

## CONCLUSION ON PESTICIDE PEER REVIEW

### Conclusion on the peer review of the pesticide risk assessment of the active substance iron sulfate<sup>1</sup>

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#### SUMMARY

Iron sulfate is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004<sup>3</sup>, as amended by Commission Regulation (EC) No 1095/2007<sup>4</sup>.

Iron sulfate was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as ‘the Regulation’), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009<sup>5</sup>, in accordance with Commission Implementing Regulation (EU) No 540/2011<sup>6</sup>, as amended by Commission Implementing Regulation (EU) No 541/2011<sup>7</sup>. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010<sup>8</sup>, the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

The United Kingdom being the designated rapporteur Member State submitted the DAR on iron sulfate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 7 January 2008. The peer review was initiated on 25 June 2008 by dispatching the DAR to the notifier the European Iron Sulphate Task Force (EISTF) and on 24 February 2011 to the Member States for consultation and comments. Following consideration of the comments received on the DAR, it was concluded that there was no need to conduct an expert consultation and EFSA should deliver its conclusions on iron sulfate.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of iron sulfate as a herbicide on amenity and sports turf for the control of moss, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2009-00260, issued on 16 December 2011.

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<sup>3</sup> OJ L 379, 24.12.2004, p.13

<sup>4</sup> OJ L 246, 21.9.2007, p.19

<sup>5</sup> OJ L 309, 24.11.2009, p.1

<sup>6</sup> OJ L 153, 11.6.2011, p.1

<sup>7</sup> OJ L 153, 11.6.2011, p.187

<sup>8</sup> OJ L 37, 10.2.2010, p.12

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Data gaps were identified for the section identity, physical and chemical properties and analytical methods.

With regard to the mammalian toxicology section, two critical areas of concern were identified: the compliance of the batches tested with the proposed specification could not be demonstrated, and the operator exposure exceeded the AOEL with the hand-held equipment (belly grinder), even with the use of personal protective equipment (PPE).

The representative use of the active substance iron sulfate is restricted to amenity turf and sports turf for the control of moss. Consequently, no residues are to be expected in food of plant or animal origin and a consumer risk assessment is therefore not necessary.

Concerning the environmental fate and behaviour section, data gaps were identified to address the impact of the concentrations of the dissociation products of iron sulfate (iron- and sulfate ions) in surface water that arise from the representative use of iron sulfate to turf. This is in the context of comparison to their background levels in the aquatic compartment, occurring naturally or from anthropogenic origin. This data gap results in the environmental exposure / risk assessment being not finalised. A data gap was also identified for satisfactory information on the natural buffering capacity of surface water bodies in Europe to neutralize acid inputs from sulfate ions potentially formed following the representative use of iron sulfate, and on the possible adverse effects on aquatic organisms. Based on the available information, supported by worst-case assumptions, there are indications that predicted environmental concentrations in groundwater of iron ions will exceed the EU drinking water indicator parameter. Finally, it cannot be concluded if the use of iron sulfate will have an impact on the natural levels of the relevant inorganic impurities (heavy metals and arsenic) in soils and surface waters in Europe.

The risk to birds and mammals, honeybees and other non-target arthropods, non-target soil organisms, terrestrial non-target plants and biological methods of sewage treatment was assessed as low for the representative use. Considering the available data, a potential high risk to aquatic organisms could not be excluded. Therefore this issue was indicated as a concern.

## **KEY WORDS**

Iron sulfate, peer review, risk assessment, pesticide, herbicide

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## BACKGROUND

Iron sulfate is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004<sup>9</sup>, as amended by Commission Regulation (EC) No 1095/2007<sup>10</sup>.

Iron sulfate was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009<sup>11</sup>, in accordance with Commission Implementing Regulation (EU) No 540/2011<sup>12</sup>, as amended by Commission Implementing Regulation (EU) No 541/2011<sup>13</sup>. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010<sup>14</sup> the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

The United Kingdom being the designated rapporteur Member State submitted the DAR on iron sulfate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 7 January 2008 (The United Kingdom, 2007). The peer review was initiated on 25 June 2008 by dispatching the DAR to the notifier the European Iron Sulphate Task Force (EISTF) and on 24 February 2011 to the Member States for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The comments and the notifier's response were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 20 June 2011. On the basis of the comments received and the RMS' evaluation thereof it was concluded that there was no need to conduct an expert consultation.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, and the additional information to be submitted by the notifier, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a herbicide on amenity and sports turf for the control of moss, as proposed by the notifier. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer

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<sup>9</sup> OJ L 379, 24.12.2004, p.13

<sup>10</sup> OJ L 246, 21.9.2007, p.19

<sup>11</sup> OJ L 309, 24.11.2009, p.1

<sup>12</sup> OJ L 153, 11.6.2011, p.1

<sup>13</sup> OJ L 153, 11.6.2011, p.187

<sup>14</sup> OJ L 37, 10.2.2010, p.12

review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (16 November 2011),
- the Evaluation Table (6 December 2011),
- the comments received on the assessment of the points of clarification,
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of October 2011 containing all individually submitted addenda (The United Kingdom, 2011)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

## THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Iron(2+) sulfate or iron(II) sulfate (IUPAC) is considered by the International Organization for Standardization not to require a common name. This substance was notified as iron sulphate, in ISO 765-1976 the name given is “ferrous sulphate”, but ISO now requires the “f” spelling for sulfur and its compounds.

The representative formulated product for the evaluation was 'Stodiek Moosvernichter mit Rasendünger', a fine granule (GR), containing 238 g/kg iron sulfate, registered under different trade names in the EU.

The representative uses evaluated comprise applications by strewing on amenity and sports turf for the control of moss. Full details of the representative uses can be found in the list of end points in Appendix A.

## CONCLUSIONS OF THE EVALUATION

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

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000), and SANCO/825/00 rev. 7 (European Commission, 2004a).

The minimum purity of iron sulfate is 350 g/kg, expressed as total iron content of the anhydrous salt. It should be noted that the members of the European Iron Sulphate Task Force produce the technical material of iron sulfate with different water content: the heptahydrate, the monohydrate and the anhydrous form. It should also be noted that the active substance also contains iron(3+) sulfate, and that the purities of the different iron sulfate forms in the approval directive<sup>15</sup> are expressed as total iron content. No FAO specification exists.

Arsenic, cadmium, chromium, lead and mercury were considered as relevant impurities, with maximum limits of 18 mg/kg, 1.8 mg/kg, 90 mg/kg, 36 mg/kg and 1.8 mg/kg of the anhydrous iron(II) sulfate content, respectively. 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 iron sulfate or the representative formulation. Data gaps were identified for validation data of the methods of analysis of the impurities, for a shelf-life study, and for the acidity of the undiluted formulation. It should be noted that studies are available, however according to Commission Regulation (EC) No 1095/2007 the submission of new studies can not be taken into account in the peer review.

The main data regarding the identity of iron sulfate and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of iron sulfate in the technical material and in the representative formulation. The justification for the acceptability of the ICP- OES (AES) method in analysing for total sulfur was considered satisfactory for the determination of the sulfate content in the technical material.

The need for methods of analysis for monitoring this compound in food of plant and animal origin, in soil and air has been waived due to the nature of the compound and the representative use. A data gap has been identified for a method of analysis for iron in water with a LOQ of 0.2 mg/L (Council Directive 98/83/EC)<sup>16</sup>. A method for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

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<sup>15</sup> OJ L153, 11.6.2011, p.1

<sup>16</sup> OJ L330, 5.12.1998, p.44

## 2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 rev. 10 - final (European Commission, 2003), and SANCO/222/2000 rev. 7 (European Commission, 2004b).

Iron sulfate is derived from natural sources. Therefore the impurity profile can vary significantly for materials of different origin. The members of the European Iron Sulphate Task Force agreed to use material with specific limits for all the present impurities (the heavy metals and arsenic are considered relevant). It is unclear whether the variation of the different batches, even if within these limits, might have an impact on the toxicological profile. The compliance of the batches tested in the toxicological studies with the proposed specification could not be demonstrated.

Toxicokinetics data on iron sulfate come from human data, showing rapid absorption and uniform distribution; 0.01 % to 0.02 % of the absorbed iron is excreted daily. In experimental animals, iron sulfate is “Harmful if swallowed” (R22 proposed); no data are available on acute dermal or inhalation toxicity, but they are not regarded as necessary. Limited human data indicate skin and eye irritation potential (R38 and R36 proposed). Iron sulfate is not a skin sensitiser. A 90-day study in mice showed liver and spleen effects (haemosiderosis), with a relevant NOAEL of 100 mg/kg bw/day iron sulfate. Overall, iron sulfate did not show genotoxic potential based on a range of *in vitro* and *in vivo* studies. No experimental studies clarifying the long-term toxicity and carcinogenicity potential, the reproductive toxicity and neurotoxicity were submitted. The relevant maternal and developmental toxicity NOAELs were 380 mg/kg bw/day iron sulfate in both rats and mice (reduced body weight in dams, increased implantation loss at 1200 mg/kg bw/day). Medical data indicate that health effects can occur with intakes from >20 mg Fe/kg bw onwards resulting in symptoms such as vomiting, gastrointestinal bleeding, diarrhoea, liver alterations; chronic intoxications (leading to liver and spleen haemosiderosis, liver cirrhosis and renal failure) can occur with repeated exposures well above the therapeutic dose for pregnant women (50 mg Fe/day), which corresponds to an Acceptable Daily Intake (ADI) of 0.8 mg Fe/kg bw/day. Taking into account a 50 % oral bioavailability, an Acceptable Operator Exposure Level (AOEL) of 0.4 mg Fe/kg bw/day can be established. An Acute Reference Dose was not deemed necessary.

Exposure to operators using hand-held equipment (e.g. belly-grinders) is above the AOEL (for both iron and sulfate), even with the use of gloves during loading and application, whereas it is below the AOEL for pedestrian-controlled application equipment (e.g. Scotts Residential type equipment) with the use of the same personal protective equipment (in the PHED model, operators are wearing gloves and normal work wear during loading and application). Worker exposure for dermal contact with treated turf during maintenance tasks is estimated to be below the AOEL, while exposure of children playing on turf immediately after treatment exceeds the AOEL (for both iron and sulfate). Bystander exposure is unlikely due to the method of application.

