|  |
| --- |
| FINAL REGISTRATION REPORT  **Part B**  Section 6  Mammalian Toxicology  Detailed summary of the risk assessment |
| Product code: SHA 105000 A  Product name: SUPER  Chemical active substance:  Ferric phosphate, 29.7 g/kg |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (Non-professional use) |
| Applicant: Sharda Cropchem Ltd  Submission date: March 2024;  MS Finalisation date: September 2024; December 2024 |

Version history

|  |  |
| --- | --- |
| When | What |
| September 2024 | ZRMS assessment |
| December 2024 | The final Registration Report |
|  |  |
|  |  |

Table of Contents

[6 Mammalian Toxicology (KCP 7) 5](#_Toc162004789)

[6.1 Summary 5](#_Toc162004790)

[6.2 Toxicological Information on Active Substance(s) 6](#_Toc162004791)

[6.3 Toxicological Evaluation of Plant Protection Product 7](#_Toc162004792)

[6.4 Toxicological Evaluation of Groundwater Metabolites 8](#_Toc162004793)

[6.5 Dermal Absorption (KCP 7.3) 8](#_Toc162004794)

[6.5.1 Justification for proposed values - Ferric phosphate 8](#_Toc162004795)

[6.6 Exposure Assessment of Plant Protection Product (KCP 7.2) 9](#_Toc162004796)

[6.6.1 Selection of critical use(s) and justification 9](#_Toc162004797)

[6.6.2 Operator exposure (KCP 7.2.1) 9](#_Toc162004798)

[6.6.2.1 Estimation of operator exposure 9](#_Toc162004799)

[6.6.2.2 Measurement of operator exposure 10](#_Toc162004800)

[6.6.3 Worker exposure (KCP 7.2.3) 10](#_Toc162004801)

[6.6.3.1 Estimation of worker exposure 10](#_Toc162004802)

[6.6.3.2 Refinement of generic DFR value (KCP 7.2) 10](#_Toc162004803)

[6.6.3.3 Measurement of worker exposure 11](#_Toc162004804)

[6.6.4 Resident and bystander exposure (KCP 7.2.2) 11](#_Toc162004805)

[6.6.4.1 Estimation of resident and bystander exposure 11](#_Toc162004806)

[6.6.4.2 Measurement of resident and/or bystander exposure 12](#_Toc162004807)

[6.6.5 Combined exposure 12](#_Toc162004808)

[Appendix 1 Lists of data considered in support of the evaluation 13](#_Toc162004809)

[Appendix 2 Detailed evaluation of the studies relied upon 15](#_Toc162004810)

[A 2.1 Statement on bridging possibilities 15](#_Toc162004811)

[A 2.2 Acute oral toxicity (KCP 7.1.1) 15](#_Toc162004812)

[A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2) 16](#_Toc162004813)

[A 2.4 Acute inhalation toxicity (KCP 7.1.3) 16](#_Toc162004814)

[A 2.5 Skin irritation (KCP 7.1.4) 16](#_Toc162004815)

[A 2.6 Eye irritation (KCP 7.1.5) 17](#_Toc162004816)

[A 2.7 Skin sensitisation (KCP 7.1.6) 17](#_Toc162004817)

[A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7) 17](#_Toc162004818)

[A 2.9 Data on co-formulants (KCP 7.4) 17](#_Toc162004819)

[A 2.9.1 Material safety data sheet for each co-formulant 17](#_Toc162004820)

[A 2.9.2 Available toxicological data for each co-formulant 17](#_Toc162004821)

[A 2.10 Studies on dermal absorption (KCP 7.3) 17](#_Toc162004822)

[A 2.11 Other/Special Studies 18](#_Toc162004823)

[Appendix 3 Exposure calculations 19](#_Toc162004824)

[A 3.1 Operator exposure calculations (KCP 7.2.1.1) 19](#_Toc162004825)

[Please, refer to KCP reports, section 6. 19](#_Toc162004826)

[Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1) 19](#_Toc162004827)

# Mammalian Toxicology (KCP 7)

## Summary

Table 6.1‑1: Information on SHA 105000 A / SUPER \*

|  |  |
| --- | --- |
| Product name and code | SHA 105000 A / SUPER |
| Formulation type | Ganular bait [Code: GB] |
| Active substance(s) (incl. content) | Ferric phosphate; 29.7 g/kg |
| Function | Molluscicide |
| Product already evaluated as the ‘representative formulation’ during the approval of the active substance(s) | No |
| Product previously evaluated in another MS according to Uniform Principles | No |

