, systemic herbicide, absorbed by the leaves and roots and translocated throughout the plant. Plant growth is inhibited, followed by the development of chlorotic patches which spread acropetally and then basipetally.

The representative formulated product for the evaluation was "Gratil", a water dispersible granule formulation (WG) containing 750 g/kg amidosulfuron.

The evaluated representative uses are as a herbicide as proposed by the applicant on cereals, linseed, meadows and pasture. For full details of the GAP see the attached end points.

## SPECIFIC CONCLUSIONS OF THE EVALUATION

### 1. Identity, physical/chemical/technical properties and methods of analysis

The minimum purity of amidosulfuron as manufactured should not be less than 970 g/kg. At the moment no FAO specification exists.

For the technical specification there are now no data gaps identified in this section. There was one data gap identified in the PRAPeR meeting of experts where it was agreed that further clarification with regard to technical material quality control data was required. In the August addendum to volume 4 this clarification is provided and accepted. However, since clarification is required on the toxicity of one of the impurities the specification for the technical material as a whole should be regarded as provisional for the moment.

The technical material contains no relevant impurities.

The content of amidosulfuron in the representative formulation is 750 g/kg (pure).

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of amidosulfuron or the respective formulations.

An additional issue on the formation of nitrosamines during the preparation of drinking water was discussed in the physchem meeting of experts and the conclusions of these discussions can be found under section 3.3 consumer risk assessment.

The main data regarding the identity of amidosulfuron and its physical and chemical properties are given in appendix 1.

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of amidosulfuron in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.

Therefore, enough data are available to ensure that quality control measurements of the plant protection product are possible.

Adequate methods are available to monitor all compounds given in the respective residue definition, i.e. amidosulfuron in food of plant origin, in soil and air. There is currently no acceptable method available for products of animal origin and if when the animal feeding study is produced MRLs are needed then further methods/validation will be required. Also the residue definition for ground water



is not finalised and therefore further methods may also be required. For surface water a data gap has been identified for a method of analysis for AEF101630.

Residues of amidosulfuron in products of plant origin can be determined by LC-MS/MS with an LOQ of 0.01 mg/kg. Amidosulfuron in soil and water is determined by LC-MS/MS with an LOQ of 0.05 µg/kg in soil and 0.05 µg/L in water. The method of analysis for amidosulfuron in air is by HPLC-UV with an LOQ of 1.0 µg/m<sup>3</sup>. A method of analysis for tissues and body fluids is not required as amidosulfuron is not classified as toxic or very toxic.

## 2. Mammalian toxicology

Amidosulfuron was discussed by the experts in mammalian toxicology in a PRAPeR meeting in June 2007 (PRAPeR 24, round 5).

### 2.1. ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

After oral administration, the maximum blood concentration was reached 0.3-1.0 h after gavage and 4.5h after dietary administration. There is no potential for bioaccumulation. The excretion occurred mainly via urine (80-90% within 24h), but also via faeces (5-10% within 24h) with biliary excretion shown after intravenous administration. The enteral resorption was therefore assumed to be greater than the amount excreted via urine (>90%).

The metabolism was not extensive; the unchanged parent was the main component in excreta samples (up to 87%). The major metabolic pathway was O-desmethylation and minor pathways were hydroxylation and sulphate conjugation.

### 2.2. ACUTE TOXICITY

Amidosulfuron had a low acute toxicity to rats after oral, dermal and inhalative administration (oral LD<sub>50</sub> > 5000 mg/kg bw, dermal LD<sub>50</sub> > 5000 mg/kg bw, LC<sub>50</sub> > 1.8 mg/L air). The compound was not irritating to the skin, slightly irritating to the eyes, and not a skin sensitizer (Magnusson and Kligman test). Based on these results, no classification was proposed.

### 2.3. SHORT TERM TOXICITY

The oral short term toxicity of amidosulfuron has been investigated in rats, mice and dogs. In addition, one study by inhalation (28 days) and 2 dermal studies (8 and 30 days) were performed in rats and presented in the DAR.

In the **rat** studies, the agreed NOAEL in the 28-day study was 215 mg/kg bw/day based on liver toxicity in males; and the agreed NOAEL in the 90-day study was 792.1 mg/kg bw/day based on the absence of adverse effects at the highest dose. In the **mouse** studies (28 and 90 days), no relevant adverse effect was observed at the high doses (up to 1882 mg/kg bw/day). The results of the **dog** studies were discussed by the experts for the setting of the relevant NOAEL since the dog was the most sensitive species. In the 1-month study (range-finding) there were indications of anaemia and

some histopathological findings (spleen, thyroid, thymus, epididymides) at the top dose. These findings were not reproduced in the other studies and were not taken into account for the derivation of the relevant NOAEL in the dog. In the 3-month and 52-week studies, the same NOAEL was agreed (2000 ppm) based on changes in the clinical chemical parameters and urinalysis. Considering the highest chemical intake below the LOAEL, the experts agreed to derive the relevant NOAEL from the 3-month study, with a value of 144.1 mg/kg bw/day.

In the rat inhalation study, no treatment related effects could be detected in all dose groups tested up to 1 mg/L (270 mg/kg bw/d for both males and males). After repeated dermal exposure (8 and 30 days), no treatment related effects could be detected in rats at 1000 mg/kg bw/d (only adaptive effects).

## 2.4. GENOTOXICITY

The mutagenic potential of amidosulfuron was tested in some *in vitro* studies (gene mutations in bacterial and mammalian cells, unscheduled DNA synthesis and chromosome aberrations tests) and in one *in vivo* test (micronucleus assay in mice). All the results were negative and it was concluded that no mutagenic potential can be attributed to amidosulfuron under the test conditions used.

## 2.5. LONG TERM TOXICITY

The long term toxicity and carcinogenicity of amidosulfuron has been investigated in rats and mice. In a 2-year rat study, the NOAEL was 97.8 mg/kg bw/day (2000 ppm) based on reduced body weight gain together with changes in haematological parameters in males. In the oncogenicity study with mice, no treatment related effect up to the highest dose level (961 mg/kg bw/day) was observed. In both studies, there was no indication of a carcinogenic potential relevant to humans.

## 2.6. REPRODUCTIVE TOXICITY

In the two-generation study with rats, the reproductive parameters were not affected by amidosulfuron. Therefore the reproductive NOAEL was 570 mg/kg bw/day (highest dose level), whereas the parental and offspring NOAEL was 22.5 mg/kg bw/day based on reduced body weight and changes in organ weights (brain, seminal vesicles).

In order to examine the developmental effects of amidosulfuron, two studies in the rat and one in the rabbit were presented in the DAR. There was no evidence of teratogenic activity in rats or rabbits. For the three studies, the proposed NOAELs for maternal and foetal/developmental effects in the rat and rabbit were higher than 1000 mg/kg bw/day (limit dose tested).

## 2.7. NEUROTOXICITY

Amidosulfuron has not a structure related to compounds capable of inducing neurotoxicity. In all studies provided, amidosulfuron exhibited no signs of neurotoxicity or histopathological changes with respect to brain, spinal cord or peripheral nerves. Therefore, no specific neurotoxicity studies were considered necessary.

## 2.8. FURTHER STUDIES

### Metabolites

The metabolites **AEF101630**<sup>6</sup> and **AEF094206**<sup>7</sup> were of low acute oral toxicity (LD<sub>50</sub> values > 5000 mg/kg bw) and not mutagenic in the bacterial reverse mutation assay. The experts concluded that they had the same toxicological profile than amidosulfuron, and considered them not relevant for groundwater according to the guidance document (SANCO/221/2000).

The metabolite **AEF092944**<sup>8</sup> was not mutagenic in a bacterial reverse mutation assay, but the LD<sub>50</sub> value was between 2000 and 5000 mg/kg bw in rats. The same metabolite was identified for nicosulfuron (ADMP, also intermediate of a major rat metabolite) and showed a higher acute oral toxicity in mice. However, the experts concluded that it was not likely to be more toxic than amidosulfuron.

No studies have been performed on the metabolite **AEF128870**<sup>9</sup>. Taking into account that this metabolite is a hydroxylated form of the rat metabolite AEF101630 (see above) and that in general, hydroxylation facilitates more rapid excretion, the experts concluded that this metabolite was not relevant for groundwater.

The compound **AE1569309**<sup>10</sup> is a ring hydroxylated form of amidosulfuron, detected in the rat metabolism (<1%). Based on the structure of this metabolite, the experts concluded that it was unlikely to be more toxic than the parent compound and that it was not relevant for groundwater.

Concerning the groundwater **metabolite D** (structure not identified) no conclusion on the toxicological relevance could be drawn by the experts since the chemical identity of the metabolite was not known.

### Impurities

Comparing the maximum content of impurities in the technical specification and their levels in the toxicological batches, the experts agreed that the technical material was covered by the batches except for the impurity AEF103452, which was not present in the toxicological batches. Therefore they concluded that the notifier should provide further information about the toxicological relevance of this impurity and its contribution to the toxicological burden of amidosulfuron in the technical specification.

EFSA notes: the results of an Ames test with amidosulfuron containing a relevant amount of this impurity could be provided to the RMS by the end of October 2007.

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<sup>6</sup> AEF101630: 3-(4-hydroxy-6-methoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)-urea

<sup>7</sup> AEF094206: 2-amino-4,6-dihydroxypyrimidine

<sup>8</sup> AEF092944: 2-amino-4,6-dimethoxypyrimidine

<sup>9</sup> AEF128870: 3-(5,6-hydroxy-4-methoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)-urea

<sup>10</sup> AE1569309: 3-(5-hydroxy-4,6-dimethoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)-urea

## 2.9. MEDICAL DATA

No documentation has been submitted. As stated by the notifier, no health disturbances caused by amidosulfuron have been observed with personnel of product development and from the formulation plant; and no cases of acute intoxication with amidosulfuron have been reported.

## 2.10. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARfD)

The agreed ADI was **0.2 mg/kg bw/day**, with the use of a safety factor 100, based on the parental NOAEL of the 2-generation study in rats.

The agreed AOEL was **1.4 mg/kg bw/day**, with the use of a safety factor 100, based on the overall dog NOAEL (3-month dog study together with the 1-year dog study).

Because of the low toxicity profile of amidosulfuron, the experts agreed that no ARfD was needed.

## 2.11. DERMAL ABSORPTION

No studies were performed with the representative formulation. Based on the physical/chemical properties of amidosulfuron, it was agreed to use the default value of 100 %.

## 2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product Gratil is a water dispersible granule (WDG) formulation containing 750 g amidosulfuron/kg for use on cereals, linseeds (flax), meadows or pasture.

### Operator exposure

According to the intended uses submitted by the applicant the maximum applied dose is 0.03 kg amidosulfuron/ha for cereals and linseed, and 0.045 kg amidosulfuron/ha for meadows/pasture. The minimum volume is 200 L water/ha, with application by tractor mounted field crop sprayer with hydraulic boom and nozzles. The estimated exposures were calculated for the application in meadows/pasture as a worst case and are provided in the table below.

Estimated exposure presented as % of AOEL (1.4 mg/kg bw/day), according to calculations with the German and UK POEM model. The default for body weight of operator is 70 kg in the German model and 60 kg in the UK-POEM model.

Use	Model	Without PPE:	With PPE:
Meadows/Pasture	German BBA	3.7	1.5
	UK POEM	27.1	2.6

PPE (personal protective equipment): gloves during mixing/loading and application

Based on the results of the operator exposure models used, the operator exposure estimates are below the AOEL with both models without the use of personal protective equipment.

#### Worker exposure

The application of Gratil to cereals and linseed is performed very early in the growing season, and there is a low potential of exposure during the inspection activities.

For meadow/pasture, a re-entry period of 7 days for grazing animals and persons being in charge of them is foreseen. The likelihood of contamination of these persons is assumed to be very low. The harvesting of grass will be performed 21 days after application, and no contamination of persons entering the treated area is expected. According to Krebs B. et al. (2000), the estimated exposure is 1.6% of the AOEL without the use of PPE.

#### Bystander exposure

With regard to exposure measurements during field crop spraying according to Lloyd and Bell (1983), the total systemic burden was calculated to be 0.03% of the AOEL.

### **3. Residues**

Amidosulfuron was discussed by the experts in residues in a PRAPeR meeting in June 2007 (PRAPeR 25, round 5).

#### **3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT**

##### **3.1.1. PRIMARY CROPS**

The metabolism of amidosulfuron has been investigated in wheat and linseed under appropriate conditions to reflect the supported representative uses. The compound is extensively metabolised and represent 10 % of the Total Radioactive Residues present in plant after 2 weeks. The metabolic pathway was established through characterisation and identification of the radioactivity in immature plants and consists in demethylation of the pyrimidine ring leading to metabolite AEF101630 and subsequent hydroxylation to metabolite AEF128870. In linseed only, breakdown of the sulfonylurea side chain was also observed. Due to the low application rate and the long pre-harvest interval residues in mature plants are very low. Total Radioactive Residues (TRR) in wheat grains and linseeds are < 0.01 mg/kg for supported rates of application. In wheat straw TRR were 0.1 mg/kg with AEF101630 representing 40 % of the radioactivity.

As residues of compounds structurally related to the active substance are extremely low in commodities used for human consumption and far below analytically quantifiable levels the proposed residue definition for monitoring is by default amidosulfuron.

For risk assessment, considering that there is a significant exposure of ruminants to metabolite AEF101630 through consumption of treated pasture or hay, it was considered by the expert meeting that this metabolite should be considered as relevant. Therefore the proposed residue definition for risk assessment in plant products is the sum of amidosulfuron and its metabolite AEF101630, expressed as amidosulfuron, even if residues in plant commodities for human consumption resulting from the representative uses are negligible. The metabolite AEF101630 is present in rat metabolism and its toxicity is considered similar to that of the parent compound.

A sufficient number of supervised residue trials were conducted supporting all representative uses. In cereals, 22 trials (11 for Northern Europe and 11 for Southern Europe) are available. Residues of the active substance and its metabolite AEF101630 were in all trials but one below the Limit of Quantification (LOQ) in grains and straw (0.01 and 0.05 mg/kg in grains and straw respectively). Only one trial showed residues of amidosulfuron amounting to 0.012 mg/kg in grains. This was considered as due to the very late and unrealistic stage of application (growth stage 49) in this specific trial rather than an actual indication of possible measurable residues in grains when the product is applied normally. For linseed, 3 trials were conducted in Northern Europe and residues were always below the LOQ in seeds (0.05 mg/kg).

Many residue trials (decay curves) were also conducted in pasture/meadow. For post application intervals of relevance (7 days before grazing to 21 days before mowing), Supervised Trial Medium Residues (STMR) were always below 0.1 mg/kg for both the active substance and its metabolite AEF101630, reflecting the rapid metabolism of the compound and/or the dilution effect due to the grass growth. Nevertheless in a restricted number of trials, residues reaching the order of magnitude of 1 mg/kg were observed for the active compound (1.22 mg/kg for a delay after application of 7 days) and AEF101630 (0.71 and 0.48 mg/kg for longer delays after application, 14 and 21 days respectively). These extreme values need to be taken into account as far as the potential transfer of residues to animal commodities is concerned.

The reliability of these residue trials is supported by storage stability studies demonstrating that residues of amidosulfuron and AEF101630 are stable in wheat grains and straw for at least 2 years.

No studies on the effect of processing were conducted as residues in grains of cereals and linseed were below the analytical LOQ.

### **3.1.2. SUCCEEDING AND ROTATIONAL CROPS**

Considering the low application rate and the soil degradation properties of amidosulfuron and its metabolites, no residues of amidosulfuron structurally related compounds are expected in rotational crops. This was confirmed by rotational crops studies demonstrating that residues remain below any relevant level.

## **3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK**

Considering the results of supervised residue trials no significant residue structurally related to amidosulfuron above the LOQ is expected in feeding items resulting from the use in wheat and linseed. However, after application of the product in pasture, a significant exposure of livestock (ruminants) to the parent compound and its main metabolite AEF101630 may be expected depending on the delay before mowing and/or grazing.

Metabolism studies of amidosulfuron in lactating goats and laying hens were therefore conducted. In goat the compound is well absorbed and rapidly excreted without any significant metabolism. There is no sign of accumulation in polar or lipophilic tissues. In hens the metabolic behaviour is similar to that observed in goats with a rapid excretion of the unchanged compound.



The goat metabolism study suggests that, at the expected critical level of dietary intake of amidosulfuron by ruminants grazing pasture 7 days after treatment, amidosulfuron residues ranging from 0.02 to 0.03 mg/kg may be expected in milk and kidneys.

When grass is consumed by ruminant 14 days or more after treatment the residual compound of relevance is AEF101630. The exposure to this metabolite is slightly lower compared to the exposure to parent compound 7 days after treatment, but of the same order of magnitude.

No metabolism study is available for this metabolite and no information can be deduced from the metabolism study with the parent compound as AEF101630 is not produced from amidosulfuron in the goat metabolism. Nevertheless, it was considered by the expert meeting that, given the structural similarity, the metabolite being of increased polarity, no major difference between amidosulfuron and AEF101630 was expected in terms of excretion or accumulation potentials. It was also considered that a request for a metabolism study with metabolite AEF101630 would be of very low benefit in terms of consumer safety, considering the low consumer exposure level and the relatively favourable toxicological profile of amidosulfuron and AEF101630.

Considering this, it was proposed by the expert meeting to define the residue in animal commodities for monitoring and risk assessment as the sum of amidosulfuron and AEF101630, expressed as amidosulfuron.

No feeding studies in ruminants were submitted in order to set MRLs in animal commodities. However low but measurable amidosulfuron residues may be expected in ruminant milk and kidneys from the metabolism study in lactating goat if pasture is grazed 7 days after application of amidosulfuron. In addition a potential transfer to milk and animal tissues of metabolite AEF101630 in case of consumption of grass 14 days after application cannot be excluded. Therefore the expert meeting concluded that a feeding study in lactating cows was necessary for MRL setting. It was advised to perform this study with simultaneous administration of amidosulfuron and metabolite AEF101630 at a 1 to 1 ratio. The results of this study could also be used for confirming or reviewing the proposed residue definition in animal commodities.