## 3. Residues

The assessment in the residue section below is based on the guidance documents listed in the document 1607/VI/97 - rev. 2 (European Commission, 1999), and the JMPR recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004 and 2007).

The representative use of the active substance iron sulfate is restricted to amenity turf and sports turf for the control of moss. Consequently, no residues are to be expected in food of plant or animal origin and a consumer risk assessment is therefore not necessary.

## 4. Environmental fate and behaviour

Iron sulfate is an inorganic salt that dissociates in the soil solution to iron- and sulfate-ions. Both iron- and sulfate-ions are naturally occurring components of terrestrial ecosystems. At agriculturally relevant pH values, nearly all sulfate present is in the soil solution, while the concentration of dissolved Fe in the soil solution is rather low, due to the low solubility of its oxide/hydroxide forms.

Predicted environmental concentrations (PEC) of iron and sulfate in soil were calculated based on a maximum application rate of 2 x 71.4 kg FeSO<sub>4</sub>/ha without degradation between applications, corresponding to a total load of 52.5 kg Fe/ha and 90.3 kg SO<sub>4</sub><sup>2-</sup>/ha. Compared to the natural contents of iron and sulfate, the additional amounts resulting from the representative use of FeSO<sub>4</sub> as a herbicide to control moss are very small, and consequently no unreasonable effects are expected.

Iron sulfate is highly soluble in water and, when dissolved in water, it readily dissociates to iron- and sulfate ions. PEC in surface water for Fe<sup>2+</sup> and SO<sub>4</sub><sup>2-</sup> were calculated with FOCUS (2001) steps 1-2 after application of 2 x 71.4 kg FeSO<sub>4</sub>/ha to lawn, with the minimum interval between the applications of 40 days. Since iron sulfate is a granular formulation, exposure to surface water via spray drift was not considered in the calculations. Initial PECs of iron and sulfate ions in surface water at step 2 (Northern Europe, Oct - Feb) were calculated to be 0.164 mg/L and 8.88 mg/L, respectively, as a result of run-off and drainage. New information on the natural background concentrations of iron- and sulfate ions in natural surface waters in Europe was provided in Addendum 2 (The United Kingdom, 2011). Although this information cannot be taken into account in the peer review in view of Commission Regulation (EC) No 1095/2007, it should be noted that a mean value of 0.46 mg/L for sulfate levels in lakes has been reported from the European Environmental Agency database. Therefore, it cannot be excluded that the use of iron sulfate will have an impact on the natural levels of sulfates in the aquatic environment. A data gap was identified for information on the natural buffering capacity of surface water bodies in Europe to neutralize acid inputs from sulfate ions potentially formed following the use of iron sulfate and on the possible adverse effects on aquatic organisms.

PEC in groundwater for iron and sulfate ions were calculated taking into account the total annual dose and the 80<sup>th</sup> percentile recharge water volume percolated below 1 m depth, using the FOCUS PELMO 3.3.2 FOCUS (2000) groundwater scenarios for grass (The United Kingdom, 2011). The resulting 80<sup>th</sup> percentile PEC<sub>gw</sub> values for sulfate ranged from 23.5 mg/L (Porto) to 249.9 mg/L (Sevilla). The respective values for iron were 13.7 mg/L (Porto) and 145.4 mg/L (Sevilla). The relevant EU drinking water indicator parameters set by the drinking water directive<sup>17</sup> are 250 mg/L (sulfate) and 200 µg/L (iron). Therefore, the resulting PEC<sub>gw</sub> for iron is approximately 730 times the maximum allowed concentration in drinking water, indicating a potential for groundwater contamination of iron following the representative use of iron sulfate. It is noted that these calculations are overestimates, based on worst-case assumptions. PEC calculations were also provided (The United Kingdom, 2007 and 2011) for the relevant inorganic impurities (arsenic, cadmium, chromium, lead and mercury) contained in iron sulfate technical. A proper comparison with the background levels of heavy metals and arsenic in European soils and surface water was not possible (refer to Evaluation Table point of clarification 4.6; EFSA, 2011), and therefore it cannot be concluded whether the amount contributed by the application of iron sulfate to turf would be significant. The estimated concentrations of the relevant impurities entering groundwater following application of iron sulfate to turf would be below the maximum levels allowable in drinking water.

## 5. Ecotoxicology

In the risk assessments the following document was considered: European Commission 2002.

The available studies revealed relatively low toxicity to **birds and mammals**. No standard risk assessments (e.g. TER calculations) were conducted, however non-validated assessments for the representative formulation were available that indicated a low acute risk to birds. No relevant long-term data for birds or mammals were available, however no assessments for long-term scale were deemed to be necessary. Overall, it was concluded that the risk to birds and mammals from the use of iron sulfate as a pesticide, based on the representative use, is low.

No standard risk assessments (e.g. TER calculations) for **aquatic organisms** were conducted on the basis that the background levels of the dissociation products of iron sulfate in the aquatic environment (natural surface waters and groundwater) are higher than the calculated worst-case PEC values.

<sup>17</sup> Council Directive 98/83/EC on the quality of water intended for human consumption

However, the background levels relevant to Europe could not be clarified on the basis of the available information (see section 4), and therefore a data gap has been identified for risk assessments for aquatic organisms. In addition, it is noted that there is a data gap identified in section 4 concerning the background levels of the relevant inorganic impurities in surface water. It is noted that a potential high risk cannot be excluded if the available end points are compared with the relevant PEC values, therefore this issue has been considered as a concern.

The risk to **honeybees** was concluded to be low since the exposure was considered as negligible for the representative use. Considering the available data with different formulations, the risk to **non-target arthropods** was assessed as low.

A high chronic risk to **earthworms** was identified based on the laboratory data. However, a higher tier field study indicated no relevant changes in the earthworm population and biomass, therefore the risk to earthworms was considered as low.

Studies on **soil micro-organisms** were available only for non-representative formulations that had high nitrogen content. Considering the results of these studies, relevant effects on carbon mineralisation and nitrification in soil from the use of iron sulfate as a pesticide, based on the representative use, cannot be excluded. Further available results from parallel studies, where similar formulations were used but without iron, indicated similar results. Considering these results and that the PEC<sub>soil</sub> values are significantly lower than the natural background concentrations of the dissociation products of iron sulfate in soil, the potential impact of the use of iron sulfate to soil micro-organisms was considered to be low. It is however noted that there is a data gap identified in section 4 concerning the background levels of the relevant inorganic impurities in soil. Pending on the outcome of this data gap the risk assessment for soil organisms may need to be reconsidered.

No data or risk assessments were available for **terrestrial non-target plants** or **biological methods for sewage treatments**. However, due to the expected low exposure, the potential risk was considered to be low.

## 6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

### 6.1. Soil

| Compound (name and/or code) <sup>(a)</sup> | Persistence           | Ecotoxicology                                   |
|--|-----------------------|---|
| Iron ions                                  | No data, not required | The risk to soil organisms was assessed as low. |
| Sulfate ions                               | No data, not required | The risk to soil organisms was assessed as low. |

<sup>(a)</sup> Provisional pending on data gap in section 4

### 6.2. Ground water

| Compound (name and/or code) <sup>(a)</sup> | Mobility in soil      | EU drinking water indicator parameters set by Council Directive 98/83/EC on the quality of water intended for human consumption | Pesticidal activity | Toxicological relevance | Ecotoxicological activity |
|--|-----------------------|---|---------------------|-------------------------|---------------------------|
| Iron ions                                  | No data, not required | EU limit of 200 µg/L exceeded in FOCUS Sevilla scenario as a worst-case calculation (refer to section 4 for details)            | Yes                 | Yes                     | Data gap                  |
| Sulfate ions                               | No data, not required | EU limit of 250 mg/L not exceeded.  |                     | No data available       | Data gap                  |

<sup>(a)</sup> Provisional pending on data gap in section 4

### 6.3. Surface water and sediment

| Compound<br>(name and/or code) | Ecotoxicology |
|--------------------------------|---------------|
| Iron ions                      | Data gap      |
| Sulfate ions                   | Data gap      |

<sup>(a)</sup> Provisional pending on data gap in section 4

### 6.4. Air

| Compound<br>(name and/or code) | Toxicology |
|--------------------------------|------------|
| -                              | -          |

## 7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Validation data in respect of precision, accuracy and linearity of the methods of analysis of the impurities (relevant for the representative use evaluated; submission date proposed by the notifier: data available, however according to Commission Regulation (EC) No 1095/2007 new studies cannot be taken into consideration in the peer review; see section 1).
- Shelf-life study (relevant for the representative use evaluated; submission date proposed by the notifier: data available, however according to Commission Regulation (EC) No 1095/2007 new studies cannot be taken into consideration in the peer review; see section 1).
- The acidity of the undiluted formulation (relevant for the representative use evaluated; submission date proposed by the notifier: data available, however according to Commission Regulation (EC) No 1095/2007 new studies cannot be taken into consideration in the peer review; see section 1).
- Method of analysis for iron in water with a LOQ of 0.2 mg/L (relevant for the representative use evaluated; submission date proposed by the notifier: unknown; see section 1).
- Satisfactory information on the natural buffering capacity of surface water bodies in Europe to neutralize acid inputs of sulfate ions potentially formed following the use of iron sulfate and on the possible adverse effects on aquatic organisms (relevant for the representative use evaluated; submission date proposed by the notifier: unknown; see section 4).
- Satisfactory information on the natural background concentrations of iron- and sulfate ions in natural surface waters in Europe in order to assess the impact of the estimated amounts of iron and sulfate following the use of iron sulfate (relevant for the representative use evaluated; submission date proposed by the notifier: data available, however according to Commission Regulation (EC) No 1095/2007 they cannot be taken into consideration in the peer review; see section 4).
- Satisfactory information on the natural background concentrations of the relevant inorganic impurities/by-products (arsenic, cadmium, chromium, lead and mercury) contained in iron sulfate in European agricultural soils and surface waters in Europe (relevant for the representative use evaluated; submission date proposed by the notifier: data available, however according to Commission Regulation (EC) No 1095/2007 they cannot be taken into consideration in the peer review; see section 4).
- Risk assessments for aquatic organisms (relevant for the representative use evaluated; submission date proposed by the notifier: unknown; see section 5).

