

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: SHA 105000 B

Product name(s): HIERRO

Chemical active substance:

Ferric Phosphate, 10 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: SHARDA Cropchem España S. L.

Submission date: November 2020

Update date: 03.2023, 05.2023

MS Finalisation date: 07.2021; 10.2021; 05.2023

Version history

| When | What |
|---------|--|
| 07.2021 | RMS Assessment |
| 10.2021 | The Final Version of the RR |
| 03.2023 | Update by Applicant - Part B5 (RI determination and analytical method validation for RI) and equivalency report |
| 05.2023 | Update by Applicant - Part B5 (update of RI determination and analytical method validation for RI) |
| 05.2023 | Assessment of Applicant's update (equivalence and RI determination and analytical methods validation for RI) by zRMS |
| | |

Table of Contents

| | | |
|-------------------|---|-----------|
| 1 | Section 1: Identity of the plant protection product..... | 4 |
| 1.1 | Applicant (KCP 1.1) | 4 |
| 1.2 | Producer of the plant protection product and of the active substances (KCP 1.2) | 4 |
| 1.2.1 | Producer(s) of the preparation | 4 |
| 1.2.2 | Producer(s) of the active substance(s) | 4 |
| 1.2.3 | Statement of purity (and detailed information on impurities) of the active substance(s) | 4 |
| 1.2.3.1 | Ferric phosphate | 4 |
| 1.3 | Trade names and producer's development code numbers for the preparation (KCP 1.3) | 5 |
| 1.4 | Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4) | 5 |
| 1.4.1 | Composition of the plant protection product (KCP 1.4.1) | 5 |
| 1.4.2 | Information on the active substance(s) (KCP 1.4.2) | 5 |
| 1.4.3 | Information on safeners, synergists and co-formulants (KCP 1.4.3) | 5 |
| 1.5 | Type and code of the plant protection product (KCP 1.5) | 6 |
| 1.6 | Function (KCP 1.6) | 6 |
| 2 | Section 2: Physical, chemical and technical properties of the plant protection product | 7 |
| 3 | Section 3 is presented as a separate document | 15 |
| 4 | Section 4: Further information on the plant protection product | 16 |
| Appendix 1 | Lists of data considered in support of the evaluation | 18 |
| Appendix 2 | Additional data on the physical, chemical and technical properties of the active substance | 21 |
| A 2.1 | Ferric phosphate | 21 |

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product.

Noticed data gap is:

The equivalence report of active substance assessment (ferric phosphate) has not been completed..
The report should be provided before product registration.
- none

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Sharda Cropchem España S.L.
Address: Edificio Atalayas Business Center,
Carril Condomina nº 3, 12th Floor,
30006 Murcia, Spain
Phone: +34868127589
FAX: +34868127588

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Ferric phosphate

| | |
|------------------|---|
| Ferric phosphate | min. 703 g/kg (SANTE/10385/2015 Rev 1 29 May 2015) min. 778.2 g/kg Sharda source |
|------------------|---|

RMS Comment:

The equivalence source assessment of active substance (ferric phosphate) has not been completed.

| | |
|------|--------------------------------------|
| Lead | max. 3 mg/kg in the active substance |
|------|--------------------------------------|

Mercury max. 0.1 mg/kg in the active substance
Cadmium max. 1 mg/kg in the active substance

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: HIERRO
Company code number: SHA 105000 B

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

| Active substance / variant | Declared content of the pure active substance / variant (g/L or g/kg) | FAO Limits (min – max) | Technical content* (g/L or g/kg) | Technical content** (%w/w) |
|----------------------------|---|--------------------------|----------------------------------|----------------------------|
| Ferric phosphate | 10 g/kg | 7.5 – 12.5 g/kg ± 25% | 12.85 g/kg | 1.285% |

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

Table 1.4-2: Relevant impurities

| Relevant impurity | Maximum content (g/L or g/kg) |
|-------------------|---|
| Lead | 3 mg/kg (0.039 mg/kg in formulation) |
| Mercury | 0.1 mg/kg (0.0013 mg/kg in formulation) |
| Cadmium | 1 mg/kg (0.013 mg/kg in formulation) |

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-3: Information on Ferric phosphate

| Type | Name/Code Number |
|-----------------|------------------|
| ISO common name | Ferric phosphate |
| CAS No. | 10045-86-0 |
| EC No. | 233-149-7 |
| CIPAC No. | 629 |

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Granular bait

[Code: GB]

1.6 Function (KCP 1.6)

Molluscicide.

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of the product is that of pale blue solid granules, with a weakly odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 260 °C. In aqueous solution, it has a pH value around 4.13 at 20 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE COEX material*.