\* Information on the detailed composition of SHA 105000 A / SUPER can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1‑2: Justified proposals for classification and labelling for SHA 105000 A / SUPER according to Regulation (EC) No 1272/2008

|  |  |
| --- | --- |
| Hazard class(es), categories | None |
| Hazard pictograms or Code(s) for hazard pictogram(s) | None |
| Signal word | None |
| Hazard statement(s) | None |
| Precautionary statement(s) | None |
| Additional labelling phrases | To avoid risks to man and the envFerricment, comply with the instructions for use. [EUH401] |

Table 6.1‑3: Summary of risk assessment for operators, workers, residents and bystanders for SHA 105000 A / SUPER

|  | Result | PPE / Risk mitigation measures |
| --- | --- | --- |
| Operators | Acceptable | Work wear |
| Workers | Acceptable | None |
| Residents | Acceptable | None |
| Bystanders | Acceptable | None |

No unacceptable risk for workers, residents and bystanders was identified when the product is used as intended. No specific PPE is necessary.

No unacceptable risk for operators was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1‑3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders is presented in the following table.

Table 6.1‑4 Critical uses and overall conclusion of exposure assessment

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Use-No.\* | Crops and situation (e.g. growth stage of crop) | F, Fn, Fpn G, Gn, Gpn or I \*\* | Application | | Application rate | | PHI (d) | Remarks:   (e.g. safener/synergist (L/ha))  critical gap for operator, worker, resident or bystander exposure based on [Exposure model] | Acceptability of exposure assessment | | | |
| Method / Kind  (incl. application technique \*\*\* | Max. number (min. interval between applications)  a) per use  b) per crop/ season | Max. application rate  kg as/ha   a) a.s. 1 b) a.s. 2 | Water L/ha  min / max | Operator | Worker | Residents | Bystander |
| 1 | **Fruit crops, Vegetable crops,  Ornamentals,**  **Grapevine**  (From seedling planting -81) | F | Spread to soil surface by hand or automatic dispenser | a) 4 (14)  b) 4 (14) | a) 0.2079  b) 0.8316 | - | - | 60-70 granular baits per m2 per application  Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032  EFSA OPEX calculator version: 1.0.0 |  |  |  |  |

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

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

\*\*\* e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 “Acceptability of exposure assessment”

|  |  |
| --- | --- |
| A | Exposure acceptable without PPE / risk mitigation measures |
| R | Further refinement and/or risk mitigation measures required |
| N | Exposure not acceptable/ Evaluation not possible |

## Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2‑1.

Table 6.2‑1: Information on active substance(s)

|  | **Ferric phosphate** |
| --- | --- |
| Common Name | Ferric phosphate |
| CAS-No. | 10045-86-0 |
| **Classification and proposed labelling** | |
| With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended) | Not classified |
| Additional C&L proposal | - |
| **Agreed EU endpoints** | |
| AOEL systemic | 0.4 mg/kg bw/d (corrected for 50% oral absorption) |
| Reference | EFSA Journal 2015;13(1):3973  RAC adoptted |
| **Conditions to take into account/critical areas of concern with regard to toxicology** | |
| According to EFSA Journal 2015;13(1):3973 for Ferric phosphate | None |

## Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for SHA 105000 A / SUPER is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3‑1: Summary of evaluation of the calculations on acute toxicity including irritancy and skin sensitisation for SHA 105000 A / SUPER

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of test, species, model system (Guideline) | Result | Acceptability | Classification  (acc. to the criteria in Reg. 1272/2008) | Reference |
| LD50 oral, rat | > 2000 mg/kg bw | Yes | None | calculated |
| LD50 dermal, rat | > 2000 mg/kg bw | Yes | None | calculated |
| LC50 inhalation, rat | > 5 mg/L air | Yes | None | calculated |
| Skin irritation, rabbit | Non-irritant and Non-corrosive | Yes | None | calculated |
| Eye irritation, rabbit | Non-irritant | Yes | None | calculated |
| Skin sensitisation, guinea pig | Non-sensitising | Yes | None | calculated |
| Supplementary studies for combinations of plant protection products | No data – not required |  |  |  |