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

- The use of personal protective equipment (gloves and normal work wear during loading and application) should be considered for operators using pedestrian-controlled application equipment (e.g. Scotts Residential type equipment) to achieve an exposure below the AOEL.

## 9. Concerns

### 9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line

with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. The impact of the use of iron sulfate on turf on the natural background concentrations of iron- and sulfate-ions in natural surface waters in Europe.
2. The impact of the use of iron sulfate on turf on the natural background concentrations of the relevant inorganic impurities/by-products (arsenic, cadmium, chromium, lead and mercury) contained in iron sulfate in European agricultural soils and surface waters.
3. Risk assessments for aquatic organisms; a potential high risk cannot be excluded based on the available data.

## 9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

4. The compliance of the batches tested in the toxicological studies with the proposed specification could not be demonstrated.
5. Operator exposure exceeds the AOEL (for both iron and sulfate) using hand-held equipment (belly grinder), even with the use of personal protective equipment (PPE), as well as the exposure of children playing on turf immediately after treatment.
6. Based on the available lowest tier assessment, the potential for groundwater contamination above the relevant drinking water indicator parameter for iron (200 µg/L) cannot be excluded.

### 9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then ‘risk identified’ is not indicated in this table.)

The column is marked with grey as it could not be demonstrated that the technical material specification proposed is comparable to the material used in the testing that was used to derive the toxicological reference values.

| Representative use   |  | Applications by strewing on sport and amenity turf for the control of moss<br>(max. application rate of 2 x 71.4 kg FeSO <sub>4</sub> /ha) |
|--|--|--|
| Operator risk  | Risk identified                                    | X <sup>5</sup>   |
|  | Assessment not finalised                           |  |
| Worker risk  | Risk identified                                    |  |
|  | Assessment not finalised                           |  |
| Bystander risk   | Risk identified                                    |  |
|  | Assessment not finalised                           |  |
| Consumer risk  | Risk identified                                    |  |
|  | Assessment not finalised                           |  |
| Risk to wild non target terrestrial vertebrates                      | Risk identified                                    |  |
|  | Assessment not finalised                           |  |
| Risk to wild non target terrestrial organisms other than vertebrates | Risk identified                                    |  |
|  | Assessment not finalised                           | X <sup>2</sup>   |
| Risk to aquatic organisms  | Risk identified                                    |  |
|  | Assessment not finalised                           | X <sup>1,2,3</sup>   |
| Groundwater exposure active substance                                | Legal parametric value breached                    |  |
|  | Assessment not finalised                           |  |
| Groundwater exposure metabolites                                     | Legal parametric value breached                    | X <sup>6</sup>   |
|  | Parametric value of 10µg/L <sup>(a)</sup> breached |  |
|  | Assessment not finalised                           |  |
| Comments/Remarks   |  |  |

The superscript numbers in this table relate to the numbered points indicated within in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information.

(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

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## APPENDICES

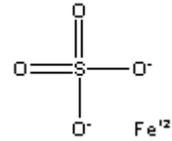
### APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

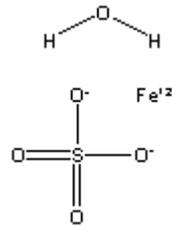
|                                      |                                   |
|--------------------------------------|-----------------------------------|
| Active substance (ISO Common Name) ‡ | Iron sulfate (no ISO common name) |
| Function ( <i>e.g.</i> fungicide)    | Herbicide (mosskiller)            |
| Rapporteur Member State              | United Kingdom                    |
| Co-rapporteur Member State           | -                                 |

#### Identity (Annex IIA, point 1)

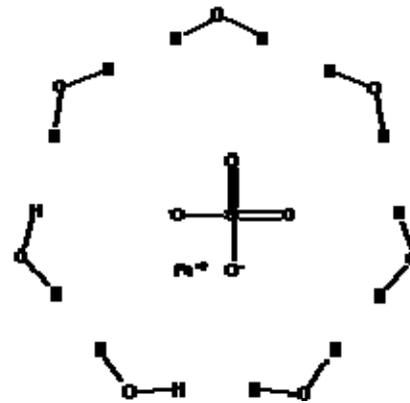
|   |  |                                     |
|---|--|-------------------------------------|
| Chemical name (IUPAC) ‡   | iron(II)sulfate or iron(2+) sulfate                    |                                     |
| Chemical name (CA) ‡  | iron(2+) sulfate (1:1)                                 |                                     |
| CIPAC No ‡  | 837  |                                     |
| CAS No ‡  | 7720-78-7  | iron(II)sulfate anhydrous           |
|   | 17375-41-6   | iron(II)sulfate monohydrate         |
|   | 7782-63-0  | iron(II)sulfate heptahydrate        |
| EC No (EINECS or ELINCS) ‡  | 231-753-5  | iron(II)sulfate anhydrous           |
| FAO Specification (including year of publication) ‡   | None   |                                     |
| Minimum purity of the active substance as manufactured ‡  | iron(II)sulfate anhydrous:<br>Min. 350 g/kg total iron |                                     |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | arsenic  | 18 mg/kg                            |
|   | cadmium  | 1.8 mg/kg                           |
|   | chromium   | 90 mg/kg                            |
|   | lead   | 36 mg/kg                            |
|   | mercury  | 1.8 mg/kg                           |
|   | expressed on the basis of the anhydrous variant        |                                     |
| Molecular formula ‡   | iron(II) sulfate anhydrous                             | FeO <sub>4</sub> S                  |
|   | iron(II) sulfate monohydrate                           | FeH <sub>2</sub> O <sub>5</sub> S   |
|   | iron(II) sulfate heptahydrate                          | FeH <sub>14</sub> O <sub>11</sub> S |
| Molecular mass ‡  | iron(II) sulfate anhydrous                             | 151.8 g/mol                         |
|   | iron(II) sulfate monohydrate                           | 169.9 g/mol                         |
|   | iron(II) sulfate heptahydrate                          | 277.8 g/mol                         |
| Structural formula ‡  | iron(II)sulfate anhydrous, FeSO <sub>4</sub>           |                                     |



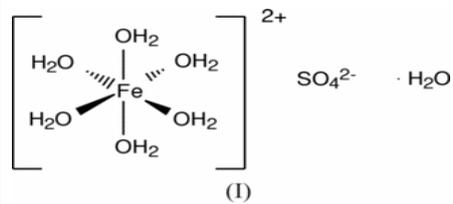
iron(II)sulfate monohydrate,  $\text{FeSO}_4 \cdot \text{H}_2\text{O}$



iron(II)sulfate heptahydrate,  $[\text{Fe}(\text{H}_2\text{O})_6]\text{SO}_4 \cdot \text{H}_2\text{O}$



i.e.:



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

|   |   |
|---|---|
| Melting point (state purity) ‡  | 90 °C (iron(II)sulfate heptahydrate)  |
| Boiling point (state purity) ‡  | 300 °C (iron(II)sulfate heptahydrate)   |
| Temperature of decomposition (state purity)                           | >300 °C (unknown)   |
| Appearance (state purity) ‡   | Pale green crystalline solid (unknown, assumed pure)  |
| Vapour pressure (state temperature, state purity) ‡                   | < 10 <sup>-5</sup> Pa at 20°C (not applicable)  |
| Henry's law constant ‡  | < 6 x 10 <sup>-7</sup> Pa m <sup>3</sup> mol <sup>-1</sup>  |
| Solubility in water (state temperature, state purity and pH) ‡        | 256-266 g/L at 20 °C (unknown pH) (unknown, assumed pure)   |
|   | 486 g/L at 50 °C  |
| Solubility in organic solvents ‡ (state temperature, state purity)    | not soluble in non-polar organic solvents   |
| Surface tension ‡ (state concentration and temperature, state purity) | Not relevant. Iron(II)sulfate is a fully dissociating salt and thus it is not expected to be surface active.              |
| Partition co-efficient ‡ (state temperature, pH and purity)           | In non-polar organic solvents the salt iron(II)sulfate is not soluble. Therefore, log K <sub>ow</sub> was not determined. |
| Dissociation constant (state purity) ‡                                | Iron(II)sulfate is a salt that completely dissociates in water.   |
| UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)                 | UV spectra from literature source submitted. Measured in range 220-450 nm. No strong absorbance at any wavelength.        |
| Flammability ‡ (state purity)   | Iron(II)sulfate does not contain chemical groups that can be ignited with a flame.  |
| Explosive properties ‡ (state purity)                                 | Not relevant as there is no gaseous development when iron(II)sulfate is sulfate by air.                                   |
| Oxidising properties ‡ (state purity)                                 | Considering the chemical structure of ferrous sulfate, oxidising properties are not expected.                             |

Summary of representative uses evaluated (*Iron sulfate*)

| Crop and/or situation<br>(a) | Member State or Country       | Product name  | F G or I<br>(b) | Pests or Group of pests controlled<br>I | Preparation   |  | Application          |                              |                        |  | Application rate per treatment<br>(for explanation see the text in front of this section) |                    |   | PHI (days)<br>(m) | Remarks |
|------------------------------|-------------------------------|---|-----------------|---|---------------|--|----------------------|------------------------------|------------------------|--|---|--------------------|---|-------------------|---------|
|                              |                               |   |                 |   | Type<br>(d-f) | Conc. Of a.s.<br>(i)                                       | method kind<br>(f-h) | growth stage & season<br>(j) | number min/ max<br>(k) | interval between applications<br>(min) | g a.s./hL min-max<br>(l)  | Water L/ha min-max | kg a.s./ha min – max<br>(l)                 |                   |         |
| Sports and amenity turf      | EU<br>(registered in Germany) | Stodiek Moosvernichter mit Rasendünger (= MV Rasen Floranid, COMPO) | F               | Moss                                    | GR            | 238 g/kg FeSO <sub>4</sub><br>(436 g/kg a.s. heptahydrate) | Strewing             | May to August                | 2                      | 40 days                                | Not applicable  | Not applicable     | 300 kg product<br>71.4 kg FeSO <sub>4</sub> | *                 | -       |