Its technical characteristics are acceptable for a *granular bait* formulation.

The intended concentration of use is 50 kg/ha

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Neither classification or labelling are relevant for this section.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No risk and safety phrases are relevant for this section.

Compliance with FAO specifications:

The product SHA 105000 B complies with FAO specifications.

Formulation used for tests

The product used to determinate the physical, chemical and technical properties is the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|-------------------------------------|--|---|---|---------|---|--------------------------|
| Colour and physical state (KCP 2.1) | OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304 | Iron Phosphate 1% GB (Batch No. SCL – 894250) | Pale blue solid granules with weakly odor. | | B. Krzysiak-Warzała, 2017 Report No. 18/2017/BA-AD | Accepted |
| Explosive properties (KCP 2.2.1) | EEC A.14 | Iron Phosphate 1% GB (Batch No. SCL – 894250) | The test item has no explosive properties. | Y | D. Buczkowski, 2017 Report No. BW-02/17 | Accepted |
| | EEC A.14 | | The test item has no explosive properties. | Y | B. Krzysiak-Warzała, 2017 Report No. 18/2017/BA-AD | |
| Oxidizing properties (KCP 2.2.2) | EEC A.17 | Iron Phosphate 1% GB (Batch No. SCL – 894250) | The test item has no oxidising properties. | Y | B. Krzysiak-Warzała, 2017 Report No. 18/2017/BA-AD | Accepted |
| Flash point (KCP 2.3.1) | - | - | Please refer to KCP 2.3.2. | - | - | Statement accepted |
| Flammability (KCP 2.3.2) | EEC A.10 | Iron Phosphate 1% GB (Batch No. SCL – 894250) | The test item is not considered to be highly flammable. | Y | B. Krzysiak-Warzała, 2017 Report No. 18/2017/BA-AD | Accepted |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|---|--------------------------|---|---|---------|---|--------------------------|
| Self-heating (KCP 2.3.3) | EEC A.16 | Iron Phosphate 1% GB (Batch No. SCL – 894250) | The self ignition temperature = 260°C | Y | B. Krzysiak-Warzała, 2017 Report No. 18/2017/BA-AD | Accepted |
| Acidity or alkalinity and pH (KCP 2.4.1) | - | - | Not relevant. | - | - | Statement accepted |
| pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2) | CIPAC MT 75.3 | Iron Phosphate 1% GB (Batch No. SCL – 894250) | pH = 4.13 | Y | B. Krzysiak-Warzała, 2017 Report No. 18/2017/BA-AD | Accepted |
| Viscosity (KCP 2.5.1) | - | - | Not relevant for solid formulation. | - | - | Statement accepted |
| Surface tension (KCP 2.5.2) | - | - | Not relevant for solid formulation. | - | - | Statement accepted |
| Relative density (KCP 2.6.1) | - | - | Not relevant for solid formulation. | - | - | Statement accepted |
| Bulk density (KCP 2.6.2) | CIPAC MT 186 | Iron Phosphate 1% GB (Batch No. SCL – 894250) | Pour density = 0.799 g/mL Tap density = 0.799 g/mL | Y | B. Krzysiak-Warzała, 2017 Report No. 18/2017/BA-AD | Accepted |

| Annex point | Method used / deviations | Test material | Findings | | | GLP Y/N | Reference | Acceptability / comments |
|--|---|--|----------------------------------|--|--|---------|---|---|
| Storage Stability after 14 days at 54° C (KCP 2.7.1) | CIPAC MT 46.3 XRF Spectrometry OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6303 CIPAC MT 75.3 CIPAC MT 170 CIPAC MT 171 CIPAC MT 178 Technical Monograph Croplife | Iron Phosphate 1% GB (Batch No. SCL – 894250) | Test | 0 days | 14 dayss at 54°C | Y | B. Krzysiak-Warzała, 2017 Report No. 18/2017/BA-AD | Accepted RMS Comment: Active substance content and stability of packaging were tested. All physical and chemical properties remained stable after the test and accepted. Test carried out in HDPE coex bottles |
| | | | A. s. content | 0.94% w/w | 1.05% w/w | | | |
| | | | Release rate of active substance | Amount of FePO ₄ released at time: 15 min: 29 µg/g 30 min: 67 µg/g 180 min: 140 µg/g | Amount of FePO ₄ released at time: 15 min: 36 µg/g 30 min: 55 µg/g 180 min: 228 µg/g | | | |
| | | | Appearance | Pale blue granules with weakly odor | Pale blue granules with weakly odor | | | |
| | | | pH 1% aqueous extract | 4.14-4.13 | 4.49 | | | |
| | | | Particle size distribution | 99.70 % of the particles have size between 2000 – 3350 µm 0.14% of the particles have size between 1000 – 2000 µm | 99.71 % of the particles have size between 2000 – 3350 µm 0.17% of the particles have size between 1000 – 2000 µm | | | |
| | | | Dust content | 0.2 mg nearly dust free | 1.1 mg nearly dust free | | | |
| | | | Attrition | 99.65% | 99.79% | | | |
| | | | Stability of packaging | - | Weight loss in the range 0.08 – 0.16% No changes in appearance of sample | | | |