A point was discussed in the evaluation meeting concerning the possible performance of a feeding study with amidosulfuron only. Considering that the AEF101630 metabolite is not expected to present a higher accumulation potential than parent compound, it was the view of the RMS and the EFSA that a feeding study with parent compound only, would represent a worst case and could be used for MRL setting and risk assessment, if the animals are fed at dose representative of the exposure to the sum of amidosulfuron and its metabolite. In this case however the results of the study could not give scientific grounds for reviewing the residue definition as proposed.

### **3.3. CONSUMER RISK ASSESSMENT**

No risk for the consumer is expected resulting from the use of amidosulfuron according to the representative uses.

Theoretical Maximum Daily Intake (TMDI) calculations were made using the WHO guidelines. The typical European diets for adult consumers as well as the German diet for the 4-6 year old girl were used. Residue levels in cereal grains and linseed were considered to be at the level of the respective LOQs proposed as MRLs. Considering the metabolism studies, the LOQ level can be considered as

covering the contribution of both parent compound and metabolite AEF101630. The resulting calculated TMDI amounted to less than 1 % of the ADI.

These calculations did not take into account the possible (low) contribution from animal commodities as no appropriate feeding study in ruminants is available. Nevertheless it can be expected from metabolism studies that this contribution would not significantly increase the potential exposure of consumers.

Acute exposure assessments were not conducted as no ARfD is necessary for amidosulfuron.

### Nitrosamines

Recently it has been observed that a metabolite of tolylfluanide dimethylsulfamid under the conditions of ozonisation of water for purification/sterilisation purposes formed the mutagenic nitrosamine N-nitroso-dimethylamine (NDMA).

Comparison of the structure of the side chain of tolylfluanide with the structure of the side chain of amidosulfuron reveals a certain similarity regarding the sulfamide moiety.

Upon request of the rapporteur Austria and the EU Commission DG Health and Consumer Protection the notifier undertook a chemico-mechanistic analysis on the likelihood of a similar reaction leading the formation of the sulfamide moiety from amidosulfuron. This was discussed in detail at the meeting of experts PRAPeR 21. The meeting agreed that during the treatment with ozone of water containing amidosulfuron it is not possible (from a structural perspective) to form NDMA. This conclusion is based on the available information.

This does not mean nitrosamines cannot be formed from ozone treatment, only that NDMA is not formed.

The notifier intends to submit additional information regarding if it is possible to generate nitrosamines from side chain reactions.

### 3.4. PROPOSED MRLs

Based on the results of supervised residue trials MRLs for amidosulfuron at the LOQ level can be proposed for cereal grains and linseed (0.01 and 0.05 mg/kg for cereal grains and linseed respectively). For ruminant commodities no MRL can be proposed as no feeding study is available.

## 4. Environmental fate and behaviour

Amidosulfuron was discussed by the experts in environmental fate and behaviour in a PRAPeR meeting in May 2007 (PRAPeR 22, round 5).

## **4.1. FATE AND BEHAVIOUR IN SOIL**

### **4.1.1. ROUTE OF DEGRADATION IN SOIL**

Soil experiments (8 different soils) were carried out under aerobic conditions in the laboratory (20°C 38-40% maximum water holding capacity (MWHC) in the dark. The formation of residues not extracted by acetonitrile:water were a sink for the applied pyrimidinyl ring-<sup>14</sup>C-radiolabel (accounting for 19-46% of the applied radiolabel (AR) after *ca.* 100 days). Mineralisation to carbon dioxide of this radiolabel accounted for 3-47 % AR after *ca.* 100 days. The major (>10AR) extractable breakdown products present in the experiments were AEF101630 (max. 49.6%AR after 7 days), AEF128870 (max. 38.6%AR after 56 days) and AE1569309 (max. 12.1%AR after 35 days). Two chromatographically separated but unidentified components 'C' and 'D' accounted for >5%AR at two consecutive time points in 2 of the soils investigated ('C' at a maximum of 7.7%AR with maxima occurring between days 3 and 14; 'D' at a maximum of 8.8%AR with maxima occurring between days 21 and 70). A groundwater exposure assessment is therefore triggered for these unidentified metabolites.

Data on anaerobic degradation in soil (laboratory 20°C) indicated that amidosulfuron was more persistent than under aerobic conditions and formed the metabolite AEF0994206 at up to 10.9%AR, that was not observed in significant amounts in the available aerobic experiments. Under anaerobic conditions mineralisation of the pyrimidinyl ring-<sup>14</sup>C-radiolabel to carbon dioxide was negligible. A laboratory soil photolysis study indicated that photolysis would not be expected to contribute significantly to the degradation of amidosulfuron under field conditions.

### **4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS**

The rate of degradation of amidosulfuron was estimated from the results of the studies described in 4.1.1 above. DT<sub>50</sub> were: 3-29 days (single first order, 20°C 38-40% MWHC, 8 different soils). After normalisation to FOCUS reference conditions<sup>11</sup> (20°C and -10kPa soil moisture content) this range of single first order DT<sub>50</sub> was the same (median that is appropriate for use in FOCUS modelling 15.6 days, see Table B. 8.6.2-1 of the DAR for details).

The rate of degradation of AEF101630 and AEF 128870 were estimated using a 4 compartment model assuming single first order kinetics (as defined in Figure B.8.1.2.2-2 of the DAR) and the TopFit software using the experiments where amidosulfuron was dosed. DT<sub>50</sub> were: 2.5-15.5 days for AEF101630 (6 soils) and 18-291 days for AEF128870 (4 soils in a further 2 soils its concentration was still increasing at the end of the study) 20°C 38-40% MWHC. After normalisation to FOCUS reference conditions (20°C and -10kPa soil moisture content) the values agreed by the experts for use in FOCUS modelling were a median single first order DT<sub>50</sub> of 5 days for AEF101630 and 64.2 days for AEF128870, (see Tables B.8.6.2-2 and B.8.6.2-3 of the DAR for details). The consequent kinetic formation fractions calculate by the model can be found in Table B.8.6.2-6 of the DAR.

<sup>11</sup> Using section 2.4.2 of the generic guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002.

The rate of degradation of AE1569309 was estimated using the 3 compartment model assuming single first order kinetics (as defined in Figure B.8.1.2.2-2 of the Addendum dated April 2007) and the MatLab software using the experiments where amidosulfuron was dosed.  $DT_{50}$  were: 28.7-187.7 days (4 soils) at 20°C 38-40% MWHC. After normalisation to FOCUS reference conditions (20°C and -10kPa soil moisture content) the value agreed by the experts for use in FOCUS modelling was a geomean single first order  $DT_{50}$  of 69.9 days (see Tables B.8.1.2.2-2 and B.8.1.2.2-2 of the Addendum dated April 2007. The consequent kinetic formation fractions calculate by the model can be found in Table B.8.1.2.2-2 of the Addendum.)

The rate of degradation of unidentified metabolites 'C' and 'D' were estimated using a 4 compartment model assuming single first order kinetics (as defined in Figure B.8.1.2.2-14 of the Addendum dated April 2007) and the MatLab software using the experiments where amidosulfuron was dosed and the 4 soils where these metabolites were resolved.  $DT_{50}$  were: 1.9-2.9 days for 'C' (3 soils enabled reasonable kinetic fits) and 300.7 days for 'D' (only 1 soil considered by the experts to give a reliable value) 20°C 38-40% MWHC. After normalisation to FOCUS reference conditions (20°C and -10kPa soil moisture content) the value agreed by the experts for use in FOCUS modelling was a geomean single first order  $DT_{50}$  of 2.4 days for 'C'. For 'D' the single value of 300.7 days was the only reliable value available, (see Table B.8.1.2.2-11 of the Addendum dated April 2007 for details). The consequent kinetic formation fractions calculate by the model can be found in Table B.8.1.2.2-12 of the Addendum dated April 2007.

The results of field dissipation experiments carried out at three sites in Germany where only amidosulfuron was analysed confirmed the range of persistence for amidosulfuron indicated by the laboratory soil experiments. The study design (sampling intervals used) precluded reliable estimates of DT values being estimated as detectable residues were not present at a sufficient number of sampling times.

#### **4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS**

The adsorption / desorption of amidosulfuron was investigated in 6 soils in satisfactory batch adsorption experiments. Calculated adsorption  $K_{oc}$  values varied from 5.7 to 83 mL/g, (mean 36.4 mL/g) (1/n 0.91 – 1.1, mean 0.98). There was no evidence of a correlation of adsorption with pH.

The adsorption / desorption of AEF101630 was investigated in 3 soils in satisfactory batch adsorption experiments. Calculated adsorption  $K_{oc}$  values varied from 11.6 to 33.1 mL/g, (mean 19.4 mL/g) (1/n 0.89 – 0.97, mean 0.93). There may be a slight decrease in adsorption with increasing soil pH, however as adsorption is low the experts agreed that in this case it would be appropriate to use mean adsorption input values in FOCUS modelling.

The applicant was unable to synthesise the identified soil metabolites AEF128870 and AE1569309 so consequently batch adsorption measurements are not available. For AEF128870 the experts agreed to use a value of 50mL/g in leaching modelling (that was estimated by inverse modelling of the available lysimeter study as outlined in the DAR). For AE1569309 the experts agreed it would be appropriate to use the measured mean  $K_{\text{foc}}$  value for AEF101630 of 19.4 mL/g ( $1/n=0.93$ ) in leaching modelling due to its similar chromatographic behaviour and structural similarity as outlined in the Addendum dated April 2007.

For unidentified metabolites 'C' and 'D', the experts agreed to use the measured mean  $K_{\text{foc}}$  value for AEF101630 of 19.4 mL/g ( $1/n=0.93$ ) in leaching modelling based on arguments from the applicant on similar chromatographic behaviour as outlined in the Addendum dated April 2007.

Laboratory column leaching and aged column leaching studies confirmed the potential mobility of amidosulfuron and its soil metabolites in soil.

A BBA guideline lysimeter study carried out over 3 years that nearly represented the applied for intended use of spring application to autumn planted wheat (application really a bit late 10<sup>th</sup> May, and slightly overdosed 53-56g /ha (ca. 1.8N for cereals, 1.2 N for grassland) was carried out in Germany. An application was only made in the first year of the experiment and ca. 32% of precipitation was collected as recharge below 1.3m, indicating reasonable 'worst case' leaching conditions. Amidosulfuron and the metabolite AEF101630 was present in leachate leaving the 1.3m soil monolith at annual average concentrations <0.1µg/L (the parametric drinking water limit, these concentrations were 0.002-0.021µg/L for amidosulfuron and not detected for AEF101630). Two metabolites AEF128870 and AEF094206 were present in individual leachate samples at up to 0.25 and 0.53µg/L respectively with these highest concentrations occurring in the second year of the experiment. It might be expected that these 2 metabolites could be present in leachate leaving the upper soil column at annual average concentrations >0.1µg/L as a consequence of the requested use on cereals particularly if applications are made to cereal crops grown in consecutive years (which was not the case in this experiment). As clarified by the RMS in the Addendum dated April 2007, there was no evidence that the unidentified soil metabolites 'C' and 'D' were formed in the lysimeter soil monoliths, therefore their confirmed absence in the lysimeter leachate is not robust evidence that these two metabolites would not leach to groundwater.

## **4.2. FATE AND BEHAVIOUR IN WATER**

### **4.2.1. SURFACE WATER AND SEDIMENT**

Amidosulfuron was essentially stable under sterile hydrolysis conditions at 25°C at pH 7 and 9. At pH 5 a single first order  $DT_{50}$  of 34 days was calculated. The metabolite AEF092944 was the major identified breakdown product formed at pH 5. Amidosulfuron was stable to aqueous photolysis under sterile laboratory conditions (sunlight at 52°N, 25°C, pH 7). A ready biodegradability test (OECD 301B) indicated that amidosulfuron is 'not readily biodegradable' using the criteria defined by the test.



In water-sediment studies (2 systems studied at 20°C in the laboratory, pH 7.7 and 8.1) remained primarily in the water column dissipating in water with first order DT<sub>50</sub> of 73 and 10 days. In the whole systems these values were 91 and 16 days. The metabolites AEF101630 and AEF094206 were formed in the water at up to 12.3% AR at 28 days after treatment and 17.1 % AR at 98 days after treatment respectively. The terminal metabolite, CO<sub>2</sub>, accounted for 6.7-8.5%AR of the pyrimidinyl ring radiolabel by 98 days. Residues not extracted from sediment by acetonitrile:water were also a sink representing 11-63%AR at 98 days. The experts agreed that for amidosulfuron water and sediment DT<sub>50</sub> of 53.3 days (arithmetic mean whole system values) were acceptable for use as FOCUS<sub>sw</sub> scenario calculation input. For AEF094206 (formed in the sediment water system), AEF101630 (formed in the sediment water system and has the potential to leach from soil) and AEF128870 and AE1569309 (have the potential to leach from soil) default sediment water system DT<sub>50</sub> of 1000 days were agreed for use in the FOCUS<sub>sw</sub> step 1 and 2 calculations.

FOCUS surface water modelling was evaluated up to step 3 for amidosulfuron and step 2 for the metabolites, AEF101630 AEF128870 (see DAR) and AE1569309 (see Addendum dated April 2007). For AEF094206 the experts agreed it was acceptable to use the values for amidosulfuron in the risk assessment (see DAR). The peer review agreed these PEC surface water and sediment were appropriate for use in risk assessment.

#### 4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The applied for representative use of autumn applications to grassland (meadows or pasture) was simulated for application dates between 4<sup>th</sup> October and 14<sup>th</sup> December (depending on the scenario) using FOCUS PEARL 1.1.1 (amidosulfuron AEF101630 & AEF128870); 2.2.2 (AE1569309) or 3.3.3, ('C' and 'D') and FOCUS PELMO 3.3.2. 90% crop interception of the applied dose was assumed and the following substance input parameters were used: amidosulfuron single first order DT<sub>50</sub> 15.6 days, K<sub>foc</sub> 36.4 mL/g (K<sub>fom</sub> 21.1 mL/g), 1/n=0.98; AEF101630 single first order DT<sub>50</sub> 5 days, formation fraction from amidosulfuron 70.4%, K<sub>foc</sub> 19.4 mL/g (K<sub>fom</sub> 11.3 mL/g), 1/n=0.93; AEF128870 single first order DT<sub>50</sub> 64.2 days, formation fraction from AEF101630 52.7%, K<sub>foc</sub> 50 mL/g (K<sub>fom</sub> 30 mL/g), 1/n=0.93; AE1569309 single first order DT<sub>50</sub> 69.9 days, formation fraction from amidosulfuron (degrading with a DT<sub>50</sub> of 9 days) 17.9%, K<sub>foc</sub> 19.4 mL/g (K<sub>fom</sub> 11.3 mL/g), 1/n=0.93; Met 'C' single first order DT<sub>50</sub> 2.4 days, formation fraction from amidosulfuron (degrading with a DT<sub>50</sub> of 12 days) 80%, K<sub>foc</sub> 19.4 mL/g (K<sub>fom</sub> 11.3 mL/g), 1/n=0.93; Met 'D' single first order DT<sub>50</sub> 300.7 days, formation fraction from amidosulfuron (degrading with a DT<sub>50</sub> of 12 days) 7.8%, K<sub>foc</sub> 19.4 mL/g (K<sub>fom</sub> 11.3 mL/g), 1/n=0.93;

For amidosulfuron and its metabolites AEF101630, AEF128870, AE1569309, unidentified 'C' and unidentified 'D' these simulations calculated that these compounds would not to be present in leachate leaving the top 1m soil layer at 80th percentile annual average concentrations >0.1µg/L (highest simulated concentration 0.082µg/L for AEF128870 at the Hamburg scenario using PEARL).



For AEF094206 no simulations were available but based on evidence from the available lysimeter study concentrations of this metabolite might be expected to be approximately half those calculated for AEF128870, so AEF094206 would not be expected to be  $>0.1\mu\text{g/L}$  (highest concentration estimate using this assumption  $0.041\mu\text{g/L}$ ). In conclusion, for the applied for representative use of autumn applications to established grassland contamination of groundwater in vulnerable situations above the parametric drinking water limit of  $0.1\mu\text{g/L}$  would not be expected for amidosulfuron, AEF101630, AEF128870, AE1569309, unidentified 'C' and unidentified 'D'.

The same modelling approach and substance parameters described above for grassland were also carried out for the applied for representative use of spring applications (application dates between 6<sup>th</sup> February and 4<sup>th</sup> May depending on the scenario) to winter cereals except only 25% crop interception of the applied dose was assumed.

For amidosulfuron and its metabolites AEF101630 and unidentified 'C' these simulations calculated that these compounds would not to be present in leachate leaving the top 1m soil layer at 80th percentile annual average concentrations  $>0.1\mu\text{g/L}$  (highest simulated concentration  $0.046\mu\text{g/L}$  for amidosulfuron at the Piacenza scenario using PEARL). However for the metabolites AEF128870, AE1569309 and unidentified 'D' concentrations  $>0.1\mu\text{g/L}$  are predicted with these concentrations (calculated at up to  $0.33\mu\text{g/L}$  for AEF128870 at the Piacenza scenario using PELMO and up to  $0.38\mu\text{g/L}$  for unidentified 'D' at the Chateaudun scenario using PEARL). Unidentified 'D' was predicted to be  $>0.1\mu\text{g/L}$  at all 9 of the FOCUS scenarios using PEARL. With PELMO just the Porto scenario was predicted to have a concentration just below  $0.1\mu\text{g/L}$  ( $0.098\mu\text{g/L}$ ). For AEF094206 concentrations might be expected to be up to ca.  $0.16\mu\text{g/L}$ . The experts considered that due to the uncertainty in the currently available modelling input parameters used to estimate unidentified 'D' concentrations, it could not be excluded that concentrations of this unidentified compound could be above the groundwater relevance assessment trigger of  $0.75\mu\text{g/L}$  for the tiered toxicological assessment at some scenarios.