\* = The waiting period is covered by the conditions of use and/or the vegetation period which remains between application and use (e.g. harvest), respectively. The definition of a waiting period is not necessary.

|   |  |
|---|--|
| <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. benthialdicarb-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> |
|---|--|

## Methods of Analysis

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

|   |   |
|---|---|
| Technical as (analytical technique)               | ICP-OES (AES)                           |
| Impurities in technical as (analytical technique) | ICP-AES<br>Data gap for validation data |
| Plant protection product (analytical technique)   | CIPAC MT 95.1.3                         |

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

#### Residue definitions for monitoring purposes

|                       |  |
|-----------------------|--|
| Food of plant origin  | Not applicable   |
| Food of animal origin | Not applicable   |
| Soil                  | Not applicable.<br>Residue definition in soil is not required. |
| Water surface         | Fe   |
| drinking/ground       | Fe   |
| Air                   | Not applicable. Residue definition in air is not required.     |

#### Monitoring/Enforcement methods

|   |                |
|---|----------------|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)  | Not applicable |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Not applicable |
| Soil (analytical technique and LOQ)   | Not applicable |
| Water (analytical technique and LOQ)  | Data gap       |
| Air (analytical technique and LOQ)  | Not applicable |
| Body fluids and tissues (analytical technique and LOQ)  | Not applicable |

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

|                  |                          |
|------------------|--------------------------|
|                  | RMS/peer review proposal |
| Active substance | Not classified           |

## Impact on Human and Animal Health

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

|   |  |
|---|--|
| Rate and extent of oral absorption ‡                      | Rapidly absorbed (10 % up to 60 % in case of iron deficiency) within 2 to 6 hours.   |
| Distribution ‡  | Human data: Uniformly distributed via blood. Greatest concentrations in liver, bone marrow, and spleen.  |
| Potential for accumulation ‡                              | Human data: Excessive iron is stored in liver, endocrine organs (pancreas) and spleen.   |
| Rate and extent of excretion ‡                            | Human data: 0.01 to 0.02 % of the absorbed iron are excreted daily.  |
| Metabolism in animals ‡                                   | Fe <sup>2+</sup> and Fe <sup>3+</sup> can be converted into each other. Most iron is bound to proteins such as haemoglobin, myoglobin, ferritin, and haemosiderin. |
| Toxicologically relevant compounds ‡ (animals and plants) | Parent compound and dissociated forms: Fe(II) and Fe (III)   |
| Toxicologically relevant compounds ‡ (environment)        | Parent compound and dissociated forms: Fe(II) and Fe (III)   |

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

|                                   |   |
|-----------------------------------|---|
| Rat LD <sub>50</sub> oral ‡       | 1185 – 1750 mg/kg bw FeSO <sub>4</sub> (R22)<br>'Harmful if swallowed'  |
| Rat LD <sub>50</sub> dermal ‡     | No data were available.<br>From the molecular structure (inorganic salt), it is suggested that it is unlikely that significant amounts of ferrous sulfate (Fe(II)SO <sub>4</sub> ) can be resorbed through intact skin.   |
| Rat LC <sub>50</sub> inhalation ‡ | No data – not necessary.<br>The active substance is neither applied as a dust with a particle size of less than 50 µm nor as an aerosol. Furthermore, the vapour pressure of the inorganic salt is negligible at ambient temperature. Therefore, no toxicologically relevant exposure occurs. |
| Skin irritation ‡                 | Irritant. Classified with R38 (human data – precautionary, based on physical properties, only one old reference with other citations in literature as moderate irritant without further evidence  |
| Eye irritation ‡                  | Irritant (R36) (human data – precautionary, based on physical properties, only one old reference)   |

|                      |                 |  |
|----------------------|-----------------|--|
| Skin sensitisation ‡ | Non-sensitising |  |
|----------------------|-----------------|--|

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

|                             |   |  |
|-----------------------------|---|--|
| Target / critical effect ‡  | Mice: liver and spleen / haemosiderosis                             |  |
| Relevant oral NOAEL ‡       | 90-day study in mice: 120 ppm (100 mg/kg bw/day FeSO <sub>4</sub> ) |  |
| Relevant dermal NOAEL ‡     | No data   |  |
| Relevant inhalation NOAEL ‡ | No data   |  |

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

|   |  |
|---|--|
| Overall, no genotoxic potential based on a range of <i>in vitro</i> and <i>in vivo</i> studies including negative in <i>S. typhimurium</i> point mutation assay; genetic analysis for induction of diploid and aneuploid cells in <i>Saccharomyces cerevisiae</i> ; and negative <i>in vivo</i> micronucleus assays in 57 BL mice and in male ddY mice at dose levels of up to 180 mg/kg bw. Positive finding in <i>in vitro</i> chromosomal aberration study in Chinese hamster fibroblasts. |  |
|---|--|

**Long term toxicity and carcinogenicity (Annex IIA, point 5.5)**

|                          |  |  |
|--------------------------|--|--|
| Target/critical effect ‡ | No data – not necessary                |  |
| Relevant NOAEL ‡         | No data                                |  |
| Carcinogenicity ‡        | No carcinogenic potential (human data) |  |

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

**Reproduction toxicity**

|   |         |  |
|---|---------|--|
| Reproduction target / critical effect ‡ | No data |  |
| Relevant parental NOAEL ‡               | No data |  |
| Relevant reproductive NOAEL ‡           | No data |  |
| Relevant offspring NOAEL ‡              | No data |  |

**Developmental toxicity**

|  |  |  |
|--|--|--|
| Developmental target / critical effect ‡ | Reduced body weight in dams at 1200 mg/kg bw/day. Increase in dams with no |  |
|--|--|--|

|                                |   |  |
|--------------------------------|---|--|
|                                | live fetuses and increased implantation loss at 1200 mg/kg bw/day.                    |  |
| Relevant maternal NOAEL ‡      | 380 mg/kg bw/day FeSO <sub>4</sub> – rat<br>380 mg/kg bw/day FeSO <sub>4</sub> – mice |  |
| Relevant developmental NOAEL ‡ | 380 mg/kg bw/day FeSO <sub>4</sub> – rat<br>380 mg/kg bw/day FeSO <sub>4</sub> – mice |  |

### Neurotoxicity (Annex IIA, point 5.7)

|                          |  |  |
|--------------------------|--|--|
| Acute neurotoxicity ‡    | No potential to induce neurotoxicity (human data). |  |
| Repeated neurotoxicity ‡ | No data  |  |
| Delayed neurotoxicity ‡  | No data  |  |

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

|  |   |
|--|---|
| Mechanism studies ‡                              | No data   |
| Studies performed on metabolites or impurities ‡ | No data. Statutory limits are available for naturally occurring impurities. |

### Medical data ‡ (Annex IIA, point 5.9)

|                       |  |
|-----------------------|--|
| ADME:                 | <ul style="list-style-type: none"> <li>- 10 % absorbed up to 60 % in case of iron deficiency</li> <li>- 0.01 % to 0.02 % of the resorbed dose excreted via urine, faeces, sweat, hair and skin</li> <li>- uniformly distributed mainly in organs having iron containing enzymes</li> <li>-</li> <li>- stored in liver, spleen, endocrine tissues, and heart</li> <li>- Fe<sup>2+</sup> is oxidised to Fe<sup>3+</sup> which can be reduced, most Fe bound to proteins</li> </ul> |
| acute intoxications:  | <ul style="list-style-type: none"> <li>- vomiting</li> <li>- GIT bleeding</li> <li>- diarrhoea</li> <li>- liver dysfunction</li> </ul>   |
| chronic intoxication: | <ul style="list-style-type: none"> <li>- liver / haemosiderosis / cirrhosis</li> <li>- spleen / haemosiderosis</li> <li>- kidney / renal failure</li> </ul>  |
|                       | GIT / fibrosis   |

**Summary (Annex IIA, point 5.10)**

|        | Value                           | Study  | Safety factor               |
|--------|---------------------------------|--|-----------------------------|
| ADI ‡  | 0.8 mg/kg bw/day (ferrous iron) | Derived from human intakes   | Not required                |
|        | 12.5 mg/kg bw/day (sulfate ion) | Derived from human intakes   | Not required                |
| AOEL ‡ | 0.4 mg/kg bw/day (Ferrous iron) | Derived from human intakes, supported by teratogenicity study in mice and rats | (50 % oral bioavailability) |
|        | 1.3 mg/kg bw/day (sulfate ion)  | Human data   | Not required                |
| ARfD ‡ | Not required                    | -  | -                           |

**Dermal absorption ‡ (Annex IIIA, point 7.3)**

Formulation (e.g. name 50 % EC)

10 % default-

**Exposure scenarios (Annex IIIA, point 7.2)**

Operator

Based on representative exposure data in <sup>Ψ</sup>PHED:

- Exposure to operators using hand-held equipment (e.g. belly-grinders) is estimated to be 1079 % and 571 % of the AOELs for iron and sulfate ions, respectively.
- Exposure to operators using pedestrian-controlled application equipment (e.g. Scotts Residential type equipment) is estimated to be 42.5 % and 23 % of the AOELs for iron and sulfate ion, respectively.