Table 6.3‑2: Additional toxicological information relevant for classification/labelling of SHA 105000 A / SUPER

|  | Substance (concentration in product, % w/w) | Classification of the  substance  (acc. to the criteria in Reg. 1272/2008) | Reference | Classification of product (acc. to the criteria in Reg. 1272/2008) |
| --- | --- | --- | --- | --- |
| Toxicological properties of active substance(s) (relevant for classification of product) | Ferric phosphate  (2.97% (w/w)) | -none | Reg. 1272/2008 | None |
| Toxicological properties of non-active substance(s) (relevant for classification of product) | Co-formulant 1  < 10% (w/w)\* | H302, H315, H319, H332, H335 | MSDS\*\* | None |
| Further toxicological information | No data – not required |  |  |  |

\*Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.

\*\*Material safety data sheet by the applicant

## Toxicological Evaluation of Groundwater Metabolites

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

## Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in SHA 105000 A / SUPER are presented in the following table.

Table 6.5‑1: Dermal absorption rates for active substances in SHA 105000 A / SUPER

|  | Ferric phosphate | |
| --- | --- | --- |
|  | Value | Reference |
| Concentrate | 50% | EFSA Journal 2017;15(6):4873 |
| Dilution | n/a | n/a |

### Justification for proposed values - Ferric phosphate

No data on dermal absorption for Ferric phosphate in SHA 105000 A / SUPER is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5‑2: Default dermal absorption rates for Ferric phosphate

|  | Value | Justification for value | Acceptability of justification |
| --- | --- | --- | --- |
| Concentrate | 50% | < 5 % of a.s Ferric phosphate in formulation | Yes |
| Dilution | - | - | Yes |

## Exposure Assessment of Plant Protection Product (KCP 7.2)

Table 6.6‑1: Product information and toxicological reference values used for exposure assessment

|  |  |
| --- | --- |
| Product name and code | SHA 105000 A / SUPER |
| Formulation type | GB |
| Category | Molluscicide |
| Active substance(s) (incl. content) | **Ferric phosphate**  29.7 g/kg |
| AOEL systemic | 0.4 mg/kg bw/d |
| Inhalation absorption | 100% |
| Oral absorption | 50% |
| Dermal absorption | Concentrate: 50%  Dilution: - |

### Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1‑4. A list of all intended uses within the zone is given in Part B, Section 0.

Justification

There is only one intended GAP.

### Operator exposure (KCP 7.2.1)

#### Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of SHA 105000 A / SUPER according to the critical use(s) is presented in Table 6.6‑2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6‑2: Exposure models for intended uses

|  |  |
| --- | --- |
| Critical use(s) | Fruit crops, vegetable crops, ornamentals, grapevine (max. 7.0 kg product/ha) |
| Model(s) | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032  EFSA OPEX calculator version: 1.0.0 |

According to the OPEX calculator, the area treated for manual application is 1 ha/day.

Due to the fact that for non-professional the maximum area is 500 m2 (0.05 ha), therefore the Applicant will divide the areas on EFSA calculator (20 times for manual application).

Table 6.6‑3: Estimated operator exposure (longer term exposure)

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Ferric phosphate | |
| Model data | Level of PPE | Total absorbed dose  (mg/kg bw/day) | % of systemic AOEL |
| Manual broadcast application of granules outdoors | | | |
| Application rate | | 0.2079 kg a.s./ha | |
| **Granule application** (OPEX;75th percentile)  Body weight: 60 kg | Potential exposure | 19.8/20 = 0.99 | 4245/20 = 212 |
| Work wear (arms, body and legs covered) M/L and A | 6/20 = 0.3 | 1286/20 **= 64** |
| Work wear (arms, body and legs covered) M/L and A  + gloves M/L and A | 0.2/20 = 0.01 | 42.9/20 **= 2** |

**Conclusion**

**According to the EFSA OPEX calculator, it can be concluded that the risk for the non-professional operator using SUPER is acceptable with work wear (arms, body and legs covered) M/L and A).**

#### Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

### Worker exposure (KCP 7.2.3)

#### Estimation of worker exposure

Since SUPER is ready to use granular bait intended to be spread to soil surface, worker exposure after entry into the treated area or handling a crop treated is considered negligible and thus acceptable. Therefore, no estimation of worker exposure was performed.

**Accepted**

#### Refinement of generic DFR value (KCP 7.2)

Not required.

If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 μg/cm2 (30 mg a.s./m2).

#### Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

### Resident and bystander exposure (KCP 7.2.2)

#### Estimation of resident and bystander exposure

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

Table 6.6‑6 shows the exposure model(s) used for estimation of resident and bystander exposure to Ferric phosphate. The outcome of the estimation is presented in Table 6.6-7 (longer term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6‑6: Exposure models for intended uses

|  |  |
| --- | --- |
| Critical use(s) | Fruit crops, vegetable crops, ornamentals (max. 4 x 7.0 kg product/ha) |
| Model | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032  EFSA OPEX calculator version: 1.0.0 |

Table 6.6‑7: Estimated resident exposure (longer term exposure)

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Ferric phosphate | |
| Model data |  | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Manual broadcast application of granules outdoors to: fruit crops, vegetable crops, ornamentals  Buffer zone: 2-3(m)  Drift reduction technology: no  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between treatments: 14 days | | | |
| Number of applications and application rate | | 4 x 0.2079 kg a.s./ha | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | NA | NA |
| Vapour (75th perc.) | 0.0008 | 0.2 |
| Deposits (75th perc.) | 0.0005 | 0.1 |
| Re-entry (75th perc.) | NA | NA |
| **Sum (mean)** | 0.001 | **0.3** |
| Resident adult  Body weight: 60 kg | Drift (75th perc.) | NA | NA |
| Vapour (75th perc.) | 0.0003 | 0.07 |
| Deposits (75th perc.) | 0.0002 | 0.05 |
| Re-entry (75th perc.) | NA | NA |
| **Sum (mean**) | 0.0005 | **0.1** |

#### The resident and/or bystander exposure estimations carried out indicated that the acceptable exposure level (AOEL) for Ferric phosphate.

#### Measurement of resident and/or bystander exposure

Since the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Ferric phosphate will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

### Combined exposure

Not relevant. The product contains only one active substance.

1. Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

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

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

No additional study submitted.

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

1. Detailed evaluation of the studies relied upon

The classification of Ferric phosphate 2.97% GB is performed by calculation. The assessment of all acute toxicological properties of Ferric phosphate 2.97% GB is derived from the classification of the active compound and co-formulants as shown below. For obvious confidentiality reasons, the names and percentages of co-formulants are disclosed in Part C:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Formulant** | **% of formulation** | **Acute Oral Toxicity** | **Acute Dermal Toxicity** | **Acute Inhalation Toxicity** | **Dermal Irritation** | **Ocular Irritation** | **Sensitising potential** |
| Ferric phosphate Technical  (CAS No.: 10045-86-0) | **3.82** | >2000 mg/kg 1) | >2000 mg/kg 1) | \* | Not Irritating1) | Not Irritating1) | Not sensitising1) |
| Co-formulant 1 | **xxx** | 500 mg/kg 2)  H302 | > 2000 mg/kg1) | 1.5 mg/l2),  H332 | Skin Irrit. 2, H315 | Eye Irrit. 2, H319 | Not sensitising1) |
| Co-formulant 2 | **xxx** | 2100 mg/kg | > 2000 mg/kg1) | \* | Not Irritating1) | Not Irritating1) | Not sensitising1) |
| Co-formulant 3 | **xxx** | >2000 mg/kg 1) | >2000 mg/kg 1) | \* | Not Irritating1) | Not Irritating1) | Not sensitising1) |
| Co-formulant 4 | **xxx** | 29700 mg/kg | >2000 mg/kg 1) | \* | Not Irritating1) | Not Irritating1) | Not sensitising1) |
| Co-formulant 5 | **xxx** | >2000 mg/kg 1) | >2000 mg/kg 1) | \* | Not Irritating1) | Not Irritating1) | Not sensitising1) |

\* No Information / but in their MSDS are not classified acutely inhalation toxic

1) As co-formulant is not classified

2) According to the Regulation (EC) n°1272/2008, Oral: ATE = 500 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 4: H302; Inhalation: ATE = 1.5 mg/l is used for the calculation for co-formulant classified as Acute Tox. 4; H332.

* 1. Statement on bridging possibilities

Not relevant.