It should be noted that the toxicological assessment (see section 2.8) has concluded that there is sufficient information available to conclude that the metabolites AEF128870, AE1569309 and AEF094206 are not relevant regarding groundwater at the expected concentrations. The toxicological assessment was however unable to conclude this for unidentified 'D' so a data gap is identified by the peer review in relation to the potential groundwater contamination of unidentified 'D' (see section list of studies to be generated).

It should be noted that the applied for intended uses include application to linseed and applications to spring planted cereals and that groundwater exposure simulation estimates are not available for these uses. Whilst an argument was made that the available modelling of spring applications to winter cereals will cover the spring cereal and linseed uses, and this is true regarding the applied dose reaching the soil, the soil hydrology (recharge pattern) will be quite different for these crops compared to winter cereals. Therefore a data gap is identified by the peer review for additional

groundwater modelling in relation to these uses (see section list of studies to be generated). Even for winter planted cereals the available modelling would not cover application patterns earlier than the beginning of February in southern Europe and the end of February in northern Europe.

#### **4.3. FATE AND BEHAVIOUR IN AIR**

The vapour pressure of amidosulfuron ( $1.3 \times 10^{-5}$  Pa at 20°C) means that amidosulfuron would be classified under the national scheme of The Netherlands as very slightly volatile, indicating losses due to volatilisation would not be expected. Calculations using the method of Atkinson for indirect photooxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half life estimated at 0.25 days (assuming an atmospheric hydroxyl radical concentration of  $5 \times 10^5$  radicals  $\text{cm}^{-3}$ ) indicating the small proportion of applied amidosulfuron that will volatilise would be unlikely to be subject to long range atmospheric transport.

### **5. Ecotoxicology**

Amidosulfuron was discussed at the PRAPeR experts' meeting on ecotoxicology (PRAPeR 23) in May 2007.

#### **5.1. RISK TO TERRESTRIAL VERTEBRATES**

Amidosulfuron is of low acute toxicity towards terrestrial vertebrates. Available studies with the lead formulation did not show higher toxicity than expected from the content of amidosulfuron.

The representative evaluated uses of amidosulfuron are as herbicide in cereals, meadows and linseeds with one application per season. The risk to birds and mammals was assessed according to SANCO/4145/2000 based on exposure to amidosulfuron by intake of contaminated arthropods or cereal shoots or grass in cereal/meadows considering the higher application rate for meadows (45 g a.s./ha). For the use in linseeds (30 g a.s./ha) intake of contaminated vegetation was considered.

The first tier risk assessment resulted in TER values well above the Annex VI trigger for large herbivorous birds, medium herbivorous birds and insectivorous birds on all time-scales ( $\text{TER}_a$ : >711 - >1000;  $\text{TER}_{st}$ : >778- >1300;  $\text{TER}_{lt}$ : 74 200). Also the TER values for small herbivorous mammals, medium herbivorous mammals and insectivorous mammals are above the relevant Annex VI trigger on an acute and long-term time scale ( $\text{TER}_a$ : >563 - >12598;;  $\text{TER}_{lt}$ : 9- 161). The endpoint used for the long-term risk assessment for mammals was based on effects on on body weight in parents and litters at the highest dose tested in a two-generation reproduction test.

The risk from uptake of contaminated drinking water was assessed according to SANCO/4145/2000 based on the five fold dilution of the sprayed solution. All TER values were well above the triggers indicating a low risk.

The  $\log P_{ow}$  for amidosulfuron is  $<3$  and hence the potential for bioaccumulation and secondary poisoning is considered as low.

Two metabolites were described in wheat shoots: AEF101630 and AEF128870. AEF101630 was also detected in the gizzard of laying hens. AE F128870 was found in the urine of male rats in an ADME study in minor amounts. Because of the low toxicity of amidosulfuron to birds and mammals, the similar structure of these metabolites to amidosulfuron and the occurrence in wheat in very low total amounts, it is considered that the risk posed by these metabolites is negligible.

In summary, it can be concluded that the risk to wild birds and mammals from exposure to amidosulfuron under conditions of the intended representative uses is low.

## **5.2. RISK TO AQUATIC ORGANISMS**

Amidosulfuron is of low toxicity to fish, aquatic invertebrates and algae, while the toxicity towards aquatic plants is very high with an  $EC_{50}$  of  $7.7 \mu\text{g}$  amidosulfuron/L for *Lemna gibba*. Available studies do not indicate that the formulation 'Gratil' is more toxic than what could be expected based on the content of amidosulfuron.

The first tier TER values were calculated as the ratio of the toxicity to  $PEC_{max}$  in surface water. The  $PEC_{max}$  for the use in winter cereals and grass were calculated with FOCUS surface water model step1, 2 and 3 for amidosulfuron and the metabolites AE F101630 (major in water) and AE F128870 (major only in soil). For metabolites AE F092944 and AE F094206 a worst case assumption was made assuming that the  $PEC_{max}$  for the metabolite was equivalent to the  $PEC_{max}$  for amidosulfuron.

All  $TER_a$  values from step 1 and step 2 are far above the relevant Annex VI trigger for fish, aquatic invertebrates and algae on both acute and long-term time scale. However, for *L. gibba*, TER values were below the triggers with FOCUS step 1 and 2  $PEC_{sw}$ . The risk assessment for aquatic plants was refined by calculating the TER with FOCUS Step 3  $PEC_{sw}$ . For the use in winter cereals the trigger of 10 was breached in 1 scenario (D2, stream and pond) out of 10 FOCUS scenarios. For the use in grass the TER values meet the standard safety factor of 10 in eight out of ten scenarios. Only the TER values for the FOCUS scenario D1 and D2 (stream and pond scenarios) were below the trigger of 10. Overall it is concluded that the risk is low in most scenarios but that risk mitigation measures such as a no-spray buffer zone are required to protect aquatic macrophytes under geoclimatic conditions represented by FOCUS scenarios D1 and D2.

The metabolites AE F092944 and AE F 092944 are not toxic to fish, aquatic invertebrates, algae or aquatic plants and all TER values are well above the relevant trigger indicating a low risk. AE F101630 is not toxic to fish, aquatic invertebrates or algae but is very toxic to *L. gibba*. However, the toxicity is approximately 2 orders of magnitude lower than for amidosulfuron and the calculated TER values indicate that the risk is low.

AE F128870 was detected as a major metabolite in aerobic soil studies and was also detected in lysimeter leachates. The metabolite cannot be synthesised and therefore no ecotoxicological studies could be performed with this metabolite. However, this metabolite is an important major metabolite in soil and could reach surface water system via runoff and drainage and hence the potential risk to aquatic organisms has to be assessed. The chemical structure of AE F128870 and AE F101630 differs by just one OH-group, thus the RMS considered it very unlikely that AE F128870 is much more toxic to aquatic organisms, in particular to the most sensitive species *L. gibba*, than AE F101630. The concentration of both metabolites in surface water is comparable and it was therefore considered that the risk of the metabolite AE F128870 for aquatic organisms is acceptable. The percolates from lysimeters treated with 49 and 54 g amidosulfuron/ha were tested for their phytotoxic effects to sunflower (*Helianthus annuus*). No phytotoxic effects or growth inhibition effects were observed. Metabolite AE 1569309 is a major metabolite in soil and can reach surface water via drainage and run-off. Since the structure of AE 1569309 is similar to amidosulfuron it was assumed in the risk assessment presented in an addendum from October 2006 (revised in April 2007) that AE 159309 has a similar toxicity as amidosulfuron. The TER for the most sensitive organism (*Lemna gibba*) was calculated as 34 with FOCUS step1 PEC<sub>sw</sub> indicating a low risk. The unidentified metabolite D exceeded the trigger in groundwater of 0.1 µg/L. No ecotox information was available for this metabolite and the experts in the PRAPeR meeting identified a data gap with regard to the ecotoxicological relevance of metabolite D.

Amidosulfuron was detected in sediment at concentrations >10% of applied at 14 days in one system of the water/sediment study. However, since NOEC for *Daphnia* is >0.1 mg/L and the concentration in sediment was declining until end of the water/sediment study no further concern for sediment dwelling organism is considered necessary.

The logP<sub>ow</sub> for amidosulfuron is <3 and hence the potential for bioaccumulation is considered as low.

Overall it is concluded that the risk to aquatic organisms is low for the representative uses evaluated except for aquatic macrophytes where the trigger was breached in FOCUS scenarios D2 for the use in cereals and D1 and D2 for the use in grass. Risk mitigation measures such as no-spray buffer zones are required in Member States for geoclimatic conditions represented by D1 and D2

### **5.3. RISK TO BEES**

Amidosulfuron technical and the formulations 'Gratil' is of low oral toxicity to honeybees. No toxic reference was included in the contact toxicity studies and the RMS considered the studies as not valid. However the available studies with contact toxicity on filter paper or studies where bees were over sprayed did not indicate any severe effects and the study endpoints were used in the risk assessment. The oral and contact HQ values were significantly below the trigger of 50 indicating a low risk to bees. In the meeting of experts it was agreed to use the contact toxicity studies in the risk assessment since apart from the missing toxic standards the studies were considered as reliable by the

RMS. Taking into consideration the full data package the experts considered that the risk to bees is low and that new contact toxicity studies with bees are not necessary.

#### **5.4. RISK TO OTHER ARTHROPOD SPECIES**

Tests on terrestrial arthropods were conducted with the formulations 'Gratil'. Hazard quotients (HQ) for in-field were calculated based on the  $LR_{50}$  values observed for *A. rhopalosiphi* and *Typhlodromus pyri*, tested in glass plate tests. For both species HQ values were  $<1$  indicating a low risk. From this follows that also the off-field risk will be low. Additional studies with non-target arthropods were available. No effects  $>50\%$  on mortality or reproduction were observed for the lacewing *Crysoperla carnea* and *Coccinella septempunctata* at rates of 45 and 60 g amidosulfuron/ha in standard laboratory tests. 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.

Laboratory studies using the ground dwelling species, *Poecilius cupreus* and *Aleochara bilineata* did not show any significant effects compared to the control.

Overall it is concluded that the risk to non-target arthropods is low for the representative uses evaluated.

#### **5.5. RISK TO EARTHWORMS**

Amidosulfuron and the formulation 'Gratil' are not acutely toxic to earthworms. The first tier acute TER values are  $>25000$  and  $>18750$  for the active substance and the formulation respectively. The  $DT_{90}$  of amidosulfuron in soil is  $<100$  days and only one application per season is proposed. Therefore a chronic toxicity study is not considered necessary.

Three metabolites AE F101630, AE F128870 and AE 1568309 were detected in amounts  $>10\%$  of applied radioactivity in the aerobic soil degradation study. The metabolite AE F101630 was assumed by the RMS to have been present in the acute study with amidosulfuron. Even if this was not the case, it can be concluded that the risk would be low since even if assuming a 10-fold higher acute toxicity compared to amidosulfuron and complete degradation of amidosulfuron to the metabolite the TER values would still be significantly above the Annex VI trigger of 10. In the expert meeting it was agreed that the risk from metabolite AE F101630 is sufficiently addressed. No studies with the metabolites AE F129970 and AE 1568309 were made available since the two metabolites could not be synthesised. The chemical structure of the metabolites AE F129970 and AE 1568309 are similar to amidosulfuron and it seems unlikely that these metabolites would be more toxic than the parent molecule. The RMS calculated acute TER values assuming  $PEC_{soil}$  from the maximum amount reached in the aerobic soil degradation studies. Even if the acute toxicity would be 100 and 10 000 times higher for the two metabolites, the TER would meet the trigger. The EFSA agrees to the assessment and it can be concluded that the risk to earthworms can be considered as low.

## 5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

The DT<sub>90</sub> value for amidosulfuron in laboratory studies is <100 days in soil. Amidosulfuron and its metabolites were shown to be of low toxicity for arthropods, earthworms and soil microorganisms. Studies on the impact on organic matter breakdown and other soil non-target macro-organisms are therefore not considered necessary.

## 5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

Amidosulfuron had no effect >25% on nitrogen turnover in soil up to a concentration of 0.8 mg/kg soil. No acceptable studies on effects on soil respiration were submitted. However, a study using the formulation 'Chekker' that contain 12% w/w amidosulfuron, 12.9% w/w of the safener mefemphyr-diethyl and 1.33% w/w iodosulfuron-methyl natrium was submitted. No effects >25% were observed up to a concentration corresponding to 151 g amidosulfuron/ha. A new soil respiration study with technical amidosulfuron was submitted and summarized in the addendum from October 2006 (revised in April 2007). No effects of >25% were observed at the tested concentrations of up to 0.3 mg amidosulfuron/kg soil equivalent to an application rate of 0.225 kg amidosulfuron/ha. It can thus be concluded that the risk to soil micro-organisms is low for the representative uses evaluated.

## 5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

A study with the formulation 'Gratil' on effects on vegetative vigour using six species (*Brassica oleracea*, *Avena sativa*, *Lolium perenne*, *Glycine max*, *Lycopersicum esculentum*, *Brassica rapa*) resulted in an EC<sub>50</sub> of 67 g a.s./ha for the most sensitive species *Glycine max*.

Amidosulfuron is mainly taken up via the leaves. Non-target plants may be exposed by spray drift from the treated field. However based on 2.77% spray drift from the application of the maximum dose of 45 g a.s./ha a TER value of 53.7 was obtained. This indicates that the risk to non-target plants at a distance of 1 m from the treated field is low.

## 5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

A test with activated sewage sludge resulted in an EC<sub>50</sub> value of >1000 mg amidosulfuron /L. It is therefore unlikely that amidosulfuron would have any adverse effects on biological methods of sewage treatment if used as proposed.



## 6. Residue definitions

### Soil

Definitions for risk assessment: amidosulfuron, AEF101630<sup>12</sup>, AEF128870<sup>13</sup>, AE1569309<sup>14</sup> anaerobic conditions AEF094206<sup>15</sup>

Definitions for monitoring: amidosulfuron

### Water

#### Ground water

Definitions for exposure assessment: amidosulfuron, AEF101630, AEF128870, AE1569309, AEF094206, unidentified 'C', unidentified 'D'

Definitions for monitoring: amidosulfuron, data gap needs to be filled before a conclusion can be drawn regarding unidentified 'D'.

#### Surface water

Definitions for risk assessment:

water: amidosulfuron, AEF101630, AEF094206, AEF128870 AE1569309

sediment: amidosulfuron

Definitions for monitoring: amidosulfuron. Member States might also choose to monitor for AEF101630 as it is included in the residue definition for monitoring for food of animal origin so is pertinent to consumer exposure and might be present in drinking water when surface water is abstracted for drinking water.

### Air

Definitions for risk assessment: amidosulfuron

Definitions for monitoring: amidosulfuron

### Food of plant origin

Definitions for risk assessment: sum of amidosulfuron and AEF101630, expressed as amidosulfuron

Definitions for monitoring: amidosulfuron

### Food of animal origin

Definitions for risk assessment: sum of amidosulfuron and AEF101630, expressed as amidosulfuron

Definitions for monitoring: sum of amidosulfuron and AEF101630, expressed as amidosulfuron

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<sup>12</sup> AEF101630: 3-(4-hydroxy-6-methoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)-urea

<sup>13</sup> AEF128870: 3-(5,6-hydroxy-4-methoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)-urea

<sup>14</sup> AE1569309: 3-(5-hydroxy-4,6-dimethoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)-urea

<sup>15</sup> AEF094206: 2-amino-4,6-dihydroxypyrimidine

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

## Soil

Compound (name and/or code)	Persistence	Ecotoxicology
amidosulfuron	Low to moderate persistence Single first order DT <sub>50</sub> 3-29 days (20°C, 38-40%MWHC soil moisture)	Low toxicity and low risk to soil dwelling organisms.
AE F101630	Low to moderate persistence Single first order DT <sub>50</sub> 2.5-15.5 days (20°C, 38-40%MWHC soil moisture)	The risk to soil dwelling organisms was considered to be low
AE F128870	Moderate to high persistence Single first order DT <sub>50</sub> 18-291 days (20°C, 38-40%MWHC soil moisture)	The risk to soil dwelling organisms was considered to be low
AE 1569309	Moderate to high persistence Single first order DT <sub>50</sub> 28.7-291 days (20°C, 38-40%MWHC soil moisture)	The risk to soil dwelling organisms was considered to be low
AE F094206 (anaerobic conditions)	High persistence Single first order DT <sub>50</sub> >300 days (20°C, flooded)	Not considered in the terrestrial risk assessment. However studies with aquatic organisms indicate a low toxicity to invertebrates and algae.

## Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
amidosulfuron	Very high to high mobility $K_{\text{foc}}$ 5.7- 83 mL/g	No	Yes	Yes	Very toxic to aquatic macrophytes.
AE F101630	Very high mobility $K_{\text{foc}}$ 11.6-33.1 mL/g	No	No Data available on 4 target weed species	Not relevant	Low toxicity to aquatic organisms, low risk
AE F128870	Very high mobility $K_{\text{foc}}$ 50 mL/g (lysimeter inverse modelling estimate)	7 out of 9 FOCUS scenarios, always <0.75µg/L for cereals. No for grassland	Unlikely At up to 0.53 µg/L no activity on irrigated sunflower seedlings, also is structurally similar to AE F101630	Not relevant	The toxicity and the risk to aquatic organisms was assumed to be low
AE 1569309	Very high mobility extrapolated from AE F101630	7 out of 9 FOCUS scenarios, always<0.75µg/L for cereals. No for grassland	No Data available on 4 target weed species	Not relevant	The toxicity and the risk to aquatic organisms was assumed to be low

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
AE F094206	-	Found above 0.1µg/L in single lysimeter leachate samples (annual average concentration not available, annual average concentrations might be expected to be about half those estimated for AE F128870), i.e. <0.75µg/L for cereals. No for grassland	No Data available on 4 target weed species	Not relevant	Low toxicity to aquatic organisms, low risk
unidentified 'C'	Very high mobility extrapolated from AE F101630	No	No data available Data not required	No data available Data not required	No data available Data not required
unidentified 'D'	Very high mobility extrapolated from AE F101630	All 9 FOCUS scenarios, may be around 0.75µg/L for cereals at some scenarios. No for grassland	No data available Data may be required	No data available Data may be required	No data available Data may be required

#### Surface water and sediment

Compound (name and/or code)	Ecotoxicology
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Compound (name and/or code)	Ecotoxicology
amidosulfuron	Low toxicity and risk to fish, aquatic invertebrates and algae but very toxic to aquatic macrophytes.
AE F101630	Low toxicity and risk to all groups of aquatic organisms
AE F094206	Low toxicity and risk to all groups of aquatic organisms
AE F128870	The toxicity and the risk to aquatic organisms was assumed to be low
AE 1569309	The toxicity and the risk to aquatic organisms was assumed to be low

## Air

Compound (name and/or code)	Toxicology
amidosulfuron	not acutely toxic by inhalation ( $LC_{50} > 1.8$ mg/L, highest technically achievable concentration) no adverse effect after repeated exposure by inhalation up to 1 mg/L

## LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- Validated method of analysis for AEF101630 in surface water (relevant for all uses evaluated, data requirement identified by EFSA September 2007, date of submission unknown, refer to chapter1).
- Assessment of the toxicological relevance of the impurity AEF103452 not present in the toxicological batches, and of its contribution to the toxicological burden of amidosulfuron in the technical specification (relevant for all representative uses; a new Ames test will be provided to the RMS by the end of October 2007; refer to point 2.8).
- Identification of unidentified soil metabolite 'D', a subsequent updated groundwater exposure assessment for metabolite 'D' and if necessary a groundwater relevance assessment and aquatic risk assessment for metabolite 'D' (relevant for use in cereals; submission date unknown; refer to points 2.8, 4.2.2 and 5.2)<sup>16</sup>.
- Groundwater exposure assessment for the intended uses on linseed and spring applications to spring cereals (submission date unknown; refer to point 4.2.2).
- A feeding study in lactating cows to be conducted preferably with simultaneous administration of amidosulfuron and metabolite AEF101630 at a 1 to 1 ratio, reflecting the exposure resulting from consumption of grass or hay in order to set MRLs (relevant for use in grass; submission date proposed by the notifier: submission date unknown; refer to point 3.2).

## CONCLUSIONS AND RECOMMENDATIONS

### Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as a herbicide as proposed by the applicant on cereals, linseed, meadows and pasture. For full details of the GAP see the attached end points.

The representative formulated product for the evaluation was "Gratil", a water dispersible granule formulation (WG) containing 750 g/kg amidosulfuron.

Methods are available to monitor for amidosulfuron in plants, soil, water and air. There are no acceptable methods available for products of animal origin and it is not concluded if MRLs will be set or not. For water the residue definition for ground water is not concluded on and therefore further methods may be required. For surface water a data gap for a method of analysis for AEF101630 has been identified. Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.

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<sup>16</sup> In practice a new soil laboratory study with soils and incubation conditions comparable to that of Till. C.P 1989 (Study M88017) will probably be required to address the identity of metabolite D. A full material balance and adequate characterisation of the extractable radioactivity will be essential in any new study conducted.



Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

The acute toxicity of amidosulfuron is low. In short term studies, the dog is the most sensitive species with effects observed in clinical chemical parameters and urinalysis. No mutagenic or carcinogenic potential was observed. The reproductive parameters and foetal/offspring development were not affected. No evidence of neurotoxicity was shown. The groundwater metabolites were considered not relevant, except for the metabolite 'D' of unknown structure that could not be concluded. The plant metabolites were assumed of lower or equal toxicity than amidosulfuron. The experts could not conclude on the toxicological relevance or contribution of the impurity AEF103452 proposed in the technical specification but not present in the toxicological batches.

The ADI is 0.2 mg/kg bw/day, the AOEL is 1.4 mg/kg bw/day, and no ARfD was considered needed. The default dermal absorption value is 100%. The operator, worker and bystander exposure assessments are below the AOEL, even without the use of personal protective equipment.

Amidosulfuron is extensively metabolised in cereals and oilseeds. A main metabolite (AEF101630) has been identified in immature plants shortly after application. Due the use of the active substance at early growth stages of wheat and linseed no residue of compounds structurally related to the parent compound is expected in mature wheat grains and straw as well as in linseed. The proposed residue definition for monitoring of cereals and oilseeds is per default restricted to the parent compound.

The absence of residues of amidosulfuron and its main plant metabolite AEF101630 in mature plant commodities has been confirmed by field supervised residue trials. MRLs for amidosulfuron are therefore proposed to be set at the LOQ level in cereal grains and linseed.

The residue definition in plant products for risk assessment is however proposed to be the sum of the parent compound and metabolite AEF101630. This is resulting from the specific residue pattern observed in pasture, at the time ruminants may re-enter in the treated area. Seven to 14 days after application residues in the order of magnitude of 1 mg/kg of both parent compound and metabolite AEF101630 can be present in grass. This leads to a significant exposure of livestock, and a metabolism study in lactating goat suggests that for this exposure rate, low, but measurable residues of the parent compound could be present in milk and kidneys. The metabolism of metabolite AEF101630 in livestock has not been investigated, but the animal metabolic behaviour of this compound is expected to be similar to that of the parent compound.

Considering this, the residue definition in products of animal origin for both monitoring and risk assessment is proposed to include the parent compound and metabolite AEF101630. In order to obtain appropriate information for MRL setting a feeding study in lactating cows should be conducted, preferably with simultaneous administration of amidosulfuron and metabolite AEF101630 at a 1 to 1 ratio, reflecting the exposure resulting from consumption of grass or hay.

No residues of compounds structurally related to amidosulfuron are expected in rotational crops.

Even in the absence of the requested feeding study in ruminants, it can be concluded that the representative uses of amidosulfuron in wheat, linseed and pasture, do not involve any risk for the consumer.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment at the EU level for the applied for intended use on established grassland (meadows and pasture). For this use the potential for groundwater exposure by amidosulfuron and the soil metabolites that trigger an assessment above the parametric drinking water limit of 0.1 µg/L, is low. For the intended use on linseed and spring applications to spring sown cereals, a data gap has been identified for further information to complete the groundwater exposure assessment. In addition for the intended use on winter cereals a data gap is identified to identify the soil metabolite described as unidentified 'D', update the groundwater exposure assessment for this metabolite and if necessary complete a non relevance assessment and aquatic risk assessment for it. The currently available assessment made on the available data indicates that for this use on winter cereals unidentified 'D' may be present in groundwater at concentrations of up to ca. 0.4µg/L, with the experts concluding that due to the uncertainty in this estimate, it cannot be excluded that concentrations of unidentified 'D' might exceed the relevance assessment concentration trigger of 0.75µg/L.

The risk to all groups of non-target organisms was assessed as low for the representative uses evaluated except for aquatic higher plants. Risk mitigation measures are required to protect aquatic macrophytes in Member States where geoclimatic conditions prevail which are represented by FOCUS scenarios D1 and D2.

#### **Particular conditions proposed to be taken into account to manage the risk(s) identified**

- Risk mitigation measures such as no-spray buffer zones are required to protect higher aquatic plants in Member States for geoclimatic conditions represented by FOCUS scenarios D1 and D2 (refer to point 5.2)

#### **Critical areas of concern**

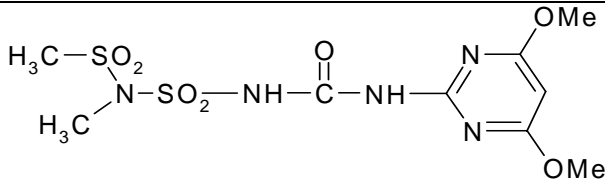
- None

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

(Abbreviations used in this list are explained in appendix 2)

#### Appendix 1.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Amidosulfuron
Function (e.g. fungicide)	Herbicide
Rapporteur Member State	Austria
Co-rapporteur Member State	Not relevant
<b>Identity (Annex IIA, point 1)</b>	
Chemical name (IUPAC) ‡	3-(4,6-dimethoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)urea or 1-(4,6-dimethoxypyrimidin-2-yl)-3-mesyl(methyl)sulfamoylurea
Chemical name (CA) ‡	N-(4,6-dimethoxy-2-pyrimidinyl)-3-methyl-2,4-dithia-3,5-diazahexan-6-amide 2,2,4,4-tetraoxide
CIPAC No ‡	515
CAS No ‡	120923-37-7
EC No (EINECS or ELINCS) ‡	407-380-0
FAO Specification (including year of publication) ‡	Not available
Minimum purity of the active substance as manufactured ‡	970 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	No impurities are considered to be of toxicological, ecotoxicological or environmental concern
Molecular formula ‡	C <sub>9</sub> H <sub>15</sub> N <sub>5</sub> O <sub>7</sub> S <sub>2</sub>
Molecular mass ‡	369.41 g/mol
Structural formula ‡	

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	179 °C (99.3% w/w)
Boiling point (state purity) ‡	No boiling point at atmospheric pressure
Temperature of decomposition (state purity)	Decomposition starts at 185 °C (99.3% w/w)
Appearance (state purity) ‡	Pure material: (99.2% w/w) Fine white powder, partially agglomerated to smooth lumps with slightly acidulous smell
	Technical material: (93.0% w/w) Fine white powder, partially agglomerated to smooth lumps with slightly acidulous smell
Vapour pressure (state temperature, state purity) ‡	1.3 x 10 <sup>-5</sup> Pa at 20 °C (99.7% w/w) 2.2 x 10 <sup>-5</sup> Pa at 25 °C 2.2 x 10 <sup>-4</sup> Pa at 50 °C
Henry's law constant ‡	K = 5.22 x 10 <sup>-4</sup> Pa·m <sup>3</sup> ·mol <sup>-1</sup> at pH 4 at 20 °C K = 1.56 x 10 <sup>-6</sup> Pa·m <sup>3</sup> ·mol <sup>-1</sup> at pH 7 at 20 °C K = 6.76 x 10 <sup>-6</sup> Pa·m <sup>3</sup> ·mol <sup>-1</sup> at pH 9 at 20 °C  Parameter used for calculation: water solubility: 9.2 mg/L at pH 4 at 20 °C 3.07 g/L at pH 7 at 20 °C 7.10 g/L at pH 9 at 20 °C vapour pressure: 1.3 x 10 <sup>-5</sup> Pa at 20 °C
Solubility in water (state temperature, state purity and pH) ‡	9.2 mg/L (buffered solution) at pH 4 and 20 °C (99.3% w/w)
	3.07 g/L (buffered solution) at pH 7 and 20 °C (99.3% w/w)
	7.10 g/L (buffered solution) at pH 9 and 20 °C (99.3% w/w)
Solubility in organic solvents ‡ (state temperature, state purity)	At 20 °C (99.7% w/w)  solvent solubility at 20 °C [g/L] n-hexane 0.001 acetone 8.1 toluene 0.256 dichloromethane 6.9 methanol 0.865 isopropanol 0.099 ethyl acetate 3.0
Surface tension ‡ (state concentration and temperature, state purity)	66.2 mN/m (99.0% w/w) c = 8.1 mg/L (20 °C)

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

**Appendix 1 - List of endpoints for the active substance and the representative formulation**

Partition co-efficient ‡  
(state temperature, pH and purity)

Dissociation constant (state purity) ‡

UV/VIS absorption (max.) incl.  $\epsilon$  ‡  
(state purity, pH)

Flammability ‡ (state purity)

Explosive properties ‡ (state purity)

Oxidising properties ‡ (state purity)

pH 4: 1.07 at 23 °C (99.4% w/w)	
pH 7: -1.56 at 22 °C (99.4% w/w)	
pH 9: -2.21 at 23 °C (99.4% w/w)	
3.58 calculation	
Concentration: 11.2 mg/L (99.3% w/w) neutral medium: MeOH	
$\lambda_{\max}$ [nm]	$\epsilon_{\max}$ [L·mol <sup>-1</sup> ·cm <sup>-1</sup> ]
201	31649
241	14938
291	10
acid medium [MeOH/HCl [90/10 (0.1 M) v/v]]	
$\lambda_{\max}$ [nm]	$\epsilon_{\max}$ [L·mol <sup>-1</sup> ·cm <sup>-1</sup> ]
201	33226
241	13978
291	20
alkaline medium [MeOH/NaOH [90/10 (0.1 M) v/v]]	
$\lambda_{\max}$ [nm]	$\epsilon_{\max}$ [L·mol <sup>-1</sup> ·cm <sup>-1</sup> ]
241	22442
291	12
Not highly flammable (99.6% w/w)	
No explosive properties (99.6% w/w)	
No oxidising properties statement	

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### Summary of representative uses evaluated \*

Crop and/or situation  (a)	Member State or Country	Product name	F G or I  (b)	Pests or Group of pests controlled  (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days)  (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	kg as/hL min – max (l)	water L/ha min – max	kg as/ha min – max (l)		
Cereals covering all wheat varieties (winter and spring) including durum, as well as barley (winter and spring), triticale, rye and oats	all EU Member States (except: Portugal, Greece)	Gratil®	F	Dicot. weeds incl. <i>Galium</i> , <i>Sinapis arvensis</i> , <i>Raphanus raphanistrum</i> , <i>Capsella</i> , <i>Myosotis</i> , <i>Scandix</i> , <i>Tordylium</i> , <i>Ranunculus</i> , volunteer oil seed rape and sunflower	WDG	750 g/kg	Ground-boom sprayers	2 leaves to flag leaf stage, GS <sup>1)</sup> 13-49  spring	1	---	0.0075 - 0.015	200 - 400	Max. 0.03	Is covered by the normal vegetation period between last application and harvest.	Statement of the notifier:  Although the dossier covers winter and spring varieties, amidosulfuron is always applied in spring. [1]
Linseeds (flax)	UK, Belgium, France	Gratil®	F	Dicot. weeds incl. <i>Galium</i> , <i>Sinapis arvensis</i> , <i>Raphanus raphanistrum</i> , <i>Capsella</i> , <i>Myosotis</i> , <i>Scandix</i> , <i>Tordylium</i> , <i>Ranunculus</i> , volunteer oil seed rape and sunflower	WDG	750 g/kg	Ground-boom sprayers	before flower buds are visible	1	---	0.0075 - 0.015	200 - 400	Max. 0.03	Is covered by the normal vegetation period between last application and harvest.	[2]

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles



## Appendix 1 - List of endpoints for the active substance and the representative formulation

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	kg as/hL min – max (l)	water L/ha min – max	kg as/ha min – max (l)		
Meadows or pasture	Northern European Countries	Gratil®	F	Dicot. weeds incl. <i>Rumex spp.</i> and <i>Taraxacum spp.</i>	WDG	750 g/kg	Ground-boom sprayers	Weed growth stage: Rosette stage of <i>Rumex</i> , flower buds are visible for <i>Taraxacum</i> autumn	1	---	0.0112 5 - 0.0225	200 - 400	Max. 0.045	21 days pre-harvest interval before mowing	

[1] Identified data gaps in sections 2.8 and 4.2.2 preclude the finalisation of the groundwater assessment

[2] Identified data gaps in section 4.2.2 preclude finalisation of the groundwater exposure assessment

<p>* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).</p> <p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</b></p> <p>(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### Appendix 1.2: Methods of Analysis

#### Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	HPLC-UV IC KF titration
Plant protection product (analytical technique)	HPLC-UV

#### Analytical methods for residues (Annex IIA, point 4.2)

##### Residue definitions for monitoring purposes

Food of plant origin	Amidosulfuron
Food of animal origin	<i>Data gap residues</i>
Soil	Amidosulfuron
Water surface	<i>Data gap method for AEF101630</i>
drinking/ground	<i>Data gap fate and behaviour</i>
Air	Amidosulfuron

##### Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS LOQ (amidosulfuron) 0.01 mg/kg cereal grain 0.01 mg/kg flax grain 0.01 mg/kg commodities with high water content 0.01 mg/kg commodities with high acid content
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Possible data gap pending the outcome of the livestock feeding study
Soil (analytical technique and LOQ)	LC-MS/MS LOQ (amidosulfuron) 0.05 µg/kg
Water (analytical technique and LOQ)	LC-MS/MS LOQ (amidosulfuron) 0.05 µg/L surface water data gap for method for AEF101630 LOQ (amidosulfuron) 0.05 µg/L drinking water residue definition not finalised.
Air (analytical technique and LOQ)	HPLC-UV LOQ (amidosulfuron) 1.0 µg/m <sup>3</sup>

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

**Appendix 1 - List of endpoints for the active substance and the representative formulation**

Body fluids and tissues (analytical technique and LOQ)

No analytical method is required as amidosulfuron is not classified as toxic or very toxic

**Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)**

Active substance

RMS/peer review proposal

None

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### Appendix 1.3: Impact on Human and Animal Health

#### Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Rapid and almost complete enteral absorption: >90% (based on urinary and assumed biliary excretion within 24h)
Distribution ‡	Widely distributed; low radioactivity residues Mainly in lung, heart, fat, skeletal muscle, blood, plasma, spleen, liver
Potential for accumulation ‡	No potential for accumulation
Rate and extent of excretion ‡	Rapid and mainly via urine (79.6 – 91.4 %)
Metabolism in animals ‡	Poorly metabolized (> 60 % excreted as parent) Major metabolic pathway: O-demethylation of amidosulfuron; minor pathway: hydroxylation of parent and sulphate conjugation
Toxicologically relevant compounds ‡ (animals and plants)	Parent compound
Toxicologically relevant compounds ‡ (environment)	Parent compound

#### Acute toxicity (Annex IIA, point 5.2)

Rat LD <sub>50</sub> oral ‡	> 5000 mg/kg bw	
Rat LD <sub>50</sub> intraperitoneal ‡	1000 – 2000 mg/kg bw	
Rat LD <sub>50</sub> dermal ‡	> 5000 mg/kg bw	
Rat LC <sub>50</sub> inhalation ‡	> 1.8 mg/L air (4 hours, nose only) (highest technically administrable dose)	
Skin irritation ‡	Not irritating	
Eye irritation ‡	Slightly irritating (no classification required)	
Skin sensitisation ‡	Not sensitising (M&K-test)	

#### Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver and bodyweight (rat); Clinical chemistry (dog)	
Relevant oral NOAEL ‡	215 mg/kg bw/day (28-day rat) 792.1 mg/kg bw/day (90-day rat) 144.1 mg/kg bw/day (90-day and 1-year dog)	
Relevant dermal NOAEL ‡	> 1000 mg/kg bw/d (28-day rat)	
Relevant inhalation NOAEL ‡	> 270 mg/kg bw/d (28-day rat, 6h/d, 5d/wk) (equivalent to 1 mg/L air)	

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### Genotoxicity ‡ (Annex IIA, point 5.4)

No evidence of a genotoxic potential	
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### Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	reduced body weight and haematological changes in males (rat)
Relevant NOAEL ‡	97.8 mg/kg bw/d (rat) 961 mg/kg bw/d (mouse)
Carcinogenicity ‡	No evidence of a carcinogenic potential

### Reproductive toxicity (Annex IIA, point 5.6)

#### Reproduction toxicity

Reproduction target / critical effect ‡	Parental: reduced body weights Reproduction: no evidence of toxicity Offspring: organ weight changes (brain, seminal vesicles)
Relevant parental NOAEL ‡	22.5 mg/kg bw/d
Relevant reproductive NOAEL ‡	570 mg/kg bw/d (highest dose tested)
Relevant offspring NOAEL ‡	22.5 mg/kg bw/d

#### Developmental toxicity

Developmental target / critical effect ‡	No treatment-related effects at the highest dose level tested (limit tests). No evidence of a teratogenic potential.
Relevant maternal NOAEL ‡	> 1000 mg/kg bw/d (rat and rabbit)
Relevant developmental NOAEL ‡	> 1000 mg/kg bw/d (rat and rabbit)

### Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data – no concern from other studies
Repeated neurotoxicity ‡	No data – no concern from other studies
Delayed neurotoxicity ‡	No data – not required

### Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data
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‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

Studies performed on metabolites or impurities ‡

Metabolite AE F101630: (rat, soil, plants, laying hen): LD<sub>50</sub> > 5000 mg/kg bw; no genotoxic potential (Ames)  
Metabolite AE F094206: (soil, water/sediment): LD<sub>50</sub> > 5000 mg/kg bw; no genotoxic potential (Ames)  
Metabolite AE F092944: (water/sediment): LD<sub>50</sub> between 2000 and 5000 mg/kg bw; no genotoxic potential (Ames)

Medical data ‡ (Annex IIA, point 5.9)

Available data indicate no detrimental effects on health of plant personnel in manufacturing of amidosulfuron; no clinical cases or poisoning incidents have been reported

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.2 mg/kg bw/d	2-generation study	100
AOEL ‡	1.4 mg/kg bw/d	3-month dog study together with the 1-year dog study	100
ARfD ‡	Not allocated – not necessary		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)

100 % (default value)

Exposure scenarios (Annex IIIA, point 7.2)

Operator

Application in meadows/pasture with the highest use rate (45 g a.s./ha) is considered as “worst case”:

<u>POEM</u>	<u>% of AOEL</u>
without PPE	27.1
with PPE (gloves during mixing/loading and application)	2.6
<u>BBA</u>	
without PPE	3.7
with PPE (gloves during mixing/loading and application)	1.5

Workers

According to Krebs B. et al., 2000:  
1.6 % of AOEL (no PPE)

Bystanders

According to Lloyd and Bell, 1983:  
0.03 % of AOEL

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles



## Appendix 1 - List of endpoints for the active substance and the representative formulation

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### Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

Active substance

RMS/peer review proposal
No classification and labelling required.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### Appendix 1.4: Residues

#### Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Cereals (wheat) Oilseed (linseed)
Rotational crops	Carrots, wheat, white cabbage, potatoes, spinach
Metabolism in rotational crops similar to metabolism in primary crops?	Similar: Concentrations of total residues in the primary crops (wheat and linseed) were very low. Amidosulfuron degraded rapidly and completely by demethylation to AE F101630; then by ring-hydroxylation to AE F128870 and further degradation products. No unchanged parent compound was found in the extracts.  Concentrations of radioactivity in the edible parts of the rotated crops were very low. No unchanged parent compound was found in the extracts. Some polar metabolites (in wheat straw also Hoe 101630) were present. Due to the very low total amounts no further identification was possible.
Processed commodities	No data. Not necessary.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No data.
Plant residue definition for monitoring	Amidosulfuron
Plant residue definition for risk assessment	Sum of amidosulfuron and AE F101630 expressed as amidosulfuron
Conversion factor (monitoring to risk assessment)	Not necessary for plant commodities for human consumption resulting from the representative uses in cereals and linseed as residues are negligible.  For feed items (grass of pasture, hay), a representative figure is not possible to derive from the available data as the ratio changes according to the post application delay.

#### Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Lactating goat Laying hen (with limited validity)
Time needed to reach a plateau concentration in milk and eggs	<u>Milk</u> : The plateau was reached within 6 hours after the first administration. <u>Eggs</u> : The maximum concentration was measured in egg white 8 hours after the final administration (104 h after first administration).
Animal residue definition for monitoring	Sum of amidosulfuron and AE F101630 expressed as amidosulfuron.  Depending on the outcome of an appropriate livestock feeding study, this definition can be re-examined

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

Animal residue definition for risk assessment	Sum of amidosulfuron and AE F101630 expressed as amidosulfuron. Depending on the outcome of an appropriate livestock feeding study, this definition can be re-examined
Conversion factor (monitoring to risk assessment)	None.
Metabolism in rat and ruminant similar (yes/no)	Yes (low rate of metabolic degradation in rats and ruminants).
Fat soluble residue: (yes/no)	No.

### Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

No field tests submitted. No detectable residues in succeeding crops, no leaching into deeper soil layers expected.

### Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

Amidosulfuron is stable for 2 years in wheat (grain, shoots and straw)

### Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock $\geq 0.1$ mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes.	No.	No.
Potential for accumulation (yes/no):	No.	No.	No.
Metabolism studies indicate potential level of residues $\geq 0.01$ mg/kg in edible tissues (yes/no)	Yes.	No.	No.
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	A feeding study with a 1/1 mixture of the parent compound and the demethylated metabolite (AE F101630) is required for MRL setting *	Not required	Not required
Liver			
Kidney			
Fat			
Milk			
Eggs		Not required	

\* In the view of the RMS and the EFSA a feeding study using parent compound only could be acceptable as basis for MRL setting in animal products (refer to point 3.2 of the EFSA conclusions)

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Wheat, barley, rye, oats	Northern Region, field use	PHI = 59 - 87 days: 10 x <0.01, 1 x 0.012: Looking at the total of the residue data and considering that the result at 0.012 mg/kg was obtained for an application at unrealistic growth stage, the PRAPeR 25 meeting agrees an MRL of 0.01* mg/kg for cereal grains.	AE F101630 in cereals was below the LOQ (both grain and straw).	0.01*	<0.01	<0.01
Wheat, barley, rye, oats	Southern Region, field use	PHI = 63 - 105 days: 11 x <0.01	AE F101630 in cereals was below the LOQ (both grain and straw).	0.01*	<0.01	<0.01
Linseed	Northern Region, field use	PHI = 77 - 85 days: 3 x <0.05	---	0.05*	<0.05	<0.05
With respect to animal intake: at a re-entry period of 14 days, exposure of livestock to the parent compound is reduced to an acceptable level, but there is a significant exposure of livestock to the demethylated metabolite which is present at significant levels after 14 days. After 14 days the amount of metabolite in grass is similar to the amount of parent compound after 7 days. Therefore a feeding study is required with a 1/1 mixture of the parent compound and the demethylated metabolite AE F101630. 1N dose should reflect the exposure to the parent and the metabolite in grass (both around 1 mg/kg grass). AE F101630 in cereals was below the LOQ (both grain and straw).						
Meadows	Northern Region, field use	Amidosulfuron in grass: PHI = 21 - 22 days: 24 x <0.05 Amidosulfuron in hay: PHI = min. 24 days: 16 x <0.05	PHI of 21 days corresponding to the timepoint for earliest possible mowing.	---	<0.05	<0.05

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Pastures	Northern Region, field use	Amidosulfuron in grass PHI = 6-8 days: 8 x <0.05, 2 x 0.06, 1 x 0.07, 2 x 0.08, 1 x 0.09, 4 x 0.1, 1 x 0.2, 1 x 0.3, 1 x 0.4, 2 x 0.6, 1 x 0.8, 1 x 1.22 Hoe 101630 in grass PHI = 6-8 days: 4 x <0.05, 0.07, 3 x 0.09, 0.11, 0.15, 0.35, 0.79	PHI is corresponding to the <b>re-entry of 7 days</b> period for livestock to grazing areas <b>defended by the notifier</b> .	---	Amidosulfuron: 1.22  Hoe 101630: 0.79	Amidosulfuron: 0.09  Hoe 101630: 0.09
		Amidosulfuron in grass: PHI = 13-15 days: 20 x <0.05, 2 x 0.07, 1 x 0.10, 2 x 0.14 Hoe 101630 in grass PHI = 13-15 days: 5 x <0.05, 0.05, 2 x 0.06, 0.09, 0.10, 0.11, 0.25, 0.48	PHI corresponding to the <b>RMS-proposed</b> re-entry period of <b>14 days</b> for livestock to grazing areas	---	Amidosulfuron: 0.14  Hoe 101630: 0.71	Amidosulfuron: <0.05  Hoe 101630: 0.06
Cereal straw	Northern Region, field use	PHI = min. 48 days: 11 x <0.05	AE F101630 in cereals was below the LOQ (both grain and straw).	---	<0.05	<0.05
Cereal straw	Southern Region, field use	PHI = min. 63 days: 11 x <0.05	AE F101630 in cereals was below the LOQ (both grain and straw).	---	<0.05	<0.05

(a) Numbers of trials in which particular residue levels were reported e.g. 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue i.e. the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.2 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	0.02 % ADI
TMDI (% ADI) according to national (to be specified) diets	TMDI (German diet; girl of 13.5 kg bw): 0.04 %
IEDI (WHO European Diet) (% ADI)	---
NEDI (specify diet) (% ADI)	---
Factors included in IEDI and NEDI	---
ARfD	Not allocated – not necessary
IENTI (% ARfD)	Not assessed.
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not assessed.
Factors included in IENTI and NESTI	---

### Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
No data required.	---	---	---	---

### Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Cereals (covering all wheat varieties (winter and spring) including durum, as well as barley (winter and spring), triticale, rye and oats)	0.01* mg amidosulfuron/kg
Linseed	0.05* mg amidosulfuron/kg

\* Indicates that the MRL is proposed to be set at the LOQ level.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles



## Appendix 1 - List of endpoints for the active substance and the representative formulation

### Appendix 1.5: Fate and Behaviour in the Environment

#### Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days	3 % - 47 %
Non-extractable residues after 100 days	19 % - 46 %
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	<p><u>AE F101630</u>: Max. 49.6 % after 7 days</p> <p><u>AE F128870*</u>: Max. 38.6 % after 56 days</p> <p><u>AE 1569309*</u>: Max. 12.1 % after 35 days</p> <p>(*metabolites can not be synthesised)</p> <p>Unidentified "C" Max 7.7 % after 14days</p> <p>Unidentified "D" Max 8.8 % after 70 days</p>

#### Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	
Mineralization after 100 days	<p>No ring opening of the ai and mineralization to CO<sub>2</sub> under anaerobic conditions.</p> <p>Half-life of amidosulfuron &gt; 300 days</p>
Non-extractable residues after 100 days	19.4% (90 days after flooding)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	<p>AEF 094206 10.9 % (90 days after flooding)</p> <p>AEF 101630 14.5 % (60 days after flooding)</p>
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	<p>Photolytic degradation on soil surface can be considered of minor importance for the elimination of amidosulfuron.</p>

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	<p><u>Amidosulfuron</u>: Single 1<sup>st</sup> order kinetics</p> <p><u>Metabolites</u>: Multicompartment model TopFit2.0 (1<sup>st</sup> order kinetics)</p>
Laboratory studies (range or median, with n value, with r <sup>2</sup> value)	<p>DT<sub>50lab</sub> (20°C, 38-40 % MWHC, aerobic): n = 9 (but: 8 different soils) 3 - 29 days; r<sup>2</sup> = 0.971 - 0.998 (geom. mean: 16.6) Normalised DT<sub>50</sub> used for FOCUS modelling: 15.6 d (median)</p> <p>DT<sub>90lab</sub> (20°C, 38-40 % MWHC, aerobic): n = 9 8 different soils 10 - 97 days; r<sup>2</sup> = 0.971 - 0.998 (geom. mean: 55)</p> <p>DT<sub>50lab</sub> (10°C, aerobic): 21 days; n = 1</p> <p>DT<sub>50lab</sub> (20°C, anaerobic): &gt; 300 days; n = 1</p>
Metabolites DT <sub>50lab</sub> (20°C, aerobic):	<p><u>AE F101630</u>: 2.5 - 15.5 days; n = 6; B = 0.918 - 0.988 (geom. mean: 6.0) Normalised DT<sub>50</sub> used for FOCUS modelling: 5 d (median)</p> <p><u>AE F128870</u>: 18 - 291 days; n = 4; B = 0.980 - 0.999 (geom. mean: 95.3) In two further soils increasing until study termination. From the study at 10° C: DT<sub>50</sub> = 49.9 d → correction to 20° C: DT<sub>50</sub> = 22.7 d → Overall arithm. mean 20° C DT<sub>50</sub> = 120 d. Moisture and temperature corrected DT<sub>50</sub>: Overall geom. mean = 60.0 days. Normalised DT<sub>50</sub> used for FOCUS modelling: 64.2 d (median)</p> <p><u>AE 1569309</u>: 28.7 – 187.7 days; n = 4; Method: 3-compartment model, MatLab 2005 (geom. mean: 81.9) Normalised DT<sub>50</sub> used for FOCUS modelling: 69.9 d (geom. mean)</p> <p><u>Unknown metabolite “C”</u>: 1.9 – 2.9 (geom. mean = 2.4) normalised DT<sub>50</sub> values; n = 3; Method: 4-compartment model, MatLab</p>

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

DT <sub>90lab</sub> (20°C, aerobic):	<p><u>Unknown metabolite "D"</u>: 300.7 (normalised); only 1 reliable value; 4-compartment model, MatLab</p> <p><u>AE F101630</u>: 8.2 – 51.4 days; n = 5; B = 0.918 - 0.988 (geom. mean: 22)</p> <p><u>AE F128870</u>: 59 - 967 days; n = 4; B = 0.985 - 0.999 (geom. mean: 317)</p> <p>In two further soils increasing until study termination.</p> <p><u>AE 1569309</u>: No modelling/estimations submitted-</p>
Field studies (state location, range or median with n value)	<p>Degradation in the saturated zone: not submitted, not required. Amidosulfuron is not expected to leach into ground water in significant amounts when used according to the GAP.</p> <p>Formulated amidosulfuron (AE F075032 00 WG75 A109) applied on winter wheat (growth stage 29-31) at a rate of 0.03 or 0.06 kg a.s./ha at three locations in Germany in spring (April/May 1993).</p> <p>DT<sub>50f</sub>: From the data available calculation not possible. Pending on the soil type and the application rate residues declined below the LOQ (&lt; 0.002 mg/kg) after 1-3 months after application in the 0-20 cm soil layer. &lt; 0.002 mg/kg in deeper soil layers.</p> <p>DT<sub>90f</sub>: From the data available calculation not possible.</p>
Soil accumulation and plateau concentration ‡	<p><u>AE F128870</u>: Plateau concentration on the basis of a DT<sub>50</sub> of 291 days: Maximum reached after ca. 6 years: 0.02 mg/kg soil. (Soil depth: 5 cm, soil density: 1.5 g/cm<sup>3</sup>, 38.6% of 30 g a.s./ha, 25% interception)</p>

### Soil adsorption/desorption (Annex IIA, point 7.1.2)

K <sub>f</sub> /K <sub>oc</sub> (L/kg)	<u>Amidosulfuron</u> : K <sub>F</sub> <sup>ads</sup> : 0.06 – 2.36 (arithm. mean: 0.66)
K <sub>d</sub>	n = 6 K <sub>F,OC</sub> : 5.7 – 83 (arithm. mean: 36.4)
pH dependence (yes / no) (if yes type of dependence)	1/n: 0.91 – 1.1 (arithm. mean: 0.98)
	r <sup>2</sup> : 0.896 – 1.000
	No pH dependence was observed
	<u>AE F101630</u> : K <sub>F</sub> <sup>ads</sup> : 0.13 – 1.04 (arithm. mean: 0.44)
	n = 3 K <sub>F,OC</sub> : 11.6 – 33.1 (arithm. mean: 19.4)
	1/n: 0.89 – 0.97 (arithm. mean: 0.93)
	r <sup>2</sup> : 0.999 – 1.000
	A slight increase of K <sub>F,OC</sub> with decreasing pH was observed.

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## Appendix 1 - List of endpoints for the active substance and the representative formulation

AE F128870: Metabolite can not be synthesised.

Estimated by inverse modelling:  $K_{OC} = 50$

AE 1569309: Metabolite can not be synthesised. The same adsorption parameters as for metabolite AE F101630 were taken for PEC<sub>sw</sub> and PEC<sub>gw</sub> modelling.

Unknown metabolites "C" and "D": The same adsorption parameters as for metabolite AE F101630 were taken for PEC<sub>gw</sub> modelling.

### Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching

Amidosulfuron formulated as WG (20% or 75%) applied at a rate equivalent to 45 g a.s./ha:  
n = 6, three different soils (Speyer standard soils)  
55 % - 91 % AR in leachates, which could be attributed to unchanged parent compound.

Aged residues leaching

Amidosulfuron formulated as 75% WG applied at a rate equivalent to 45 g a.s./ha on one sand soil:  
44 % - 47 % AR in the leachates as amidosulfuron plus 9 % - 12 % AR in the leachates as sum of metabolites.