<sup>Ψ</sup>Estimates assume operators wearing gloves and normal work wear during loading and application in line with the PPE worn in the PHED studies.

|                            |  |
|----------------------------|--|
| Children's Exposure        | <p><u>Ferrous iron</u></p> <p>The total systemic exposure to iron for a child playing immediately after treatment is calculated to be 1.09 mg/kg bw/day, which is equivalent to 273 % of the AOEL for iron .</p> <p><u>Sulfate</u></p> <p>The total systemic exposure to sulfate for a child playing on turf immediately after treatment is calculated to be 1.9 mg/kg bw/day, equivalent to 146 % of the AOEL for sulfate (1.3 mg/kg bw/day).</p> |
| Worker (Re-entry) Exposure | <p>Worker exposure predicted for dermal contact with treated turf during maintenance tasks (adapted US EPA model). Predicted exposures 16% of AOEL for iron and 8 % of AOEL for sulfate.</p>   |
| Bystanders                 | <p>Bystander exposure is unlikely.</p>   |

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

|  |   |
|--|---|
| Substance classified (ferrous sulfate) | <p>RMS/peer review proposal</p> <p>R22 – ‘Harmful if swallowed’ (based on data)</p> <p>R38 – ‘Irritating to skin’ (precautionary – indicated in human data but with limited characterisation of effect)</p> <p>R36 – ‘Irritating to eyes’ (precautionary – indicated in human data but with limited characterisation of effect)</p> |
|--|---|

## Residues

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

|   |                                 |
|---|---------------------------------|
| Plant groups covered  | Not applicable as no edible use |
| Rotational crops  | Not applicable as no edible use |
| Metabolism in rotational crops similar to metabolism in primary crops?                  | Not applicable as no edible use |
| Processed commodities   | Not applicable as no edible use |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Not applicable as no edible use |
| Plant residue definition for monitoring   | Not applicable as no edible use |
| Plant residue definition for risk assessment  | Not applicable as no edible use |
| Conversion factor (monitoring to risk assessment)                                       | Not applicable as no edible use |

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

|   |                                 |
|---|---------------------------------|
| Animals covered   | Not applicable as no edible use |
| Time needed to reach a plateau concentration in milk and eggs | Not applicable as no edible use |
| Animal residue definition for monitoring                      | Not applicable as no edible use |
| Animal residue definition for risk assessment                 | Not applicable as no edible use |
| Conversion factor (monitoring to risk assessment)             | Not applicable as no edible use |
| Metabolism in rat and ruminant similar (yes/no)               | Not applicable as no edible use |
| Fat soluble residue: (yes/no)                                 | Not applicable as no edible use |

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

Not applicable as no edible use

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

Not applicable as no edible use

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

|   | <b>Ruminant:</b>   | <b>Poultry:</b> | <b>Pig:</b> |
|---|--|-----------------|-------------|
| Expected intakes by livestock $\geq 0.1$ mg/kg diet (dry weight basis) (yes/no - If yes, specify the level) | Not applicable as no edible use  |                 |             |
| Potential for accumulation (yes/no):  | Not applicable as no edible use  |                 |             |
| Metabolism studies indicate potential level of residues $\geq 0.01$ mg/kg in edible tissues (yes/no)        | Not applicable as no edible use  |                 |             |
|   | Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant)<br>Residue levels in matrices : Mean (max) mg/kg |                 |             |
| Muscle  | Not applicable as no edible use  |                 |             |
| Liver   | Not applicable as no edible use  |                 |             |
| Kidney  | Not applicable as no edible use  |                 |             |
| Fat   | Not applicable as no edible use  |                 |             |
| Milk  | Not applicable   |                 |             |
| Eggs  |  | Not applicable  |             |

**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<br>(a) | Recommendation/comments | MRL estimated from trials according to the representative use | HR<br>(c) | STMR<br>(b) |
|---------------------------------|---|---|-------------------------|---|-----------|-------------|
| Not applicable as no edible use |   |   |                         |   |           |             |

(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

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

|  |  |
|--|--|
| ADI  | 0.8 mg/kg bw/day (ferrous iron)<br>12.5 mg/kg bw/day (sulfate ion) |
| TMDI (% ADI) according to WHO European diet                | Not applicable as no edible use                                    |
| TMDI (% ADI) according to national (to be specified) diets | Not applicable as no edible use                                    |
| IEDI (WHO European Diet) (% ADI)                           | Not applicable as no edible use                                    |
| NEDI (specify diet) (% ADI)                                | Not applicable as no edible use                                    |
| Factors included in IEDI and NEDI                          | Not applicable as no edible use                                    |
| ARfD   | Not required   |
| IESTI (% ARfD)   | Not relevant   |
| NESTI (% ARfD) according to national (to be specified)     | Not relevant   |
| Factors included in IESTI and NESTI                        | Not relevant   |

**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 |                                   |
| Not applicable as no edible use  |                   |                    |              |                                   |

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

Not applicable as no edible use

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

**Fate and behaviour in the environment**

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

|   |                |
|---|----------------|
| Mineralization after 100 days ‡   | Not applicable |
| Non-extractable residues after 100 days ‡   | Not applicable |
| Metabolites requiring further consideration ‡<br>- name and/or code, % of applied (range and maximum) | Not applicable |

Iron sulfate is an inorganic salt that dissociates in the soil solution to iron- and sulfate-ions. Both iron- and sulfate-ions are naturally occurring components of terrestrial ecosystems.

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

|   |                |
|---|----------------|
| Anaerobic degradation ‡   |                |
| Mineralization after 100 days   | Not applicable |
| Non-extractable residues after 100 days   | Not applicable |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | Not applicable |
| Soil photolysis ‡   |                |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | Not applicable |

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

Laboratory studies ‡

|        |                    |
|--------|--------------------|
| Parent | Aerobic conditions |
|        | Not applicable     |

|       |                    |
|-------|--------------------|
| Met 1 | Aerobic conditions |
|       | Not applicable     |

Field studies ‡

|        |                    |
|--------|--------------------|
| Parent | Aerobic conditions |
|        | Not applicable     |

|       |                    |
|-------|--------------------|
| Met 1 | Aerobic conditions |
|       | Not applicable     |

pH dependence ‡  
(yes / no) (if yes type of dependence)

Not applicable

Soil accumulation and plateau concentration ‡

Not applicable

Laboratory studies ‡

|        |                      |
|--------|----------------------|
| Parent | Anaerobic conditions |
|        | Not applicable       |

|       |                      |
|-------|----------------------|
| Met 1 | Anaerobic conditions |
|       | Not applicable       |

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

|   |  |
|---|--|
| <b>Sulfate</b> ‡  |  |
| Mobile in soils and readily leached (Kf 2.6 – 21.1)   |  |
| pH dependence, Yes or No  | Yes. Sorption increases with decreasing pH. Above pH 6 all sulfate is found in solution. |
| <b>Iron</b>   |  |
| Under typical aerobic environmental conditions (pH 5 – pH 9), the highly soluble Fe (II) salts will be rapidly oxidised to less soluble Fe (III) oxides and hydroxides. Due to the low solubility of the oxide/hydroxide forms, the concentration of dissolved Fe in the soil solution is rather low (< 0.01 - 0.5 mg/L). |  |

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

**Parent**

Method of calculation

Application data

|  |
|--|
| DT <sub>50</sub> (d): No degradation considered  |
| Field or Lab: Not applicable   |
| Crop: grass  |
| Depth of soil layer: 5 cm.   |
| Soil bulk density: 1.5 g/cm <sup>3</sup>   |
| % plant interception: 40%  |
| Number of applications: 2*   |
| Interval (d): 40 d *   |
| Application rate(s):   |
| Fe: 26.25 kg a.s./ha, SO <sub>4</sub> <sup>2-</sup> : 45.15 kg a.s./ha   |
| FeSO <sub>4</sub> ·7 H <sub>2</sub> O: 130.8 kg a.s./ha  |
| *Since no degradation is assumed, the PECsoil calculation is based on a total load of 52.5 kg a.s./ha (Fe), 90.3 kg a.s./ha (SO <sub>4</sub> <sup>2-</sup> ) and 261.6 kg a.s./ha (FeSO <sub>4</sub> ·7 H <sub>2</sub> O). |

| PEC <sub>(s)</sub><br>(mg/kg) | Iron (Fe) | Iron (Fe)             | Sulfate | Sulfate               |
|-------------------------------|-----------|-----------------------|---------|-----------------------|
|                               | Actual    | Time weighted average | Actual  | Time weighted average |
| Initial                       | 42        | -                     | 72.2    | -                     |

**Impurities I**

Method of calculation

Application data

|   |
|---|
| The calculation of PECsoil for impurities are based on the % impurities and PECsoil for iron (42 mg/kg) |
| Application rate assumed: total load of 52.5 kg a.s./ha (Fe) corrected for mol. mass                    |

|                                     |                |  |                |  |
|-------------------------------------|----------------|--|----------------|--|
| <b>PEC<sub>(s)</sub></b><br>(mg/kg) | Impurity       | Content in techn. material anhyd max % | PEC(s) initial |  |
|                                     | Arsenic        | 0.0018                                 | 0.0021         |  |
|                                     | Chromium       | 0.009                                  | 0.0103         |  |
|                                     | Cadmium        | 0.00018                                | 0.0002         |  |
|                                     | Lead           | 0.0036                                 | 0.0041         |  |
|                                     | Mercury        | 0.00018                                | 0.0002         |  |
| Plateau concentration               | Not applicable |  |                |  |

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

|   |                                   |
|---|-----------------------------------|
| Hydrolytic degradation of the active substance and metabolites > 10 % ‡   | pH 5: Not applicable              |
|   | pH 7: Not applicable              |
|   | pH 9: Not applicable              |
| Photolytic degradation of active substance and metabolites above 10 % ‡   | Not applicable                    |
| Quantum yield of direct phototransformation in water at $\Sigma > 290$ nm | Not applicable                    |
| Readily biodegradable ‡ (yes/no)  | Not applicable to inorganic salts |

**Degradation in water / sediment**

|   |   |
|---|---|
| Parent                                      | Not applicable  |
| Mineralization and non extractable residues | Iron sulfate is an inorganic salt with high solubility in water. When dissolved in water, it readily dissociates to iron- and sulfate ions. |

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

|  |   |
|--|---|
| <b>Parent</b><br>Parameters used in FOCUSsw step 1 and 2 | Version control no. of FOCUS calculator:<br>FOCUS Steps 1-2 v 1.1<br>Molecular weight (g/mol): Fe 55.9, SO <sub>4</sub> <sup>2-</sup> 96.06<br>Water solubility (mg/L): 266000<br>K <sub>OC</sub> (L/kg): Fe <sup>2+</sup> , SO <sub>4</sub> <sup>2-</sup> = 0<br>DT <sub>50</sub> soil (d): Fe <sup>2+</sup> = 1, SO <sub>4</sub> <sup>2-</sup> = 1000 d<br>DT <sub>50</sub> water/sediment system (d): Fe <sup>2+</sup> = 1 d SO <sub>4</sub> <sup>2-</sup> = 1000<br>DT <sub>50</sub> water (d): Fe <sup>2+</sup> = 1 d, SO <sub>4</sub> <sup>2-</sup> = 1000 d<br>DT <sub>50</sub> sediment (d): Fe <sup>2+</sup> = 1 d, SO <sub>4</sub> <sup>2-</sup> = 1000 d<br>Crop interception (%): 40% |
| Parameters used in FOCUSsw step 3 (if performed)         | Not performed   |
| Application rate   | Crop interception: 40%<br>Number of applications: 2<br>Interval (d): 40<br>Application rate(s): 26250 g Fe <sup>2+</sup> /ha<br>45150 g SO <sub>4</sub> <sup>2-</sup> /ha<br>Route of entry: Runoff/drainage only   |