| Annex point | Method used / deviations | Test material | Findings | | | | | GLP Y/N | Reference | Acceptability / comments |
|---|---------------------------------|---|----------------------------------|---|--|-----------|-----------|---------|---|---|
| | SANCO/3030/99 rev. 5 | Iron Phosphate 1% GB (Batch No. SCL-900802 SCL-52331) | Relevant impurity content | Cadmium: 0.000020% 0.0000002% w/w (0.0018 mg/kg) Lead: 0.000021% 0.0000002% w/w (0.0018 mg/kg) Mercury: 0.000013% 0.000000004% w/w (0.000044 mg/kg) | Iron Phosphate is inorganic compound with relevant impurities of (eco)toxicological concern: lead, cadmium, mercury which are elements. From the scientific point of view elements are not expected to form or increase their content in the formulation during the storage therefore no determination after storage is required for this product. | | | Y | K. Vasu, 2023 Report No. 11255/2022 K. Vasu, 2023 Report No. 13033/2023 | The content of relevant impurities before storage was below the levels of SANTE/ 10385/2015 Rev 1 (29 May 2015). The content of the RI after the storage was not determined. However, as RIs do not form on the storage and the content of the a.s. was stable during the storage it can be accepted. Accepted. |
| Stability after storage for other periods and/or temperatures (KCP 2.7.2) | - | - | Not relevant. | | | | | - | - | Statement accepted |
| Minimum content after heat stability testing (KCP 2.7.3) | XRF spectrometry CIPAC MT 46.3 | Iron Phosphate 1% GB (Batch No. SCL – 894250 | 1.05% w/w | | | | | Y | B. Krzysiak-Warzała, 2017 Report No. 18/2017/BA-AD | |
| Effect of low temperatures on stability (KCP 2.7.4) | - | - | Not relevant for GB formulation. | | | | | - | - | Statement accepted |
| Ambient temperature shelf life | XRF Spectrometry OPPTS 830.6302 | Iron Phosphate | Test | 0 days | 6 months | 12 months | 24 months | Y | B. Krzysiak-Warzała, 2019 | Accepted |
| | | | A. s. | 0.94% | 0.89% | 0.96% | 0.99% | | | |

| Annex point | Method used / deviations | Test material | Findings | | | | | GLP Y/N | Reference | Acceptability / comments |
|-------------|---|-----------------------------------|----------------------------|--|--|--|--|---------|--------------------------|--|
| (KCP 2.7.5) | OPPTS 830.6303 OPPTS 830.6304 CIPAC MT 75.3 CIPAC MT 170 CIPAC MT 171 | 1% GB (Batch No. SCL – 894250) | content | w/w | w/w | | | | Report No. 19/2017/BA-AD | <p>RMS Comment: Active substance content and stability of packaging were tested. All physical and chemical properties remained stable after the test and accepted.</p> <p>Test carried out in HDPE coex bottles.</p> <p>Storage stability – 2 years</p> |
| | | | Appearance | Pale blue granules with weakly odor | Pale blue granules with weakly odor | Pale blue granules with weakly odor | Pale blue granules with weakly odor | | | |
| | | | pH 1% aqueous extract | 4.14 | 4.27 | 4.33 | 4.38 | | | |
| | | | Particle size distribution | 99.70 % of the particles have size between 2000 – 3350 µm 0.14% of the particles have size between 1000 – 2000 µm | 99.72 % of the particles have size between 2000 – 3350 µm 0.11% of the particles have size between 1000 – 2000 µm | 99.84 % of the particles have size between 2000 – 3350 µm 0.05% of the particles have size between 1000 – 2000 µm | 99.76 % of the particles have size between 2000 – 3350 µm 0.05% of the particles have size between 1000 – 2000 µm | | | |
| | | | Dust content | 0.2 mg nearly dust free | 0.1 mg nearly dust free | 0.2 mg nearly dust free | 0.2 mg nearly dust free | | | |
| | | | Attrition | 99.65% | 99.94% | 99.97 | 99.79% | | | |
| | | | Stability of packaging | - | Weight loss 0.0% | Weight loss 0.01% | Weight loss 0.03% | | | |