Lysimeter/ field leaching studies

Duration: Three years  
Location: Germany  
Test substance: Amidosulfuron as a 75% WG formul.  
Crop: Winter wheat  
Intermediate crop: Rape  
Application date: 10<sup>th</sup> May 1990 (post emergence)  
Application rate: 1 x 53.75 g a.s./ha or 56.25 g a.s./ha.  
Irrigation: Supplementary to ensure at least 800 mm precipitation per year.  
Soil: Weak loamy sand; 1 % OC; pH approx. 7.4

Results:

1<sup>st</sup> year: Extractable radioactivity < 0.05 – 0.33 µg ai equivalents/L, not extractable radioactivity 0.2 – 0.82 µg/L. Leachate: 327 - 328 L

2<sup>nd</sup> year: Extractable radioactivity 0.28 – 0.67 µg ai equivalents/L, not extractable radioactivity 0.02 – 0.18 µg/L. Leachate: 246 - 256 L

3<sup>rd</sup> year: Extractable radioactivity 0.07 – 0.49 µg ai equivalents/L, not extractable radioactivity 0.01 – 0.17 µg/L. Leachate: 288 - 304 L

Amidosulfuron: Detected only at the first and second sampling dates (0.025 µg/L each) in the 1<sup>st</sup>

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## Appendix 1 - List of endpoints for the active substance and the representative formulation

year (lysimeter X) and at the first three sampling dates (0.14 µg/L, 0.06 µg/L and 0.025 µg/L) in lysimeter IX (LOD: 0.01 µg/L).

$^{14}\text{CO}_2$ : 0.01 – 0.11 µg/L during 1<sup>st</sup> year and up to 0.02 µg/L during 2<sup>nd</sup> and 3<sup>rd</sup> year.

AE F101630: not detected

AE F128870: up to 0.53 µg/L

AE F094206: up to 0.25 µg/L (identification in selected samples only)

Overall loss of radioactivity: 80 %

### PEC (soil) (Annex IIIA, point 9.1.3)

#### Parent

Method of calculation

$$PEC_s(t) = \sum_{i=1}^n PEC_{s, \text{init}, i} \cdot e^{-k(t-t_i)}$$

$$TWAC_{1 \text{ day}}(T_j) = \frac{PEC(T_{j-1}) + PEC(T_j)}{2} \cdot (T_j - T_{j-1})$$

$$TWAC_{m \text{ days}}(T_j) = \frac{1}{m} \cdot \sum_{k=1}^m TWA_{1 \text{ day}}(T_{j+1-k})$$

Application rate

Application rate: 30 g a.s./ha; cereals spring applic. (BBCH 13-49)

Crop interception: 25 %

DT<sub>50</sub>: 38 d (worst case lab. value)

Soil bulk density: 1.5 g/cm<sup>3</sup>

Mixing depth of soil: 5 cm

PEC<sub>(s)</sub>  
(mg/kg)

Initial

Short term 24h  
2d  
4d

Long term 7d  
28d  
50d  
100d

Single application Actual	Single application Time weighted average
0.030	
0.029	0.030
0.029	0.029
0.028	0.029
0.026	0.028
0.018	0.024
0.012	0.020
0.005	0.014

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### Metabolites

Method of calculation

$$PEC_s(t) = \sum_{i=1}^n PEC_{s, init, i} \cdot e^{-k(t-t_i)}$$

$$TWAC_{1\text{ day}}(T_j) = \frac{PEC(T_{j-1}) + PEC(T_j)}{2} \cdot (T_j - T_{j-1})$$

$$TWAC_{m\text{ days}}(T_j) = \frac{1}{m} \cdot \sum_{k=1}^m TWA_{1\text{ day}}(T_{j+1-k})$$

Application rate

Application rate: 30 g a.s./ha in cereals spring application (BBCH 13-49)

Max. amount reached in soil: AE F101630: 49.6 %  
AE F128870: 38.6 %  
AE 1569309: 12.1 %

Crop interception: 25 %

DT<sub>50</sub> AE F101630: 15.5 d (worst case lab. value)  
DT<sub>50</sub> AE F128870: 291 d (worst case lab. value)

Soil bulk density: 1.5 g/cm<sup>3</sup>  
Mixing depth of soil: 5 cm

PEC<sub>(s)</sub>  
(mg/kg)

Initial

Short term 24h  
2d  
4d

Long term 7d  
28d  
50d  
100d

AE F101630		AE F128870	
Actual	Time weighted average	Actual	Time weighted average
0.014		0.012	
0.014	0.014	0.012	0.012
0.013	0.014	0.012	0.012
0.012	0.013	0.011	0.012
0.010	0.012	0.011	0.012
0.004	0.008	0.011	0.011
0.002	0.006	0.010	0.011
<0.001	0.003	0.009	0.010
Plateau concentration (plateau <sub>max</sub> ) reached after ca. 6 years:		<b>0.02</b>	

PEC<sub>(s)</sub>  
(mg/kg)

Initial

AE F1569309			
0.004			

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles



### Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance (DT <sub>50</sub> ) (state pH and temperature)	25°C pH 5: 33.9 pH 7, 9: stable
Photolytic degradation of active substance and relevant metabolites	25°C pH 7: 2370 ± 1194 d (52°N), stable
Readily biodegradable (yes/no)	no
Degradation in -DT <sub>50</sub> water	10 d (S2) (1 <sup>st</sup> order, r <sup>2</sup> = 0.989) 73 d (S1) (1 <sup>st</sup> order, r <sup>2</sup> = 0.994)
-DT <sub>50</sub> whole system	16 d (S2) (1 <sup>st</sup> order, r <sup>2</sup> = 0.981) 91 d (S1) (1 <sup>st</sup> order, r <sup>2</sup> = 0.997)
water/sediment -DT <sub>90</sub> water	34 d (S2) (1 <sup>st</sup> order, r <sup>2</sup> = 0.989) 244 d (S1) (1 <sup>st</sup> order, r <sup>2</sup> = 0.994)
-DT <sub>90</sub> whole system	54 d (S2) (1 <sup>st</sup> order, r <sup>2</sup> = 0.981) 302 d (S1) (1 <sup>st</sup> order, r <sup>2</sup> = 0.997)
Mineralization	18.8 and 25.2 % AR (after 180d = end of study)
Non-extractable residues	max: 27.2 % AR (after 180 d in S1) and 71.5 % AR (after 120 d in S2)
Distribution in water/sediment systems (active substance)	water: max: 103.3 – 100.7 % AR (0 d, n=2) min: 9.5 – 21.9 % AR (180 d, n=2) sediment: max: 13.1 – 24.9 % AR (4 d, n=2) min 0.3 – 3.3 % AR (180 d, n=2)
Distribution in water/sediment systems (metabolites)	<u>AE F101630:</u> water: max: 6.7 – 12.3 % AR (28 d, n=2) sed.: max: 6.5 – 6.7 % AR (28 d, n=2) both phase: < 1 % AR at end of the test <u>AE F094206:</u> water: max: 14.6 % AR (S1, 20 d), 17.1 % AR (S2, 98 d) sed.: max: 3.3 % AR (S1, 180 d), 6.7 % AR (S2, 98 d) <u>AE F092944:</u> water+sed.: max: 5.5 % AR (S1, 98 d), 3.7 % AR (S2, 28 d)

### PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Parent Amidosulfuron	Molecular weight (g/mol): 369.4
Parameters used in FOCUS <sub>sw</sub> step 1 and 2	Water solubility (mg/L): 9 Koc (L/kg): 36.4 DT <sub>50</sub> soil (d): 15.6 DT <sub>50</sub> water/sediment system (d): 53.5 (Arith. mean value of the two water/sediment systems (Knoch, 2000). Since no DT50 was determined for the sediment phase, the mean value of the whole systems was used also for the water and for the sediment phase) DT <sub>50</sub> water (d): 53.5

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

Parameters used in FOCUS <sub>sw</sub> step 3 (if performed)	DT <sub>50</sub> sediment (d): 53.5 Crop interception (%): 25% for cereals (spring application) and 75% for grass (autumn application)
	Vapour pressure: 1.3 x 10 <sup>-5</sup> Pa Koc / Kom: 36.4 / 21.1 (general) 1/n: 0.98 (arith. Mean value, n=6)
Application rate	Crop: winter cereals and grass Crop interception: 25% for cereals (spring application) and 75% for grass (autumn application) Number of applications: 1 Application rate(s): winter cereals: 30 g as/ha, grass: 45 g as/ha Depth of water body: 30 cm (Step 1 and 2) pond: 1m; stream: 0.3 m; ditch: 0.3-0.5 m (Step 3) Application window: 30 d (default value)
Main routes of entry	2.76 % drift from 1 meter (Step 1 and 2) pond: 1 m; stream: 0.3 m; ditch: 0.3-0.5 m (Step 3) 10% of applied runoff/drainage (FOCUS <sub>sw</sub> Step 1) Cereals: 2% (North), 4% (South) of soil residues runoff/drainage (FOCUS <sub>sw</sub> Step 2) Grass: 5% (North), 4% (South) of soil residues runoff/drainage (FOCUS <sub>sw</sub> Step 2)

FOCUS STEP 1 Scenario	crop	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		max	7 d TWA	max	7 d TWA
North & South Europe	winter cereals	9.813	9.37	3.472	3.404
	grass	14.72	14.055	5.207	5.105

FOCUS STEP 2 Scenario	crop	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		max	7 d TWA	max	7 d TWA
North Europe	winter cereals	1.451	1.384	0.520	0.475
	grass	1.878	1.79	0.673	0.643
South Europe	winter cereals	2.649	2.529	0.950	0.909
	grass	1.578	1.504	0.565	0.540

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# Appendix 1 - List of endpoints for the active substance and the representative formulation

FOCUS STEP 3 Scenario	water body	winter cereals (30 g a.s./ha, spring)		grass (45 g a.s./ha, autumn)	
		PEC <sub>SW</sub> (µg/L)		PEC <sub>SW</sub> (µg/L)	
		maximum	7 d TWA	maximum	7 d TWA
D1	ditch	0.242	0.220	1.623	1.543
	stream	0.190	0.059	1.096	0.895
D2	ditch	4.251	2.131	10.37	5.952
	stream	2.656	1.207	6.690	2.934
D3	ditch	0.191	0.027	0.290	0.039
D4	pond	0.009	0.009	0.046	0.046
	stream	0.151	0.003	0.246	0.089
D5	pond	0.008	0.008	0.190	0.188
	stream	0.149	0.001	0.265	0.128
D6	ditch	0.198	0.022	-	-
R1	pond	0.009	0.009	-	-
	stream	0.237	0.014	-	-
R2	stream	-	-	0.338	0.031
R3	stream	0.580	0.040	0.262	0.010
R4	stream	0.372	0.042	-	-

## Metabolite AE F101630

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 355.4  
Water solubility (mg/l): 9  
Soil or water metabolite: Soil and water metabolite  
Koc (L/kg): 19.4  
DT<sub>50</sub> soil (d): 5 days  
DT<sub>50</sub> water/sediment system (d): 1000 (conservative default value)  
DT<sub>50</sub> water (d): 1000  
DT<sub>50</sub> sediment (d): 1000  
Crop interception (%): 25 % for cereals (spring application) and 75 % for grass (autumn application)  
Maximum occurrence observed:  
Water + sediment: 18.8 %  
Maximum in soil: 49.6 % AR

Parameters used in FOCUSsw step 3 (if performed)

Step 3 not performed and not necessary

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

Application rate	<p>Crop: Winter cereals and grass</p> <p>Number of applications: 1</p> <p>Application rate(s): winter cereals: 30 g as/ha, grass: 45 g as/ha</p> <p>Depth of water body: 30 cm</p>
Main routes of entry	<p>2.76 % drift from 1 metre</p> <p>Cereals: 2 % and 4 % runoff/drainage for N and S Europe, respectively. (FOCUSsw Step 2)</p> <p>Grass: 5 % and 4 % runoff/drainage for N and S Europe, respectively. ( FOCUSsw Step 2)</p>

FOCUS STEP 1 Scenario	crop	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		max	7 d TWA	max	7 d TWA
North & South Europe	winter cereals	4.702	4.689	0.902	0.909
	grass	7.052	7.034	1.354	1.364

FOCUS STEP 2 Scenario	crop	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		max	7 d TWA	max	7 d TWA
North Europe	winter cereals	0.45	0.448	0.087	0.087
	grass	0.574	0.572	0.111	0.111
South Europe	winter cereals	0.850	0.848	0.165	0.164
	grass	0.474	0.472	0.092	0.092

### Metabolite AE F128870

Parameters used in FOCUSsw step 1 and 2

<p>Molecular weight: 371.4 (g/mole)</p> <p>Water solubility (mg/l): 9</p> <p>Soil or water metabolite: Soil metabolite</p> <p>Koc (L/kg): 51.7</p> <p>DT<sub>50</sub> soil (d): 64.2</p> <p>DT50 water/sediment system (d): 1000 (conservative default value)</p> <p>DT50 water (d): 1000</p> <p>DT50 sediment (d): 1000</p> <p>Crop interception (%): 25 % for cereals (spring application) and 75 % for grass (autumn application)</p> <p>Maximum occurrence observed: The metabolite was not observed in the water/sediment studies. Therefore this value was set to 0.1 %.</p> <p>Maximum in soil: 38.6 % AR</p>
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‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

Parameters used in FOCUSsw step 3 (if performed)	Step 3 not performed and not necessary
Application rate	Crop: Winter cereals and grass Number of applications: 1 Depth of water body: 30 cm
Main routes of entry	2.76 % drift from 1 meter Cereals: 2 % and 4 % runoff/drainage for N and S Europe, respectively. (FOCUSsw Step 2) Grass: 5 % and 4 % runoff/drainage for N and S Europe, respectively. ( FOCUSsw Step 2)

FOCUS STEP 1 Scenario	crop	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		max	7 d TWA	max	7 d TWA
North & South Europe	winter cereals	3.631	3.622	1.877	1.873
	grass	5.446	5.433	2.816	2.809

FOCUS STEP 2 Scenario	crop	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		max	7 d TWA	max	7 d TWA
North Europe	winter cereals	0.522	0.521	0.27	0.269
	grass	0.652	0.651	0.337	0.336
South Europe	winter cereals	1.043	1.041	0.539	0.538
	grass	0.522	0.521	0.27	0.269

### Metabolite AE 1569309

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 290.34  
Water solubility (mg/L): 3070  
Soil or water metabolite: Soil metabolite  
Koc (L/kg): 19.5 (taken from metabolite AE F101630)  
DT<sub>50</sub> soil (d): 69.9 days  
DT50 water/sediment system (d): 1000 (conservative default value)  
DT50 water (d): 1000  
DT50 sediment (d): 1000  
Crop interception (%): 25 % for cereals (spring application) and 75 % for grass (autumn application)  
Maximum occurrence observed:  
Water/sediment: 0.1 % (default value)  
Maximum in soil: 12.1 % AR

Parameters used in FOCUSsw step 3 (if performed)

Step 3 not performed and not necessary

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## Appendix 1 - List of endpoints for the active substance and the representative formulation

Application rate	<p>Crop: Winter cereals and grass</p> <p>Number of applications: 1</p> <p>Application rate(s): winter cereals: 30 g as/ha, grass: 45 g as/ha</p> <p>Depth of water body: 30 cm</p>
Main routes of entry	<p>2.76 % drift from 1 meter</p> <p>Cereals: 2 % and 4 % runoff/drainage for N and S Europe, respectively. (FOCUSsw Step 2)</p> <p>Grass: 5 % and 4 % runoff/drainage for N and S Europe, respectively. ( FOCUSsw Step 2)</p>

FOCUS STEP 1 Scenario	crop	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		max	7 d TWA	max	7 d TWA
North & South Europe	winter cereals	0.927	0.9249	0.181	0.1802
	grass	1.391	1.3874	0.271	0.2703

FOCUS STEP 2 Scenario	crop	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		max	7 d TWA	max	7 d TWA
North Europe	winter cereals	0.134		0.026	
	grass	<b>0.167</b>		0.033	
South Europe	winter cereals	<b>0.268</b>		0.052	
	grass	0.134		0.026	

### Metabolite AE F094206

As a worst case PEC<sub>SW</sub> for amidosulfuron were considered appropriate to assess the risk from metabolite AE F094206.

### PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (e.g. modelling, monitoring, lysimeter )

FOCUS PEARL 1.1.1 for parent, AE F101630, AE F128870  
FOCUS PEARL 2.2.2 for AE 1569309  
FOCUS PEARL 3.3.3 for metabolites "C" and "D"

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

Application rate

•Application of 30 g a.s./ha to winter cereals in early spring. Crop interception 25 %.			
•Application of 45 g a.s./ha to grassland in autumn. Crop interception 90%.			
	<u>DT<sub>50</sub></u>	<u>K<sub>OM</sub></u>	<u>1/n</u>
<u>Amidosulfuron</u> :	15.6	21.1	0.98
<u>AE F101630</u> :	5.0	11.3	0.93
<u>AE F128870</u> :	64.2	30	0.93
<u>AE 1569309</u> :	69.9	11.3*	0.93*
Met. "C":	2.4	11.3*	0.93*
Met. "D":	300.7	11.3*	0.93*
*taken from metabolite AE F101630			
Formation percentage:			
AE F101630: 70.4 % from amidosulfuron			
AE F128870: 52.7 % from AE F101630			
Formation percentage from amidosulfuron			
for AE 1569309:	17.88 (arithm. mean)		
for met. "C":	80.06		
for met. "D":	7.79 (single value)		

## PEC(gw) - FOCUS modelling results (80<sup>th</sup> percentile annual average concentration at 1m)

Winter cereals/spring application FOCUS PEARL 1.1.1	Scenario	Parent (µg/l)	Metabolites (µg/l)	
			AE F101630	AE F128870
	Châteaudun	0.005	0.001	<b>0.124</b>
	Hamburg	0.019	0.006	<b>0.239</b>
	Jokioinen	0.017	0.005	<b>0.144</b>
	Kremsmünster	0.018	0.006	<b>0.218</b>
	Okehampton	0.033	0.011	<b>0.260</b>
	Piacenza	0.046	0.015	<b>0.285</b>
	Porto	0.001	<0.001	0.029
	Sevilla	<0.001	<0.001	0.023
	Thiva	0.002	0.001	<b>0.105</b>

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles



**Appendix 1 - List of endpoints for the active substance and the representative formulation**

Grassland/autumn application FOCUS PEARL 1.1.1	Scenario		Parent (µg/l)	Metabolites (µg/l)	
				AE F101630	AE F128870
	Châteaudun		0.004	0.001	0.044
	Hamburg		0.019	0.006	0.082
	Jokioinen		0.016	0.005	0.062
	Kremsmünster		0.005	0.002	0.050
	Okehampton		0.027	0.009	0.075
	Piacenza		0.023	0.007	0.076
	Porto		0.001	<0.001	0.010
	Sevilla		<0.001	<0.001	0.012
Thiva		0.001	<0.001	0.029	

Winter cereals/spring application FOCUS PEARL 2.2.2	Scenario	AE 1569309 (µg/l)	Grassland/autumn application FOCUS PEARL 2.2.2	Scenario	AE 1569309 (µg/l)
	Châteaudun	0.182		Châteaudun	0.043
	Hamburg	0.273		Hamburg	0.075
	Jokioinen	0.259		Jokioinen	0.069
	Kremsmünster	0.230		Kremsmünster	0.044
	Okehampton	0.237		Okehampton	0.066
	Piacenza	0.220		Piacenza	0.052
	Porto	0.062		Porto	0.017
	Sevilla	0.048		Sevilla	0.020
	Thiva	0.152		Thiva	0.025

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

Winter cereals/spring application FOCUS PEARL 3.3.3	Scenario	<b>Unknown metabolite "C"</b> (µg/l parent equivalent)	Grassland/autumn application FOCUS PEARL 3.3.3	Scenario	<b>Unknown metabolite "C"</b> (µg/l parent equivalent)
	Châteaudun	<0.001		Châteaudun	<0.001
	Hamburg	0.001		Hamburg	0.002
	Jokioinen	0.001		Jokioinen	0.001
	Kremsmünster	0.001		Kremsmünster	<0.001
	Okehampton	0.002		Okehampton	0.003
	Piacenza	0.004		Piacenza	0.003
	Porto	<0.001		Porto	<0.001
	Sevilla	<0.001		Sevilla	<0.001
	Thiva	<0.001		Thiva	<0.001
Winter cereals/spring application FOCUS PEARL 3.3.3	Scenario	<b>Unknown metabolite "D"</b> (µg/l parent equivalent)	Grassland/autumn application FOCUS PEARL 3.3.3	Scenario	<b>Unknown metabolite "D"</b> (µg/l parent equivalent)
	Châteaudun	<b>0.378</b>		Châteaudun	0.056
	Hamburg	<b>0.328</b>		Hamburg	0.078
	Jokioinen	<b>0.366</b>		Jokioinen	0.093
	Kremsmünster	<b>0.262</b>		Kremsmünster	0.056
	Okehampton	<b>0.234</b>		Okehampton	0.056
	Piacenza	<b>0.303</b>		Piacenza	0.040
	Porto	<b>0.136</b>		Porto	0.031
	Sevilla	<b>0.222</b>		Sevilla	0.037
	Thiva	<b>0.345</b>		Thiva	0.043

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter )

Application rate

FOCUS PELMO 3.3.2

The same input parameters were used as for the PEARL-modelling ( $K_{OC} = 1.724 \times K_{OM}$ )

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### PEC(gw) - FOCUS modelling results (PELMO)

Winter cereals/spring application FOCUS PELMO 3.3.2	Scenario	Parent (µg/l)	Metabolites (µg/l)	
			AE F101630	AE F128870
	Châteaudun	0.002	0.001	0.074
	Hamburg	0.014	0.004	<b>0.200</b>
	Jokioinen	0.005	0.002	<b>0.104</b>
	Kremsmünster	0.010	0.003	<b>0.181</b>
	Okehampton	0.022	0.007	<b>0.226</b>
	Piacenza	0.042	0.014	<b>0.334</b>
	Porto	0.001	<0.001	0.017
	Sevilla	<0.001	<0.001	0.001
	Thiva	0.001	<0.001	0.035

Grassland/autumn application FOCUS PELMO 3.3.2	Scenario	Parent (µg/l)	Metabolites (µg/l)	
			AE F101630	AE F128870
	Châteaudun	0.001	<0.001	0.027
	Hamburg	0.011	0.004	0.058
	Jokioinen	0.012	0.004	0.053
	Kremsmünster	0.004	0.001	0.037
	Okehampton	0.021	0.007	0.073
	Piacenza	0.021	0.006	0.076
	Porto	0.002	0.001	0.010
	Sevilla	<0.001	<0.001	0.005
	Thiva	0.001	<0.001	0.024

Winter cereals/spring application FOCUS PELMO 3.3.2	Scenario	AE 1569309 (µg/l)	Grassland/autumn application FOCUS PELMO 3.3.2	Scenario	AE 1569309 (µg/l)
	Châteaudun	<b>0.104</b>		Châteaudun	0.025
	Hamburg	<b>0.170</b>		Hamburg	0.043
	Jokioinen	<b>0.175</b>		Jokioinen	0.050
	Kremsmünster	<b>0.164</b>		Kremsmünster	0.029
	Okehampton	<b>0.168</b>		Okehampton	0.049
	Piacenza	<b>0.174</b>		Piacenza	0.036
	Porto	0.045		Porto	0.016
	Sevilla	0.012		Sevilla	0.008
	Thiva	0.059		Thiva	0.018

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1 - List of endpoints for the active substance and the representative formulation

Winter cereals/spring application FOCUS PELMO 3.3.2	Scenario	Unknown metabolite "C" (µg/l parent equivalent)	Grassland/autumn application FOCUS PELMO 3.3.2	Scenario	Unknown metabolite "C" (µg/l parent equivalent)
	Châteaudun	<0.001		Châteaudun	<0.001
	Hamburg	0.001		Hamburg	0.001
	Jokioinen	<0.001		Jokioinen	0.001
	Kremsmünster	0.001		Kremsmünster	<0.001
	Okehampton	0.002		Okehampton	0.002
	Piacenza	0.006		Piacenza	0.003
	Porto	<0.001		Porto	<0.001
	Sevilla	<0.001		Sevilla	<0.001
	Thiva	<0.001		Thiva	<0.001

Winter cereal/spring application FOCUS PELMO 3.3.2	Scenario	Unknown metabolite "D" (µg/l parent equivalent)	Grassland/autumn application FOCUS PELMO 3.3.2	Scenario	Unknown metabolite "D" (µg/l parent equivalent)
	Châteaudun	<b>0.219</b>		Châteaudun	0.035
	Hamburg	<b>0.204</b>		Hamburg	0.049
	Jokioinen	<b>0.243</b>		Jokioinen	0.053
	Kremsmünster	<b>0.199</b>		Kremsmünster	0.037
	Okehampton	<b>0.158</b>		Okehampton	0.036
	Piacenza	<b>0.223</b>		Piacenza	0.026
	Porto	<b>0.098</b>		Porto	0.021
	Sevilla	<b>0.127</b>		Sevilla	0.024
	Thiva	<b>0.225</b>		Thiva	0.027

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### PEC<sub>(gw)</sub> From lysimeter / field studies

Maximum concentrations

Maximum concentrations in lysimeter leachates (measured not predicted values)  
(53.6/56.3 g a.s./ha on 10<sup>th</sup> May to winter wheat):  
Amidosulfuron: 0.14 µg/L (detected only at the first 3 sampling dates: 0.025-0.06 µg/L)  
AE F101630: not detected (LOD: 0.01 µg/L)  
AE F128870: 0.53 µg/L (out of selected samples)  
AE F094206: 0.25 µg/L (out of selected samples)  
AE 1569309: not detected  
Met. "C": not detected  
Met. "D": not detected

### Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡

Amidosulfuron was stable in the aqueous photolysis study

Quantum yield of direct phototransformation

Almost no photodegradation in aqueous solution, calculation of the quantum yield is not possible

Photochemical oxidative degradation in air ‡

DT<sub>50</sub>: 0.25 days, calculated according to the Atkinson method (OH-radical concentration: 5 x 10<sup>5</sup> molecules/cm<sup>3</sup>)

Volatilisation ‡

From plant surfaces: not submitted, not required

from soil: not submitted, not required

Metabolites

Information not available, not required

### PEC (air)

Method of calculation

With a Henry's constant of 1.6 x 10<sup>-6</sup> Pa m<sup>3</sup>/mol and a vapour pressure of 1.3 x 10<sup>-5</sup> Pa (20° C) amidosulfuron is not expected to volatilise in significant amounts. Additionally, the atmospheric half-life (0.25 days, photochemical oxidative degradation) is very short. Thus, no significant concentrations of amidosulfuron are expected in the atmosphere.

### PEC<sub>(a)</sub>

Maximum concentration

Negligible

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

**Appendix 1 - List of endpoints for the active substance and the representative formulation**

**Residues requiring further assessment**

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.

Soil:  
Amidosulfuron, AE F101630, AE F128870, AE 1569309 (AE F094206 under anaerobic conditions)  
Surface water:  
Amidosulfuron, AE F101630, AE F094206, AE F128870, AE 1569309,  
Sediment: Amidosulfuron  
Groundwater:  
Amidosulfuron, AE F128870, AE F094206, AE 1569309, AE F101630, unknown metabolite "D", unknown metabolite "C"  
Air: Amidosulfuron

**Monitoring data, if available (Annex IIA, point 7.4)**

Soil (indicate location and type of study)	-
Surface water (indicate location and type of study)	-
Ground water (indicate location and type of study)	-
Air (indicate location and type of study)	-

**Points pertinent to the classification and proposed labelling with regard to fate and behaviour data**

Candidate for R 53

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### Appendix 1.6: Effects on non-target Species

#### Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
<i>Coturnix c. japonica</i>	a.s.	Acute	> 2000	/
<i>Coturnix c. japonica</i>	Formulation Gratil	Acute	> 2000	/
<i>Coturnix c. japonica</i>	a.s.	Short-term	> 1170	> 5000
<i>Coturnix c. japonica</i>	a.s.	Long-term	100	1000
Mammals ‡				
<i>Mus musculus</i>	a.s.	Acute	≥ 5000	/
<i>Rattus norvegicus</i>	Formulation Gratil	Acute	5000	/
<i>Rattus norvegicus</i>	a.s.	Long-term	22.5	400
Additional higher tier studies ‡				
not required				

#### Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

##### meadows, 45 g a.s./ha

Indicator species/Category	Time scale	ETE	TER <sup>1</sup>	Annex VI Trigger
Tier 1 (Birds)				
large herbivorous bird	Acute	2.8	> 711	10
insectivorous bird		2.4	> 822	
large herbivorous bird	Short-term	1.5	> 778	10
insectivorous bird		1.4	> 862	
large herbivorous bird	Long-term	0.8	125	5
insectivorous bird		1.4	74	
Higher tier refinement (Birds)				
not required				
Tier 1 (Mammals)				
small herbivorous mammal	Acute	8.9	563	10
insectivorous mammal		0.4	12598	
small herbivorous mammal	Long-term	2.5	9	5
insectivorous mammal		0.14	161	

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles



## Appendix 1 - List of endpoints for the active substance and the representative formulation

Indicator species/Category	Time scale	ETE	TER <sup>1</sup>	Annex VI Trigger
Higher tier refinement (Mammals)				
not required				

<sup>1</sup> in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)

Indicator species/Category	Time scale	ETE	TER <sup>1</sup>	Annex VI Trigger
Tier 1 (Birds)				
medium herbivorous bird	Acute	2	> 1000	10
medium herbivorous bird	Short-term	0.9	> 1300	10
medium herbivorous bird	Long-term	0.5	200	5
Higher tier refinement (Birds)				
not required				
Tier 1 (Mammals)				
medium herbivorous mammal	Acute	0.7	6842	10
medium herbivorous mammal	Long-term	0.18	126	5
Higher tier refinement (Mammals)				
not required				

<sup>1</sup> in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)

## Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity <sup>1</sup> (mg a.s./L)
Laboratory tests				
Fish				
<i>Oncorhynchus mykiss</i>	amidosulfuron	96 hr (static)	Mortality, EC50	> 320
<i>Lepomis macrochirus</i>	amidosulfuron	96 hr (static)	Mortality, EC50	> 100
<i>Oncorhynchus mykiss</i>	amidosulfuron	21 d (flow-through)	Growth NOEC	6.41
<i>Oncorhynchus mykiss</i>	formulation Gratil	96 h (static)	Mortality, EC50	113.9
<i>Oncorhynchus mykiss</i>	formulation Gratil	21 d (flow-through)	Growth NOEC	7.59
<i>Oncorhynchus mykiss</i>	AE F101630	96 h (static)	Mortality, EC50	> 100
<i>Oncorhynchus mykiss</i>	AE F092944	96 h (static)	Mortality, EC50	254
<i>Oncorhynchus mykiss</i>	AE F094206	96 h (static)	Mortality, EC50	> 100

<sup>†</sup> Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

**Appendix 1 - List of endpoints for the active substance and the representative formulation**

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity <sup>†</sup> (mg a.s./L)
<i>Brachidanio rerio</i>	Lysimeter IX percolate <sup>4</sup>	96 h (static)	Mortality/intoxication	no effects
<i>Brachidanio rerio</i>	Lysimeter X percolate <sup>5</sup>	96 h (static)	Mortality/intoxication	no effects
Aquatic invertebrate				
<i>Daphnia magna</i>	amidosulfuron	48 h (static)	Mortality, EC50	36
<i>Daphnia magna</i>	amidosulfuron	21 d (semi static)	Reproduction, NOEC	1
<i>Daphnia magna</i>	formulation Gratil	48 h (static)	Mortality, EC50	141.9
<i>Daphnia magna</i>	formulation Gratil	21 d (semi static)	Reproduction, NOEC	24.3
<i>Daphnia magna</i>	AE F101630	48 h (static)	Mortality, EC50	3.6
<i>Daphnia magna</i>	AE F092944	48 h (static)	Mortality, EC50	223
<i>Daphnia magna</i>	AE F094206	48 h (static)	Mortality, EC50	> 100
<i>Daphnia magna</i>	Lysimeter IX percolate <sup>4</sup>	48 h (static)	Immobility	no effects
<i>Daphnia magna</i>	Lysimeter X percolate <sup>5</sup>	48 h (static)	Immobility	no effects
Algae				
<i>Scenedesmus subspicatus</i>	amidosulfuron	72 h (static)	Biomass: E <sub>b</sub> C50	47
<i>Navicula pelliculosa</i>	amidosulfuron	96 h (static)	Biomass: E <sub>b</sub> C50 Growth rate: E <sub>r</sub> C50	> 84.2
<i>Scenedesmus subspicatus</i>	formulation Gratil	72 h (static)	Biomass: E <sub>b</sub> C50 Growth rate: E <sub>r</sub> C50	25.8 93
<i>Scenedesmus subspicatus</i>	AE F101630	72 h (static)	Biomass: E <sub>b</sub> C50 Growth rate: E <sub>r</sub> C50	> 1000 > 1000
<i>Scenedesmus subspicatus</i>	AE F092944	72 h (static)	Biomass: E <sub>b</sub> C50	403
<i>Scenedesmus subspicatus</i>	Lysimeter IX percolate <sup>4</sup>	48 h (static)	growth inhibition	no effects in diluted and undiluted lysimeter percolate

<sup>†</sup> Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity <sup>1</sup> (mg a.s./L)
<i>Scenedesmus subspicatus</i>	Lysimeter X percolate <sup>5</sup>	48 h (static)	growth inhibition	no effects in diluted lysimeter percolate (dilution factor 2 and 4)
Higher plant				
<i>Lemna gibba</i>	amidosulfuron	7 d (static)	Growth rate: E <sub>r</sub> C <sub>50</sub> Biomass: E <sub>b</sub> C <sub>50</sub>	0.0092 <sup>2</sup> 0.0092 <sup>3</sup>
<i>Lemna gibba</i>	formulation Gratil	7 d (static)	Growth rate: E <sub>r</sub> C <sub>50</sub> Biomass: E <sub>b</sub> C <sub>50</sub>	0.00765 0.00773
<i>Lemna gibba</i>	AE F101630	7 d (semi static)	Growth rate: E <sub>r</sub> C <sub>50</sub> Biomass: E <sub>b</sub> C <sub>50</sub>	0.92 0.75
<i>Lemna gibba</i>	AE F092944	7 d (semi static)	Growth rate: E <sub>r</sub> C <sub>50</sub> Biomass: E <sub>b</sub> C <sub>50</sub>	> 100 > 100
<i>Lemna gibba</i>	AE F094206	7 d (semi static)	Growth rate: E <sub>r</sub> C <sub>50</sub> Biomass: E <sub>b</sub> C <sub>50</sub>	> 100 > 100
Microcosm or mesocosm tests: not required				

<sup>1</sup> Toxicity values of preparations are presented as mg a.s./L

<sup>2</sup> Actual inhibition at this concentration was 55.03 %

<sup>3</sup> Actual inhibition at this concentration was 53.01 %

<sup>4</sup> Lysimeter IX percolate = 0.37 – 2.53 µg/L AE F128870 and 0.07 – 0.25 µg/L AE F94206

<sup>5</sup> Lysimeter X percolate = 0.32 – 0.43 µg/L AE F128870 and 0.07 – 0.18 µg/L AE F94206

## Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

### FOCUS Step1

#### FOCUS Step1 and Step2 (Southern Europe)

#### Winter cereals 1 x 30 g a.s./L

Test substance	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PECmax Step1 (mg/L)	PECmax Step2 (mg/L)	TER Step1	TER Step2	Annex VI Trigger
a.s.	Fish	> 100	96 h	0.009813	0.002649	>10191	>37750	100
a.s.	Fish	6.41	21 d	0.009813	0.002649	653	2420	10
a.s.	Aquatic invertebrates	36	48 h	0.009813	0.002649	3669	13590	100
a.s.	Aquatic invertebrates	1.0	21 d	0.009813	0.002649	102	378	10