**Fe<sup>2+</sup>**

| FOCUS STEP 1<br>Scenario | Day after<br>overall<br>maximum | PEC <sub>sw</sub> (µg/L) |          |
|--------------------------|---------------------------------|--------------------------|----------|
|                          |                                 | Actual                   | TWA      |
|                          | 0 h                             | 5.25E+03                 |          |
|                          | 24 h                            | 2.63E+03                 | 3.94E+03 |
|                          | 2 d                             | 1.31E+03                 | 2.92E+03 |
|                          | 4 d                             | 328.125                  | 1.81E+03 |
|                          | 7 d                             | 41.0156                  | 1.1E+03  |
|                          | 14 d                            | 0.3204                   | 551.722  |
|                          | 21 d                            | 0.0025                   | 367.837  |
|                          | 28 d                            | 0.0000                   | 275.878  |
|                          | 42 d                            | 0.0000                   | 183.918  |

| FOCUS STEP 2<br>Scenario   | Day after<br>overall<br>maximum | PEC <sub>sw</sub> (µg/L) |         |
|----------------------------|---------------------------------|--------------------------|---------|
|                            |                                 | Actual                   | TWA     |
| Northern EU<br>(Oct – Feb) | 0 h                             | 164.063                  |         |
|                            | 24 h                            | 82.031                   | 123.047 |
|                            | 2 d                             | 41.016                   | 92.285  |
|                            | 4 d                             | 10.254                   | 57.678  |
|                            | 7 d                             | 1.282                    | 34.882  |
|                            | 14 d                            | 0.010                    | 17.577  |
|                            | 21 d                            | 0.000                    | 11.719  |
|                            | 28 d                            | 0.000                    | 8.789   |
|                            | 42 d                            | 0.000                    | 5.859   |

SO<sub>4</sub><sup>2-</sup>

| FOCUS STEP 1<br>Scenario | Day after overall maximum | PEC <sub>sw</sub> (µg/L) |          |
|--------------------------|---------------------------|--------------------------|----------|
|                          |                           | Actual                   | TWA      |
|                          | 0 h                       | 1.81E+04                 |          |
|                          | 24 h                      | 1.8E+04                  | 1.81E+04 |
|                          | 2 d                       | 1.8E+04                  | 1.8E+04  |
|                          | 4 d                       | 1.8E+04                  | 1.8E+04  |
|                          | 7 d                       | 1.8E+04                  | 1.8E+04  |
|                          | 14 d                      | 1.79E+04                 | 1.8E+04  |
|                          | 21 d                      | 1.78E+04                 | 1.79E+04 |
|                          | 28 d                      | 1.77E+04                 | 1.79E+04 |
|                          | 42 d                      | 1.75E+04                 | 1.78E+04 |

| FOCUS STEP 2<br>Scenario   | Day after overall maximum | PEC <sub>sw</sub> (µg/L) |          |
|----------------------------|---------------------------|--------------------------|----------|
|                            |                           | Actual                   | TWA      |
| Northern EU<br>(Oct – Feb) | 0 h                       | 8.88E+03                 |          |
|                            | 24 h                      | 8.88E+03                 | 8.88E+03 |
|                            | 2 d                       | 8.87E+03                 | 8.88E+03 |
|                            | 4 d                       | 8.86E+03                 | 8.87E+03 |
|                            | 7 d                       | 8.84E+03                 | 8.86E+03 |
|                            | 14 d                      | 8.8E+03                  | 8.84E+03 |
|                            | 21 d                      | 8.75E+03                 | 8.82E+03 |
|                            | 28 d                      | 8.71E+03                 | 8.8E+03  |
|                            | 42 d                      | 8.63E+03                 | 8.75E+03 |

Metabolite X

No metabolites

**Impurities**  
(µg/L)

| Calculation based on the max % impurities and the Step 2 PEC <sub>sw</sub> for iron (164 µg/L) |  |                          |
|--|--|--------------------------|
| Impurity   | Content in techn. material anhyd max % | PEC <sub>sw</sub> (µg/L) |
| Arsenic  | 0.0018                                 | 0.0080                   |
| Chromium   | 0.009                                  | 0.0401                   |
| Cadmium  | 0.00018                                | 0.0008                   |
| Lead   | 0.0036                                 | 0.0160                   |

|         |         |        |
|---------|---------|--------|
| Mercury | 0.00018 | 0.0008 |
|---------|---------|--------|

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

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

| Calculation based on the 80 <sup>th</sup> percentile water volume percolated at 1 m depth using the FOCUS scenario grass (FOCUS PELMO 3.3.2) and total load 52.5 kg Fe and 90.3 kg SO <sub>4</sub> .<br>Crop: grass |                              |                               |  |
|---|------------------------------|-------------------------------|--|
| Scenario  | Recharge (L/m <sup>2</sup> ) | PECgw Fe <sup>2+</sup> (mg/L) | PECgw SO <sub>4</sub> <sup>2-</sup> (mg/L) |
| Porto   | 384.3                        | 13.7                          | 23.5                                       |
| Sevilla   | 36.1                         | 145.4                         | 249.9                                      |

**Impurities (µg/L)**

| Calculation based on the max % impurities and the worst case PECgw for iron (145.4 mg/L) from the Sevilla scenario |  |              |
|--|--|--------------|
| Impurity   | Content in techn. material anhyd max % | PECgw (µg/L) |
| Arsenic  | 0.0018                                 | 2.6          |
| Chromium   | 0.009                                  | 13.1         |
| Cadmium  | 0.00018                                | 0.3          |
| Lead   | 0.0036                                 | 5.2          |
| Mercury  | 0.00018                                | 0.3          |

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

|  |   |
|--|---|
| Direct photolysis in air ‡                   | Not studied - no data requested                 |
| Quantum yield of direct phototransformation  | Not determined                                  |
| Photochemical oxidative degradation in air ‡ | Not calculated                                  |
| Volatilisation ‡                             | from plant surfaces (BBA guideline): negligible |
|  | from soil surfaces (BBA guideline): negligible  |
| Metabolites                                  | None  |

**PEC (air)**

|                       |  |
|-----------------------|--|
| Method of calculation | Expert judgement, based on vapour pressure, dimensionless Henry's Law Constant and information on volatilisation from plants and soil. |
|-----------------------|--|

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

|                       |            |
|-----------------------|------------|
| Maximum concentration | Negligible |
|-----------------------|------------|

**Residues requiring further assessment**

|   |  |
|---|--|
| Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology), and or requiring consideration for groundwater exposure. | <p>Soil: iron ions, sulfate ions (provisional pending on data gap)</p> <p>Surface water: iron ions, sulfate ions (provisional pending on data gap)</p> <p>Sediment: iron ions, sulfate ions (provisional pending on data gap)</p> <p>Ground water: iron ions, sulfate ions, and relevant impurities arsenic ions, cadmium ions, chromium ions, lead ions and mercury ions.</p> <p>Air: -</p> |
|---|--|

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

|   |                |
|---|----------------|
| Soil (indicate location and type of study)          | Not applicable |
| Surface water (indicate location and type of study) | Not applicable |
| Ground water (indicate location and type of study)  | Not applicable |
| Air (indicate location and type of study)           | Not applicable |

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

|                |
|----------------|
| Not applicable |
|----------------|

## Ecotoxicology

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

| Species                                 | Test substance                 | Time scale | End point<br>(mg<br>FeSO <sub>4</sub> /kg<br>bw/(day)) | End point<br>(mg/kg feed) |
|---|--------------------------------|------------|--|---------------------------|
| <b>Birds ‡</b>                          |                                |            |  |                           |
| <i>Colin virginianus</i>                | iron (II) sulfate <sup>1</sup> | Acute      | >1230.75   | -                         |
| <i>Colin virginianus</i>                | iron (II) sulfate <sup>1</sup> | Short-term | >683.1   | -                         |
| <i>Anas platyrhynchos</i>               | iron (II) sulfate <sup>1</sup> | Short-term | >783.3   | -                         |
|   |                                | Long-term  | No data submitted.                                     | -                         |
| <b>Mammals ‡</b>                        |                                |            |  |                           |
| Rat                                     | Iron(II)sulfate heptahydrate   | Acute      | 1185 mg FeSO <sub>4</sub> 7H <sub>2</sub> O /kg bw     | -                         |
|   |                                | Long-term  | No data submitted.                                     | -                         |
| <b>Additional higher tier studies ‡</b> |                                |            |  |                           |
| No data submitted.                      |                                |            |  |                           |

<sup>1</sup> Tested as iron (II) sulfate heptahydrate. A conversion factor of 0.547 has been applied to the toxicity endpoint to take account of the molecular weight of the seven water molecules.

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

Granular application to sports and amenity turf (71.4 kg FeSO<sub>4</sub>/ha)

| Indicator species/Category | Time scale | ETE | TER <sup>1</sup> | Annex VI Trigger |
|----------------------------|------------|-----|------------------|------------------|
| <b>Tier 1 (Birds)</b>      |            |     |                  |                  |
|                            | Acute      | -   | n/a <sup>1</sup> | 10               |
|                            | Short-term | -   | n/a <sup>1</sup> | 10               |
|                            | Long-term  | -   | n/a <sup>2</sup> | 5                |
| <b>Tier 1 (Mammals)</b>    |            |     |                  |                  |
|                            | Acute      | -   | n/a <sup>1</sup> | 10               |
|                            | Long-term  | -   | n/a <sup>2</sup> | 5                |

<sup>1</sup> Proposed application of iron (II) sulfate is as a granule to sports and amenity turf. As such, standard TER calculations were not considered necessary. However, an avian risk assessment, according to EPPO 2003, has been conducted by the notifier and was included in Vol. 3, B.9.1.7.2 of the DAR (The United Kingdom, 2007).