| Annex point | Method used / deviations | Test material | Findings | | | | | GLP Y/N | Reference | Acceptability / comments |
|---|--------------------------|---|--|--|------------------------------------|------------------------------------|------------------------------------|---------|---|--------------------------|
| | | | | | No changes in appearance of sample | No changes in appearance of sample | No changes in appearance of sample | | | |
| Shelf life in months (if less than 2 years) (KCP 2.7.6) | - | - | Not relevant. | | | | | - | - | Statement accepted |
| Wettability (KCP 2.8.1) | - | - | Not relevant for GB formulation. | | | | | - | - | Statement accepted |
| Persistence of foaming (KCP 2.8.2) | - | - | Not relevant for solid formulation. | | | | | - | - | Statement accepted |
| Suspensibility (KCP 2.8.3.1) | - | - | Not relevant for solid formulation. | | | | | - | - | Statement accepted |
| Spontaneity of dispersion (KCP 2.8.3.2) | - | - | Not relevant for solid formulation. | | | | | - | - | Statement accepted |
| Dispersion stability (KCP 2.8.3.3) | - | - | Not relevant for solid formulation. | | | | | - | - | Statement accepted |
| Degree of dissolution and dilution stability (KCP 2.8.4) | - | - | Not relevant for solid formulation. | | | | | - | - | Statement accepted |
| Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1) | CIPAC MT 170 | Iron Phosphate 1% GB (Batch No. SCL – 894250) | 99.70 % of the particles have size between 2000 – 3350 µm 0.14% of the particles have size between 1000 – 2000 µm | | | | | Y | B. Krzysiak-Warzała, 2017 Report No. 18/2017/BA-AD | Accepted |
| Wet sieve test (KCP 2.8.5.1.2) | - | - | Not relevant for GB formulation. | | | | | - | - | Statement accepted |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|---|-------------------------------|---|---|---------|---|--------------------------|
| Dust content (KCP 2.8.5.2.1) | CIPAC MT 171 | Iron Phosphate 1% GB (Batch No. SCL – 894250) | 0.2 mg Nearly dust free | Y | B. Krzysiak-Warzała, 2017 Report No. 18/2017/BA-AD | Accepted |
| Particle size of dust (KCP 2.8.5.2.2) | - | - | Not relevant. | - | - | Statement accepted |
| Attrition (KCP 2.8.5.3) | CIPAC MT 178 | Iron Phosphate 1% GB (Batch No. SCL – 894250) | Attrition resistance: 99.65% | Y | B. Krzysiak-Warzała, 2017 Report No. 18/2017/BA-AD | Accepted |
| Hardness and integrity (KCP 2.8.5.4) | - | - | Not relevant for GB formulation. | - | - | Statement accepted |
| Emulsifiability (KCP 2.8.6.1) | - | - | Not relevant for solid formulation. | - | - | Statement accepted |
| Emulsion stability (KCP 2.8.6.2) | - | - | Not relevant for solid formulation. | - | - | Statement accepted |
| Re-emulsifiability (KCP 2.8.6.3) | - | - | Not relevant for solid formulation. | - | - | Statement accepted |
| Flowability (KCP 2.8.7.1) | - | - | Sample drops through the sieve spontaneously. | - | - | Statement accepted |
| Pourability (KCP 2.8.7.2) | - | - | Not relevant for solid formulation. | - | - | Statement accepted |
| Dustability following accelerated storage (KCP 2.8.7.3) | CIPAC MT 171 CIPAC MT 46.3 | Iron Phosphate 1% GB (Batch | 1.1 mg nearly dust free | Y | B. Krzysiak-Warzała, 2017 Report No. 18/2017/BA-AD | Accepted |

| Annex point | Method used / deviations | Test material | Findings | GLP Y/N | Reference | Acceptability / comments |
|--|--------------------------|------------------|---------------|---------|-----------|--------------------------|
| | | No. SCL – 894250 | | | | |
| Physical compatibility of tank mixes (KCP 2.9.1) | - | - | Not relevant. | - | - | Statement accepted |
| Chemical compatibility of tank mixes (KCP 2.9.2) | - | - | Not relevant. | - | - | Statement accepted |
| Adhesion to seeds (KCP 2.10.1) | - | - | Not relevant. | - | - | Statement accepted |
| Distribution to seed (KCP 2.10.2) | - | - | Not relevant. | - | - | Statement accepted |
| Other/special studies (KCP 2.11) | - | - | Not relevant. | - | - | Statement accepted |