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

**Appendix 1 - List of endpoints for the active substance and the representative formulation**

Test substance	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PECmax Step1 (mg/L)	PECmax Step2 (mg/L)	TER Step1	TER Step2	Annex VI Trigger
a.s.	Algae	47	72 h	0.009813	0.002649	4790	17743	10
a.s.	Higher plants	0.0092	7 d	0.009813	0.002649	0.9	<b>3.5</b>	10
AE F101630	Fish	> 100	96 h	0.004702	0.00085	>21268	>117647	100
AE F101630	Aquatic invertebrates	3.6	48 hr	0.004702	0.00085	766	4235	100
AE F101630	Algae	>1000	72 h	0.004702	0.00085	>212675	>1176471	10
AE F101630	Higher plants	0.75	7 d	0.004702	0.00085	160	882	10
AE F092944	Fish	254	96 h	0.009813	0.002649	25884	95885	100
AE F092944	Aquatic invertebrates	223	48 h	0.009813	0.002649	22725	84183	100
AE F092944	Algae	403	72 h	0.009813	0.002649	41068	152133	10
AE F092944	Higher plants	>100	7 d	0.009813	0.002649	>10191	>37750	10
AE F094206	Fish	>100	96 h	0.009813	0.002649	>10191	>37750	100
AE F094206	Aquatic invertebrates	>100	48 hr	0.009813	0.002649	>10191	>37750	100
AE F094206	Higher plants	>100	72 h	0.009813	0.002649	>10191	>37750	10
AE 1569309	Higher plants	0.0092 <sup>17</sup>	7 d	0.000268	0.000167	34	55	10
formulation	Fish	113.9	96 h	0.009813	0.002649	11607	42997	100
formulation	Fish	7.59	21 d	0.009813	0.002649	773	2865	10
formulation	Aquatic invertebrates	141.9	48 h	0.009813	0.002649	14460	53567	100
formulation	Aquatic invertebrates	24.3	21 d	0.009813	0.002649	2476	9173	10
formulation	Algae	25.8	72 h	0.009813	0.002649	2629	9740	10
formulation	Higher plants	0.00765	7 d	0.009813	0.002649	0.8	<b>2.9</b>	10

<sup>17</sup> A measured endpoint for AE 1269309 is not available; therefore it is assumed that the metabolite has the same toxicity like the active substance amidosulfuron.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## FOCUS Step1 and Step2 (Northern Europe)

### Grass 1 x 45 g a.s./L

Test substance	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PECmax Step1 (mg/L)	PECmax Step2 (mg/L)	TER Step1	TER Step2	Ann ex VI Trigger
a.s.	Fish	> 100	96 h	0.01472	0.001878	>6793	>14180	100
a.s.	Fish	6.41	21 d	0.01472	0.001878	435	3413	10
a.s.	Aquatic invertebrates	36	48 h	0.01472	0.001878	2446	19169	100
a.s.	Aquatic invertebrates	1.0	21 d	0.01472	0.001878	68	532	10
a.s.	Algae	47	72 h	0.01472	0.001878	3193	25027	10
a.s.	Higher plants	0.0092	7 d	0.01472	0.001878	0.6	<b>4.9</b>	10
AE F101630	Fish	> 100	96 h	0.007052	0.000574	>14180	>174216	100
AE F101630	Aquatic invertebrates	3.6	48 h	0.007052	0.000574	510	6272	100
AE F101630	Algae	>1000	72 h	0.007052	0.000574	>141804	>1742160	10
AE F101630	Higher plants	0.75	7 d	0.007052	0.000574	106	1307	10
AE F092944	Fish	254	96 h	0.01472	0.001878	17255	135250	100
AE F092944	Aquatic invertebrates	223	48 h	0.01472	0.001878	15149	118743	100
AE F092944	Algae	403	72 h	0.01472	0.001878	27378	214590	10
AE F092944	Higher plants	>100	7 d	0.01472	0.001878	>6793	>53248	10
AE F094206	Fish	>100	96 h	0.01472	0.001878	>6793	>53248	100
AE F094206	Aquatic invertebrates	>100	48 h	0.01472	0.001878	>6793	>53248	100
AE F094206	Higher plants	>100	72 h	0.01472	0.001878	>6793	>53248	10
formulation	Fish	113.9	96 h	0.01472	0.001878	7738	60650	100
formulation	Fish	7.59	21 d	0.01472	0.001878	516	4042	10
formulation	Aquatic invertebrates	141.9	48 h	0.01472	0.001878	9640	75559	100
formulation	Aquatic invertebrates	24.3	21 d	0.01472	0.001878	1651	12939	10
formulation	Algae	25.8	72 h	0.01472	0.001878	1753	13738	10
formulation	Higher plants	0.00765	7 d	0.01472	0.001878	0.52	<b>4.1</b>	10

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1 - List of endpoints for the active substance and the representative formulation

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Winter cereals, 1 x 30 g a.s./ha

Test substance	Scenario <sup>1</sup>	Water body type <sup>2</sup>	Test organism <sup>3</sup>	Time scale	Toxicity endpoint (µg a.s./L)	PEC <sub>max</sub> (µg/L)	TER	Annex VI trigger
amido-sulfuron	D1	ditch	Higher plants	7 d	9.2	0.242	38	10
	D1	stream				0.190	48	
	D2	ditch				4.251	<b>2.2</b>	
	D2	stream				2.656	<b>3.5</b>	
	D3	ditch				0.191	48	
	D4	pond				0.009	1022	
	D4	stream				0.151	61	
	D5	pond				0.008	1150	
	D5	stream				0.149	62	
	D6	ditch				0.198	47	
	R1	pond				0.009	1022	
	R1	stream				0.237	39	
	R2	stream				-	-	
	R3	stream				0.58	16	
	R4	stream				0.372	25	
formulation	D1	ditch	Higher plants	7 d	7.65	0.242	32	10
	D1	stream				0.190	40	
	D2	ditch				4.251	1.8	
	D2	stream				2.656	2.9	
	D3	ditch				0.191	40	
	D4	pond				0.009	850	
	D4	stream				0.151	51	
	D5	pond				0.008	956	
	D5	stream				0.149	51	
	D6	ditch				0.198	39	
	R1	pond				0.009	850	
	R1	stream				0.237	32	
	R2	stream				-	-	
	R3	stream				0.58	13	

<sup>‡</sup> Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

**Appendix 1 - List of endpoints for the active substance and the representative formulation**

Test substance	Scenario <sup>1</sup>	Water body type <sup>2</sup>	Test organism <sup>3</sup>	Time scale	Toxicity endpoint (µg a.s./L)	PEC <sub>max</sub> (µg/L)	TER	Annex VI trigger
	R4	stream				0.372	21	

<sup>1</sup> drainage (D1-D6) and run-off (R1-R4)

**FOCUS Step 3**

**Grass, 1 x 45 g a.s./ha**

Test substance	Scenario <sup>1</sup>	Water body type <sup>2</sup>	Test organism <sup>3</sup>	Time scale	Toxicity endpoint (µg a.s./L)	PEC <sub>max</sub> (µg/L)	TER	Annex VI trigger
amido-sulfuron	D1	ditch	Higher plants	7 d	9.2	1.623	<b>5.7</b>	10
	D1	stream				1.096	<b>8.4</b>	
	D2	ditch				10.37	<b>0.9</b>	
	D2	stream				6.69	<b>1.4</b>	
	D3	ditch				0.29	32	
	D4	pond				0.046	200	
	D4	stream				0.246	37	
	D5	pond				0.19	49	
	D5	stream				0.265	35	
	D6	ditch				-	-	
	R1	pond				-	-	
	R1	stream				-	-	
	R2	stream				0.338	27	
	R3	stream				0.262	35	
	R4	stream				-	-	
formulation	D1	ditch	Higher plants	7 d	7.65	1.623	<b>4.7</b>	10
	D1	stream				1.096	<b>7.0</b>	
	D2	ditch				10.37	<b>0.7</b>	
	D2	stream				6.69	<b>1.1</b>	
	D3	ditch				0.29	26	
	D4	pond				0.046	166	
	D4	stream				0.246	31	
	D5	pond				0.19	40	
	D5	stream				0.265	29	

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles



## Appendix 1 - List of endpoints for the active substance and the representative formulation

Test substance	Scenario <sup>1</sup>	Water body type <sup>2</sup>	Test organism <sup>3</sup>	Time scale	Toxicity endpoint (µg a.s./L)	PEC <sub>max</sub> (µg/L)	TER	Annex VI trigger
	D6	ditch				-	-	
	R1	pond				-	-	
	R1	stream				-	-	
	R2	stream				0.338	23	
	R3	stream				0.262	29	
	R4	stream				-	-	

<sup>1</sup> drainage (D1-D6) and run-off (R1-R4)

### Bioconcentration

Bioconcentration factor (BCF)

Annex VI Trigger: for the bioconcentration factor

Clearance time (CT<sub>50</sub>)

(CT<sub>90</sub>)

Level of residues (%) in organisms after the 14 day depuration phase

Log POW < 3, no study required
Not relevant
Not relevant
Not relevant

### Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD <sub>50</sub> µg/bee)	Acute contact toxicity (LD <sub>50</sub> µg/bee)
a.s. ‡	/	> 100 <sup>2</sup>
Formulation Gratil <sup>1</sup>	> 101	/
Field or semi-field tests		
Not required		

<sup>1</sup> expressed in units of a.s.

<sup>2</sup> study of limited validity, argumentation given in DAR

### Hazard quotients for honey bees (Annex IIIA, point 10.4)

meadows, 45 g a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	< 0.45	50
a.s.	oral	/	50

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

Test substance	Route	Hazard quotient	Annex VI Trigger
Preparation	Contact	/	50
Gratil	oral	< 0.45	50

### cereals, linseeds, 30 g a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	< 0.3	50
a.s.	oral	/	50
Preparation	Contact	/	50
Gratil	oral	< 0.3	50

### Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR <sub>50</sub> g a.s./ha)
<i>Typhlodromus pyri</i> ‡	Gratil	Mortality	> 45
<i>Aphidius rhopalosiphi</i> ‡	Gratil	Mortality	> 45

### meadows, 45 g a.s./ha

Test substance	Species	Effect (LR <sub>50</sub> g a.s./ha)	HQ in-field	HQ off-field <sup>1</sup>	Trigger
Gratil	<i>Typhlodromus pyri</i>	> 45	< 1	< 0.03	2
Gratil	<i>Aphidius rhopalosiphi</i>	> 45	< 1	< 0.03	2

<sup>1</sup> 1 m distance assumed to calculate the drift rate

### cereals, linseed, 30 g a.s./ha

Test substance	Species	Effect (LR <sub>50</sub> g a.s./ha)	HQ in-field	HQ off-field <sup>1</sup>	Trigger
Gratil	<i>Typhlodromus pyri</i>	> 45	< 0.7	< 0.02	2
Gratil	<i>Aphidius rhopalosiphi</i>	> 45	< 0.7	< 0.02	2

<sup>1</sup> 1 m distance assumed to calculate the drift rate

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

### Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g a.s./ha) <sup>1</sup>	End point	% effect <sup>2</sup>	Trigger value
laboratory studies						
<i>Aphidius rhopalosiphii</i>	adults	Gratil	30	mortality fecundity comb.effect	24.3 44.2 57.7	50 %
<i>Typhlodromus pyri</i>	larvae and protonymphs	Gratil	45	mortality fecundity comb.effect	2.3 ~ 9 20.8	50 %
<i>Coccinella septempunctata</i>	larvae until adult	Gratil	60	mortality fecundity total effect	46.1 - 240.7 - 38.8	50 %
<i>Chrysoperla carnea</i>	larvae until adult	Gratil	45	mortality fecundity total effect	- 7.5 25.7 20.5	50 %
<i>Episyrphus balteatus</i>	larvae	Gratil	45	mortality fecundity	12.0 100	50 %
<i>Poecilus cupreus</i>	adults	Gratil	45	mortality feeding act.	no effect no effect	50 %
<i>Poecilus cupreus</i>	adults	Gratil	45	mortality feeding act.	no effect no effect	50 %
<i>Aleochara bilineata</i>	adults	Gratil	44	mortality parasitisation	no effect no effect	50 %
<i>Aleochara bilineata</i>	adults	Gratil	45	mortality parasitisation	no effect no effect	50 %
extended laboratory test						
<i>Aphidius rhopalosiphii</i>	adults	Gratil	2.8 - 45	mortality fecundity	0 - 3.3 < 7	50 %

<sup>1</sup> initial residues

<sup>2</sup> positive percentages relate to adverse effects

Field or semi-field tests

Not required

### Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5, Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point <sup>1</sup>
Earthworms			

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Appendix 1 - List of endpoints for the active substance and the representative formulation

Test organism	Test substance	Time scale	End point <sup>1</sup>
<i>Eisenia fetida</i>	Amidosulfuron	Acute 14 days	LC <sub>50</sub> > 1000 mg a.s./kg d.w.soil (mg a.s./ha)
	Amidosulfuron	Chronic	not required
<i>Eisenia fetida</i>	Gratil	Acute	> 750 mg a.s./kg dw soil
<i>Eisenia fetida</i>	Metabolite AE F101630	Acute	> 52 (estimated)
Other soil macro-organisms			
not required			
Soil micro-organisms			
Nitrogen mineralisation	Amidosulfuron	28 days	4 % effect at day 28 at 0.8 mg a.s./kg d.w.soil (0.6 kg a.s./ha)
Carbon mineralisation	Amidosulfuron	28 days	13 % effect at day 28 at 0.06 mg a.s./kg d.w.soil (mg 0.045a.s/ha) 22 % effect at day 28 at 0.3 mg a.s./kg d.w.soil (mg 0.225a.s/ha)
Field studies			
not required			

<sup>1</sup> indicate where end point has been corrected due to log Pow >2.0 (e.g. LC<sub>50corr</sub>)

## Toxicity/exposure ratios for soil organisms

meadows, 45 g a.s./ha

Test organism	Test substance	Time scale	Soil PECmax	TER	Trigger
Earthworms					
<i>Eisenia fetida</i>	Amidosulfuron	Acute	0.04	> 25000	10
<i>Eisenia fetida</i>	Gratil	Acute	0.04	> 18750	10
<i>Eisenia fetida</i>	Metabolite AE F101630	Acute	0.02	> 2600*	10
<p>*Remarks: It was assumed that metabolite AE F101630 was included in the tests with the parent compound. On the basis of its amounts of formation in soil laboratory studies the concentration in the acute earthworm test with the parent compound was assumed to be between 52-496 mg/kg soil.</p> <p>For metabolite AE F128870 no earthworm study can be conducted as this metabolite can not be synthesised. On the basis of structural analysis it is concluded that it is unlikely that this metabolite bears an unacceptable risk for soil organisms. Metabolite AE F128870 differs by just one OH-group from AE F101630.</p> <p>The metabolite AE F 1569309 appears shortly after application of amidosulfuron to soil in laboratory studies, thus the metabolite was included by the test with active substance. In addition a risk assessment was done by the assumption that the metabolite is 10 000-fold more toxic than amidosulfuron (0.1 mg/kg) and PECmax in soil is 0.0072 mg/kg, this would result in a TER of 14.</p>					
Other soil macro-organisms					
/					

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

## Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

### Preliminary screening data

Not required for herbicides as ER<sub>50</sub> tests should be provided

### Laboratory dose response tests

Most sensitive species	Test substance	ER <sub>50</sub> (g a.s./ha) vegetative vigour	ER <sub>50</sub> (g a.s./ha) emergence	Exposure <sup>1</sup> (g a.s./ha)	TER	Trigger
<i>Glycine max</i>	Gratil	67	/	1.247	53.7	5

<sup>1</sup> 2.77 % drift at 1 m based on Ganzelmeier drift data, meadows, 45 g a.s./ha

### Additional studies (e.g. semi-field or field studies)

Not required

## Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	Endpoint
Activated sludge	EC <sub>50</sub> > 1000 mg a.s./L
<i>Pseudomonas sp</i>	/

## Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Amidosulfuron
water	Amidosulfuron
sediment	-
groundwater	Amidosulfuron
air	Amidosulfuron

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

**Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)**

Active substance

RMS/peer review proposal	
N,	harmful
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Preparation

RMS/peer review proposal	
N,	harmful
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

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‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

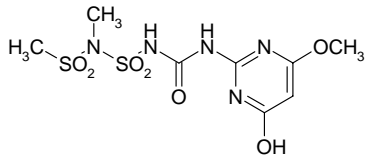
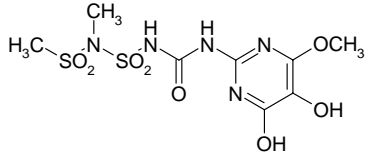
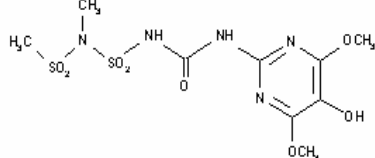
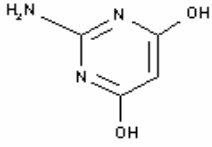
## APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT <sub>50</sub>	period required for 50 percent dissipation (define method of estimation)
DT <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC <sub>50</sub>	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K <sub>oc</sub>	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC <sub>50</sub>	lethal concentration, median



LD <sub>50</sub>	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC <sub>A</sub>	predicted environmental concentration in air
PEC <sub>S</sub>	predicted environmental concentration in soil
PEC <sub>SW</sub>	predicted environmental concentration in surface water
PEC <sub>GW</sub>	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK <sub>a</sub>	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10 <sup>-6</sup> )
ppp	plant protection product
r <sup>2</sup>	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year

### APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
AE F101630 Hoe 101630 “metabolite B”	3-(4-hydroxy-6-methoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)-urea	
AE F128870	3-(5,6-hydroxy-4-methoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)-urea	
AE 1569309 “metabolite E” “U4” Ring-hydroxylated amidosulfuron	3-(5-hydroxy-4,6-dimethoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)-urea	
AE F094206 Hoe 094206	2-amino-4,6-dihydroxypyrimidine	
AE F092944 Hoe 092944	2-amino-4,6-dimethoxypyrimidine	