<sup>2</sup> No long-term exposure predicted for the representative use of iron (II) sulfate as a granule.

**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<br>(Test type) | End point   | Toxicity<br>(mg/L)   |
|---|--|---------------------------|---|--|
| Laboratory tests ‡                          |  |                           |   |  |
| Fish  |  |                           |   |  |
| Zebra fish<br><i>Brachydanio rerio</i>      | iron (II) sulfate <sup>1</sup>           | 96 hr (semi-static)       | Mortality, <sub>nom</sub> LC <sub>50</sub>                            | 181.1 mg FeSO <sub>4</sub> /L  |
| Rainbow trout<br><i>Oncorhynchus mykiss</i> | iron (II) sulfate <sup>1</sup>           | 96 hr (flow-through)      | Mortality, <sub>nom</sub> LC <sub>50</sub>                            | 45.1 mg FeSO <sub>4</sub> /L <sup>2</sup>  |
| <i>Oncorhynchus mykiss</i>                  | iron (II) sulfate                        | 21 d (semi-static)        | Growth <sub>nom</sub> NOEC  | 3.4 mg FeSO <sub>4</sub> /L  |
| Aquatic invertebrate                        |  |                           |   |  |
| <i>Daphnia magna</i>                        | iron (II) sulfate <sup>1</sup>           | 48-hour (semi-static)     | Mortality, <sub>mm</sub> EC <sub>50</sub>                             | 31.2 mg FeSO <sub>4</sub> /L   |
| <i>Daphnia magna</i>                        | iron (II) sulfate                        | 21 d (semi-static)        | Reproduction, <sub>nom</sub> NOEC                                     | Less than 1.08 mg FeSO <sub>4</sub> /L   |
| Sediment dwelling organisms                 |  |                           |   |  |
|   |  |                           |   | No data submitted.   |
| Algae                                       |  |                           |   |  |
| <i>Anabaena variabilis</i>                  | iron (II) sulfate <sup>1</sup>           | 96 h (static)             | Biomass: <sub>nom</sub> E <sub>b</sub> C <sub>50</sub>                | 36.2 mg FeSO <sub>4</sub> /L   |
|   |  |                           | Growth rate: <sub>nom</sub> E <sub>r</sub> C <sub>50</sub>            | >76.6 mg FeSO <sub>4</sub> /L  |
| <i>Chlorella vulgaris</i>                   | iron (II) sulfate                        | 72 h (static)             | Growth rate: <sub>nom</sub> E <sub>r</sub> C <sub>50</sub>            | 22 FeSO <sub>4</sub> mg /L   |
|   |  |                           |   |  |
| <i>Selenastrum capricornutum</i>            | ‘Stodiek Moosvernichter mit Rasendünger’ | 72-hour static            | Biomass and growth rate <sub>nom</sub> EC <sub>50</sub>               | >100 mg formulation/L, (corresponding to 9.4 mg Fe/L or 23.8 mg FeSO <sub>4</sub> /L) <sup>2</sup> |
| Higher plant                                |  |                           |   |  |
| <i>Lemna gibba</i>                          | iron (II) sulfate <sup>1</sup>           | 7 d (semi-static)         | Biomass, growth rate and frond number <sub>nom</sub> EC <sub>50</sub> | >103.4 mg FeSO <sub>4</sub> /L   |
| Microcosm or mesocosm tests                 |  |                           |   |  |
| No data available - Not required            |  |                           |   |  |

nominal (<sub>nom</sub>) or mean measured concentrations (<sub>mm</sub>).

<sup>1</sup> Tested as iron (II) sulfate heptahydrate. A conversion factor of 0.547 has been applied to the toxicity endpoint to take account of the molecular weight of the seven water molecules.

<sup>2</sup> The test concentrations were not maintained 80% to 120% of nominal concentrations.

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

#### FOCUS Step1

| Test substance | Organism                    | Toxicity end point (mg/L) | Time scale | PEC <sub>i</sub> | PEC <sub>twa</sub> | TER              | Annex VI Trigger |
|----------------|-----------------------------|---------------------------|------------|------------------|--------------------|------------------|------------------|
| a.s.           | Fish                        |                           | Acute      |                  |                    | n/a <sup>1</sup> | 100              |
| a.s.           | Fish                        |                           | Chronic    |                  |                    | n/a <sup>1</sup> | 10               |
| a.s.           | Aquatic invertebrates       |                           | Acute      |                  |                    | n/a <sup>1</sup> | 100              |
| a.s.           | Aquatic invertebrates       |                           | Chronic    |                  |                    | n/a <sup>1</sup> | 10               |
| a.s.           | Algae                       |                           | Chronic    |                  |                    | n/a <sup>1</sup> | 10               |
| a.s.           | Higher plants               |                           | Chronic    |                  |                    | n/a <sup>1</sup> | 10               |
| a.s.           | Sediment-dwelling organisms |                           | Chronic    |                  |                    | n/a <sup>1</sup> | 10               |

<sup>1</sup> n/a TER values for aquatic organisms were not calculated, on the basis that the PECs were within background levels. However, data gaps were identified for information on the background levels during the peer review.

| Bioconcentration    |                  |              |              |              |
|---------------------|------------------|--------------|--------------|--------------|
|                     | Active substance | Metabolite 1 | Metabolite 2 | Metabolite 3 |
| Log P <sub>ow</sub> | -0.37            | -            | -            | -            |

### 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.                              | No data submitted.                                     | No data submitted.                                     |
| Preparation                       | No data with the representative formulation submitted. | No data with the representative formulation submitted. |
| Field or semi-field tests         |  |  |
| No data available - Not required. |  |  |

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

Granular application to sports and amenity turf (71.4 kg FeSO<sub>4</sub>/ha)

| Test substance | Route   | Hazard quotient  | Annex VI Trigger |
|----------------|---------|------------------|------------------|
| a.s.           | Contact | n/a <sup>1</sup> | 50               |
| a.s.           | oral    | n/a <sup>1</sup> | 50               |
| Preparation    | Contact | n/a <sup>1</sup> | 50               |
| Preparation    | oral    | n/a <sup>1</sup> | 50               |

<sup>1</sup> Representative use of iron (II) sulfate is as a granule to sports and amenity turf. Therefore there is limited exposure to bees and hazard quotient calculations are not required.

### 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 <sup>1</sup> | Effect (LR <sub>50</sub> g/ha) |
|------------------------------|----------------|------------------------|--------------------------------|
| <i>Typhlodromus pyri</i>     | -              | Mortality              | -                              |
| <i>Aphidius rhopalosiphi</i> | -              | Mortality              | -                              |

<sup>1</sup> No LR<sub>50</sub> studies with the representative formulation submitted. Representative use is as a granule and therefore LR<sub>50</sub> studies with standard tier 1 indicator species are not required.

Granular application to sports and amenity turf (71.4 kg FeSO<sub>4</sub>/ha)

Further laboratory and extended laboratory studies

| Species                    | Test substance, substrate and duration  | Dose                             | End point  | % effect                     | Trigger value |
|----------------------------|---|----------------------------------|--|------------------------------|---------------|
| <i>Aleochara bilineata</i> | ‘Stodiek Moosvernichter mit Rasendünger’ 22-days, quartz-sand. Test substance granules scattered in test vessel | 600 kg formulation/ha            | Reduction in reproduction compared to the control.                         | 11% at 600 kg formulation/ha | 50 %          |
| <i>Pardosa spec.</i>       | 18-0-0 + 8% Fe ‘UKS092A’ 21-days, quartz-sand. Test substance granules scattered in test vessel.                | 800 kg formulation/ha            | LR <sub>50</sub> > 800 kg formulation/ha<br>No effect on food consumption. | -                            | 50 %          |
| <i>Poecilus cupreus</i>    | ‘Moos Ko Neu’ 15-days, quartz-sand. Test substance granules scattered in test vessel                            | cca. 250 kg iron (II) sulfate/ha | No effect on mortality or feeding activity.                                | -                            | 50 %          |

Field or semi-field tests

No data available - 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  |
|--|--|-----------------|--|
| Earthworms   |  |                 |  |
|  | iron (II) sulfate <sup>1</sup>               | Acute 14 days   | 4376 mg FeSO <sub>4</sub> /kg soil > LC <sub>50</sub> > 3829 mg FeSO <sub>4</sub> /kg soil   |
|  | ‘Stodiek Moosvernichter mit Rasendünger’     | Chronic 56 days | NOEC < 300 kg product/ha (cca. < 70 kg FeSO <sub>4</sub> /ha)  |
| Other soil macro-organisms   |  |                 |  |
| No data submitted.   |  |                 |  |
| Soil micro-organisms   |  |                 |  |
| Nitrogen mineralisation  | ‘Rasendünger Sanguano MV’                    | 109 days        | +128% effect compared to the control.  |
| Nitrogen mineralisation  | ‘18-0-0 + 8% Fe’ and ‘18-0-0’ (without iron) | 85 days         | The effects of the fertiliser with Fe were compared with those of the fertiliser without Fe. The treatments of the 1.07 g/kg soil and 5.33 g/kg revealed a difference of 15% after 85 days and 0.2% after 56 days, respectively. |
| Carbon mineralisation  | ‘Rasendünger Sanguano MV’                    | 28 days         | -19% effect compared to the control.   |
| Carbon mineralisation  | ‘18-0-0 + 8% Fe’ and ‘18-0-0’ (without iron) | 85 days         | For ‘18-0-0 + 8% Fe’ there was a significant effect on soil respiration rates (-82% by day 56 compared to the control).<br><br>For ‘18-0-0’ product (with no iron) was tested. There was a -81% effect by day 56. <sup>2</sup>   |
| Field studies  |  |                 |  |
| <p>Earthworm field study:</p> <p>Earthworm populations were determined for an 18-month period following applications of 1 x 300 and 2 x 300 kg ‘Stodiek Moosvernichter mit Rasendünger’/ha. The study demonstrated that applications of ‘Stodiek Moosvernichter mit Rasendünger’ did not significantly affect populations of earthworm species over one year, and the number of <i>Tanilobous</i> and <i>Epilobous</i> juveniles remained at the same level as before application. No effect on species composition was found throughout the test. The biomass of the earthworms was comparable to the control over the study period. Therefore, ‘Stodiek Moosvernichter mit Rasendünger’ applied once or twice per season at a rate of 300 kg/ha does not affect earthworm populations.</p> |  |                 |  |

<sup>1</sup> Tested as iron (II) sulfate heptahydrate. A conversion factor of 0.547 has been applied to the toxicity endpoint to take account of the molecular weight of the seven water molecules.

