

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 days 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	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. Storage stability – 2 years
			Appearance	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			
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