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

Table 1.6-1: Packaging information for 250 g (500 mL bottle)

| Type | Description |
|------------------------|---|
| Material: | HDPE |
| Shape/size: | Bottle / approx. 75 mm x 75 mm x 161 mm |
| Opening: | approx. 42.5 mm inner diameter |
| Closure: | HDPE screw cap |
| Seal: | Induction heat seal |
| Manner of construction | coextrusion |
| UN/ADR | compliant |

Table 1.6-2: Packaging information for 500 g (750 mL bottle)

| Type | Description |
|------------------------|---|
| Material: | HDPE |
| Shape/size: | Bottle / approx. 85 mm x 85 mm x 186 mm |
| Opening: | approx. 42.5 mm inner diameter |
| Closure: | HDPE screw cap |
| Seal: | Induction heat seal |
| Manner of construction | coextrusion |
| UN/ADR | compliant |

Table 1.6-3: Packaging information for 1.75 kg (2.5 litre bottle)

| Type | Description |
|------------------------|---|
| Material: | HDPE |
| Shape/size: | Bottle / approx. 122 mm x 122 mm x 258 mm |
| Opening: | approx. 69 mm inner diameter |
| Closure: | HDPE screw cap |
| Seal: | Induction heat seal |
| Manner of construction | coextrusion |
| UN/ADR | compliant |

Table 1.6-4: Packaging information for 3.5 kg (5.5 litre bottle)

| Type | Description |
|-------------|---|
| Material: | HDPE |
| Shape/size: | Bottle / approx. 150 mm x 150 mm x 335 mm |
| Opening: | approx. 69 mm inner diameter |

| Type | Description |
|------------------------|---------------------|
| Closure: | HDPE screw cap |
| Seal: | Induction heat seal |
| Manner of construction | coextrusion |
| UN/ADR | compliant |

Table 1.6-5: Packaging information for 5 kg (7.4 litre bottle)

| Type | Description |
|------------------------|--|
| Material: | PP |
| Shape/size: | Rounded cube / approx. 174 mm x 255 mm |
| Opening: | approx. 255 mm inner diameter |
| Closure: | PP cap |
| Seal: | Induction heat seal |
| Manner of construction | coextrusion |
| UN/ADR | compliant |

Table 1.6-6: Packaging information for 10 kg (13.75 litre bottle)

| Type | Description |
|------------------------|--|
| Material: | PP |
| Shape/size: | Rounded cube / approx. 303 mm x 260 mm |
| Opening: | approx. 260 mm inner diameter |
| Closure: | PP cap |
| Seal: | Induction heat seal |
| Manner of construction | coextrusion |
| UN/ADR | compliant |

RMS Comments:

Recommended packaging have been accepted.

Appendix 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 2.1 KCP 2.2.2 KCP 2.3.2 KCP 2.3.3 KCP 2.4.2 KCP 2.6.2 KCP 2.7.1 KCP 2.7.3 KCP 2.8.5.1.1 KCP 2.8.5.2.1 KCP 2.8.7.3 | B. Krzysiak-Warzała | 2017 | Iron phosphate 1.0% GB: Analysis of active substances content and physicochemical properties of initial preparation and preparation after accelerated storage procedure (CIPAC MT 46.3) Report No. 18/2017/BA-AD GLP Unpublished | N | Sharda Cropchem Limited |
| KCP 2.2.1 | D. Buczkowski | 2017 | Iron Phosphate 1.0% GB. Determination of explosive properties. Report No. BW-02/17 GLP Unpublished | N | Sharda Cropchem Limited |
| KCP 2.7.5 | B. Krzysiak-Warzała | 2019 | Iron phosphate 1.0% GB: Evaluation of stability of the product after storage in accordance with the CropLife Technical Monograph No. 17 (6months, 1 year, 2 years). Report No. 19/2017/BA-AD GLP Unpublished | N | Sharda Cropchem Limited |
| KCP 2.7.1 | Mr. K. Vasu | 2023 | Method validation and determination of relevant impurities Lead, Mercury and Cadmium in Iron Phosphate 1% GB | N | Sharda Cropchem |

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|------------|-------------|------|---|-------------------------|-------------------------|
| | | | Report No.: 11255/2022 Bioscience Research Foundation GLP Unpublished | | Limited |
| KCP 2.7.1 | Mr. K. Vasu | 2023 | Method validation and determination of relevant impurities Lead, Mercury and Cadmium in Iron Phosphate 1% GB, Report No.: 13033/2023 Bioscience Research Foundation GLP Unpublished | N | Sharda Cropchem Limited |

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

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

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Ferric phosphate