<sup>2</sup> Comparison of effects between the formulations with and without iron indicate that iron had no effect on soil respiration or soil nitrification.

**Toxicity/exposure ratios for soil organisms**

 Granular application to sports and amenity turf (71.4 kg FeSO<sub>4</sub>/ha)

| Test organism | Test substance                           | Time scale | Soil PEC   | TER                         | Trigger |
|---------------|--|------------|--|-----------------------------|---------|
| Earthworms    |  |            |  |                             |         |
|               | iron (II) sulfate ‡                      | Acute      | 42 mg Fe/kg and 72.2 mg SO <sub>4</sub> <sup>2-</sup> /kg soil | >33.5                       | 10      |
|               | ‘Stodiek Moosvernichter mit Rasendünger’ | chronic    | 42 mg Fe/kg and 72.2 mg SO <sub>4</sub> <sup>2-</sup> /kg soil | Not calculated <sup>1</sup> | 5       |

<sup>1</sup> NOEC from chronic study with the formulation was less than the lowest dose tested (expressed in kg/ha) and therefore no TER value was calculated. The lowest tested dose is comparable with the application rate of the representative use, therefore the end point indicates potential risk.

**Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)**
**Preliminary screening data**

|                    |
|--------------------|
| No data submitted. |
|--------------------|

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

| Test type/organism | end point          |
|--------------------|--------------------|
| Activated sludge   | No data submitted. |

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

| Compartment |                       |
|-------------|-----------------------|
| soil        | Iron ion, sulfate ion |
| water       | Iron ion, sulfate ion |
| sediment    | Iron ion, sulfate ion |
| groundwater | Iron ion, sulfate ion |

**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 |
|--------------------------|

|          |
|----------|
| R52/R53. |
|----------|

|  |
|--|
| It is noted that iron sulfate monohydrate and iron sulfate heptahydrate were not classified regarding environmental effects by the Commission Working Group on Classification and Labelling in 2005. |
|--|

## ABBREVIATIONS

|                   |  |
|-------------------|--|
| 1/n               | slope of Freundlich isotherm   |
| $\lambda$         | wavelength   |
| $\varepsilon$     | decadic molar extinction coefficient                                       |
| °C                | degree Celsius (centigrade)  |
| $\mu\text{g}$     | microgram  |
| $\mu\text{m}$     | micrometer (micron)  |
| a.s.              | active substance   |
| AChE              | acetylcholinesterase   |
| ADE               | actual dermal exposure   |
| ADI               | acceptable daily intake  |
| AF                | assessment factor  |
| AOEL              | acceptable operator exposure level   |
| AP                | alkaline phosphatase   |
| AR                | applied radioactivity  |
| ARfD              | acute reference dose   |
| AST               | aspartate aminotransferase (SGOT)  |
| AV                | avoidance factor   |
| BCF               | bioconcentration factor  |
| BUN               | blood urea nitrogen  |
| bw                | body weight  |
| CAS               | Chemical Abstracts Service   |
| CFU               | colony forming units   |
| ChE               | cholinesterase   |
| CI                | confidence interval  |
| CIPAC             | Collaborative International Pesticides Analytical Council Limited          |
| CL                | confidence limits  |
| cm                | centimetre   |
| d                 | day  |
| DAA               | days after application   |
| DAR               | draft assessment report  |
| DAT               | days after treatment   |
| DM                | dry matter   |
| DT <sub>50</sub>  | period required for 50 percent disappearance (define method of estimation) |
| DT <sub>90</sub>  | period required for 90 percent disappearance (define method of estimation) |
| dw                | dry weight   |
| EbC <sub>50</sub> | effective concentration (biomass)  |
| EC <sub>50</sub>  | effective concentration  |
| ECHA              | European Chemical Agency   |
| EEC               | European Economic Community  |
| EINECS            | European Inventory of Existing Commercial Chemical Substances              |
| ELINCS            | European List of New Chemical Substances                                   |
| EMDI              | estimated maximum daily intake   |
| ER <sub>50</sub>  | emergence rate/effective rate, median                                      |
| ErC <sub>50</sub> | effective concentration (growth rate)                                      |
| EU                | European Union   |
| EUROPOEM          | European Predictive Operator Exposure Model                                |
| f(twa)            | time weighted average factor   |
| FAO               | Food and Agriculture Organisation of the United Nations                    |
| FIR               | Food intake rate   |
| FOB               | functional observation battery   |
| FOCUS             | Forum for the Co-ordination of Pesticide Fate Models and their Use         |
| g                 | gram   |
| GAP               | good agricultural practice   |

|                  |  |
|------------------|--|
| GC               | gas chromatography   |
| GCPF             | Global Crop Protection Federation (formerly known as GIFAP)  |
| GGT              | gamma glutamyl transferase   |
| GM               | geometric mean   |
| GS               | growth stage   |
| GSH              | glutathion   |
| GR               | granule  |
| h                | hour(s)  |
| ha               | hectare  |
| Hb               | haemoglobin  |
| Hct              | haematocrit  |
| hL               | hectolitre   |
| HPLC             | high pressure liquid chromatography<br>or high performance liquid chromatography   |
| HQ               | hazard quotient  |
| IEDI             | international estimated daily intake   |
| IESTI            | international estimated short-term intake  |
| ICP-AES          | inductively coupled plasma atomic emission spectroscopy  |
| ICP-OES          | inductively coupled plasma optical emission spectroscopy   |
| ISO              | International Organisation for Standardisation   |
| IUPAC            | International Union of Pure and Applied Chemistry  |
| JMPR             | Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| $K_{doc}$        | organic carbon linear adsorption coefficient   |
| kg               | kilogram   |
| $K_{Foc}$        | Freundlich organic carbon adsorption coefficient   |
| L                | litre  |
| LC               | liquid chromatography  |
| LC <sub>50</sub> | lethal concentration, median   |
| LC-MS            | liquid chromatography-mass spectrometry  |
| LC-MS-MS         | liquid chromatography with tandem mass spectrometry  |
| LD <sub>50</sub> | lethal dose, median; dosis letalis media   |
| LDH              | lactate dehydrogenase  |
| LOAEL            | lowest observable adverse effect level   |
| LOD              | limit of detection   |
| LOQ              | limit of quantification (determination)  |
| m                | metre  |
| M/L              | mixing and loading   |
| MAF              | multiple application factor  |
| MCH              | mean corpuscular haemoglobin   |
| MCHC             | mean corpuscular haemoglobin concentration   |
| MCV              | mean corpuscular volume  |
| mg               | milligram  |
| mL               | millilitre   |
| mm               | millimetre   |
| mN               | milli-newton   |
| MRL              | maximum residue limit or level   |
| MS               | mass spectrometry  |
| MSDS             | material safety data sheet   |
| MTD              | maximum tolerated dose   |
| MWHC             | maximum water holding capacity   |
| NESTI            | national estimated short-term intake   |
| ng               | nanogram   |
| NOAEC            | no observed adverse effect concentration   |

|                     |  |
|---------------------|--|
| NOAEL               | no observed adverse effect level                                 |
| NOEC                | no observed effect concentration                                 |
| NOEL                | no observed effect level   |
| OM                  | organic matter content   |
| Pa                  | pascal   |
| PD                  | proportion of different food types                               |
| PEC                 | predicted environmental concentration                            |
| PEC <sub>air</sub>  | predicted environmental concentration in air                     |
| PEC <sub>gw</sub>   | predicted environmental concentration in ground water            |
| PEC <sub>sed</sub>  | predicted environmental concentration in sediment                |
| PEC <sub>soil</sub> | predicted environmental concentration in soil                    |
| PEC <sub>sw</sub>   | predicted environmental concentration in surface water           |
| pH                  | pH-value   |
| PHED                | pesticide handler's exposure data                                |
| PHI                 | pre-harvest interval   |
| PIE                 | potential inhalation exposure                                    |
| pK <sub>a</sub>     | negative logarithm (to the base 10) of the dissociation constant |
| P <sub>ow</sub>     | partition coefficient between <i>n</i> -octanol and water        |
| PPE                 | personal protective equipment                                    |
| ppm                 | parts per million (10 <sup>-6</sup> )                            |
| ppp                 | plant protection product   |
| PT                  | proportion of diet obtained in the treated area                  |
| PTT                 | partial thromboplastin time                                      |
| QSAR                | quantitative structure-activity relationship                     |
| r <sup>2</sup>      | coefficient of determination                                     |
| RPE                 | respiratory protective equipment                                 |
| RUD                 | residue per unit dose  |
| SC                  | suspension concentrate   |
| SD                  | standard deviation   |
| SFO                 | single first-order   |
| SSD                 | species sensitivity distribution                                 |
| STMR                | supervised trials median residue                                 |
| t <sub>1/2</sub>    | half-life (define method of estimation)                          |
| TER                 | toxicity exposure ratio  |
| TER <sub>A</sub>    | toxicity exposure ratio for acute exposure                       |
| TER <sub>LT</sub>   | toxicity exposure ratio following chronic exposure               |
| TER <sub>ST</sub>   | toxicity exposure ratio following repeated exposure              |
| TK                  | technical concentrate  |
| TLV                 | threshold limit value  |
| TMDI                | theoretical maximum daily intake                                 |
| TRR                 | total radioactive residue  |
| TSH                 | thyroid stimulating hormone (thyrotropin)                        |
| TWA                 | time weighted average  |
| UDS                 | unscheduled DNA synthesis  |
| UV                  | ultraviolet  |
| W/S                 | water/sediment   |
| w/v                 | weight per volume  |
| w/w                 | weight per weight  |
| WBC                 | white blood cell   |
| WHO                 | World Health Organisation  |
| wk                  | week   |
| yr                  | year   |