* 1. Acute oral toxicity (KCP 7.1.1)

|  |  |
| --- | --- |
| Comments of zRMS: | **The acute oral toxicity of Ferric phosphate 2.97% GB was estimated to be > 2000 mg/kg.**  **According to the Regulation EC No. 1272/2008, Ferric phosphate 2.97% GB is not classified. No signal word or hazard statement is required for this hazard.** |

The acute oral toxicity classification for Ferric phosphate 2.97% GB is calculated:

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Ferric phosphate 2.97% GB can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

**Conclusion**

The acute oral toxicity of Ferric phosphate 2.97% GB was estimated to be > 2000 mg/kg.

According to the Regulation EC No. 1272/2008, Ferric phosphate 2.97% GB is **not classified**. No signal word or hazard statement is required for this hazard.

* 1. Acute percutaneous (dermal) toxicity (KCP 7.1.2)

|  |  |
| --- | --- |
| Comments of zRMS: | **According to the Regulation EC No. 1272/2008, Ferric phosphate 2.97% GB is not classified. No signal word or hazard statement is required for this hazard** |

Neither the active substance nor co-formulant in the Ferric phosphate 2.97% GB recipe classified as danger through dermal contact.

According to the Regulation EC No. 1272/2008, Ferric phosphate 2.97% GB is **not classified**. No signal word or hazard statement is required for this hazard.

* 1. Acute inhalation toxicity (KCP 7.1.3)

|  |  |
| --- | --- |
| Comments of zRMS: | **Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute inhalation toxicity of Ferric phosphate 2.97% GB can be found in an appendix to the confidential dossier of this submission** |

The acute inhalation toxicity classification for Ferric phosphate 2.97% GB is calculated:

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute inhalation toxicity of Ferric phosphate 2.97% GB can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

**Conclusion**

The acute inhalation toxicity of Ferric phosphate 2.97% GB is estimated to be > 5 mg/l.

According to the Regulation EC No. 1272/2008, Ferric phosphate 2.97% GB is **not classified**. No signal word or hazard statement is required for this hazard.

* 1. Skin irritation (KCP 7.1.4)

|  |  |
| --- | --- |
| Comments of zRMS: | **According to the Regulation EC No. 1272/2008, Ferric phosphate 2.97% GB is not classified. No signal word or hazard statement is required for this hazard**. |

The product contains < 10% of co-formulants considered as skin irritant (classified as: Skin Irrit. 2; H315). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Ferric phosphate 2.97% GB is **not classified**. No signal word or hazard statement is required for this hazard.

* 1. Eye irritation (KCP 7.1.5)

|  |  |
| --- | --- |
| Comments of zRMS: | **According to the Regulation EC No. 1272/2008, Ferric phosphate 2.97% GB is not classified. No signal word or hazard statement is required for this hazard.** |

The product contains < 10% of co-formulants considered as eye irritation (classified as: Eye Irrit. 2, H319). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Ferric phosphate 2.97% GB is **not classified**. No signal word or hazard statement is required for this hazard.

* 1. Skin sensitisation (KCP 7.1.6)

|  |  |
| --- | --- |
| Comments of zRMS: | **According to the Regulation EC No. 1272/2008, Ferric phosphate 2.97% GB is not classified. No signal word or hazard statement is required for this hazard.** |

Neither the active substance nor co-formulant in the Ferric phosphate 2.97% GB recipe are classified as skin sensitiser.

1. According to the Regulation EC No. 1272/2008, Ferric phosphate 2.97% GB is not classified. No signal word or hazard statement is required for this hazard.
   1. Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No data available.

* 1. Data on co-formulants (KCP 7.4)
     1. Material safety data sheet for each co-formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

* + 1. Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

* 1. Studies on dermal absorption (KCP 7.3)

According to the new EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 adopted: 24 May 2017) a default dermal absorption value 10% (concentrate) and 50% (diluted) of may be applied for products that are water-based/dispersed (c) or solid-formulated(d)

(c): Formulation types: soluble concentrate (SL), suspension concentrate (SC), flowable concentrate for seed treatment (FS), flowable (FL) (SC).

(d): Formulation types: wettable powder (WP), water-dispersible granules (WG/WDG), water-soluble granules (SG), water-soluble powder (SP), powder for dry seed treatment (DS).

Considering < 5 % of Ferric phosphate in formulation, dermal absorption value of 50% (concentrate) is used for exposure calculations.

**ACCEPTED**

* 1. Other/Special Studies

No data submitted.

1. Exposure calculations
   1. Operator exposure calculations (KCP 7.2.1.1)

Please, refer to KCP reports, section 6.



1. Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Not relevant.