

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 105000 B

Product name(s): HIERRO

Chemical active substance:

Ferric phosphate, 10.0 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: November 2020

MS Finalisation date: 06.2021; 10.2021

Version history

When	What
06/2021	Assessment
10.2021	The Final Version of the RR

Table of Contents

7	Metabolism and residue data (KCA section 6)	5
7.1	Summary and zRMS Conclusion.....	5
7.1.1	Critical GAP(s) and overall conclusion	5
7.1.2	Summary of the evaluation	7
7.1.2.1	Summary for Ferric phosphate.....	7
7.1.2.2	Summary for Iron phosphate 1% GB.....	7
7.2	Ferric phosphate.....	9
7.2.1	Stability of Residues (KCA 6.1)	9
7.2.1.1	Stability of residues during storage of samples	9
7.2.1.2	Stability of residues in sample extracts (KCA 6.1).....	10
7.2.2	Nature of residues in plants, livestock and processed commodities	10
7.2.2.1	Nature of residue in primary crops (KCA 6.2.1)	10
7.2.2.2	Nature of residue in rotational crops (KCA 6.6.1).....	10
7.2.2.3	Nature of residues in processed commodities (KCA 6.5.1).....	11
7.2.2.4	Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)	11
7.2.2.5	Nature of residues in livestock (KCA 6.2.2-6.2.5)	12
7.2.2.6	Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)	12
7.2.3	Magnitude of residues in plants (KCA 6.3).....	13
7.2.3.1	Conclusion on the magnitude of residues in plants	13
7.2.4	Magnitude of residues in livestock	13
7.2.4.1	Dietary burden calculation.....	13
7.2.4.2	Livestock feeding studies (KCA 6.4.1-6.4.3)	13
7.2.5	Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3).....	13
7.2.5.1	Available data for all crops under consideration	13
7.2.5.2	Conclusion on processing studies	13
7.2.6	Magnitude of residues in representative succeeding crops.....	13
7.2.6.1	Field rotational crop studies (KCA 6.6.2).....	14
7.2.7	Other / special studies (KCA6.10, 6.10.1).....	14
7.2.8	Estimation of exposure through diet and other means (KCA 6.9).....	14
7.2.8.1	Input values for the consumer risk assessment.....	14
7.2.8.2	Conclusion on consumer risk assessment	14
7.3	Combined exposure and risk assessment.....	14
7.4	References.....	15
Appendix 1	Lists of data considered in support of the evaluation	16
Appendix 2	Detailed evaluation of the additional studies relied upon	18
A 2.1	Ferric phosphate.....	18
A 2.1.1	Stability of residues.....	18
A 2.1.2	Nature of residues in plants, livestock and processed commodities	18
A 2.1.3	Magnitude of residues in plants	19
A 2.1.4	Magnitude of residues in livestock	19
A 2.1.5	Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)	19
A 2.1.6	Magnitude of residues in representative succeeding crops.....	19

A 2.1.7	Other/Special Studies	19
Appendix 3	Pesticide Residue Intake Model (PRIMo).....	19
A 3.1	TMDI calculations	19
A 3.2	IEDI calculations	19
A 3.3	IESTI calculations - Raw commodities	19
A 3.4	IESTI calculations - Processed commodities.....	19
Appendix 4	Additional information provided by the applicant	19

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Ferric phosphate is listed in Annex IV of Regulation (EC) No 396/2005. Therefore, a residue definition and MRLs were not established.

Residue data are not required. Uses are accepted.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation Iron phosphate 1% GB are presented in Table 7.1-1. They have been selected from the individual GAPs in the central zone for fruit crops, vegetables crops, field crops, grapevine, ornamentals and hop. A list of all intended uses within the central zone is given in Part B, Section 0.

Overall conclusion

According to the Commission Regulation (EC) No 2015/1166, The Commission further considers that ferric phosphate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. The chronic and the short-term intakes of ferric phosphate residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, Poland agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

- None

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
						Type	Conc. of as g/kg	method kind	growth stage & season	Number max	interval between applications (min)	kg as/hL max	water L/ha max	kg as/ha max		
1	Fruit crops	SEU	SHA 105000 B	F	Slugs and Snails	GB	10.0	Spread to soil surface	From seedling/planting until BBCH 79	4	14	-	-	0.5	-	A
2	Vegetable crops	SEU	SHA 105000 B	F	Slugs and Snails	GB	10.0	Spread to soil surface	From seedling/planting until BBCH 81	4	14	-	-	0.5	-	A
3	Field crops	SEU	SHA 105000 B	F	Slugs and Snails	GB	10.0	Spread to soil surface	From seedling/planting until BBCH 89	4	14	-	-	0.5	-	A
4	Grapevine	SEU	SHA 105000 B	F	Slugs and Snails	GB	10.0	Spread to soil surface	From seedling/planting until BBCH 81	4	14	-	-	0.5	-	A
5	Ornamentals	SEU	SHA 105000 B	F	Slugs and Snails	GB	10.0	Spread to soil surface	From seedling/planting until BBCH 69	4	14	-	-	0.5	-	A
6	Hop	SEU	SHA 105000 B	F	Slugs and Snails	GB	10.0	Spread to soil surface	From seedling/planting until BBCH 82	4	14	-	-	0.5	-	A

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** 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

Explanation for Column 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation Iron phosphate 1% GB is composed of Ferric phosphate.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of Ferric phosphate

Reference value	Source	Year	Value	Study relied upon	Safety factor
Ferric phosphate					
ADI	EFSA	2015	0.8 mg/kg bw per day. (iron)	Derived from human intakes.	Not required.
ARfD	Not applicable				

7.1.2.1 Summary for Ferric phosphate

Table 7.1-3: Summary for Ferric phosphate

Use- No.*	Crop	Plant me- tabolism covered?	Sufficient residue trials?	PHI suffi- ciently sup- ported?	Sample storage covered by stabil- ity data?	MRL com- pliance	Chronic risk for consumers identified?	Acute risk for con- sumers identified?
1	Fruit crops	NR	NR	NR	NR	NR	No	NR
2	Vegetable crops	NR	NR	NR	NR	NR		NR
3	Field crops	NR	NR	NR	NR	NR		NR
4	Grapevine	NR	NR	NR	NR	NR		NR
5	Ornamentals	NR	NR	NR	NR	NR		NR
6	Hop	NR	NR	NR	NR	NR		NR

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

7.1.2.2 Summary for Iron phosphate 1% GB

Table 7.1-4: Information on Iron phosphate 1% GB (KCA 6.8)

Crops	PHI for Iron phosphate 1% GB proposed by applicant	PHI/ Withhold- ing period* suf- ficiently sup- ported for	PHI for Iron phos- phate 1% GB proposed by zRMS	zRMS Comments (if different PHI proposed)
		Ferric phosphate		
Fruit crops	NR	NR	-	
Vegetable crops	NR	NR	-	
Field crops	NR	NR	-	

Crops	PHI for Iron phosphate 1% GB proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Iron phosphate 1% GB proposed by zRMS	zRMS Comments (if different PHI proposed)
		Ferric phosphate		
Grapevine	NR	NR	-	
Ornamentals	NR	NR	-	
Hop	NR	NR	-	

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Ferric phosphate

General data on Ferric phosphate are summarized in the table below (last updated 2019/29/01)

Table 7.2-1: General information on Ferric phosphate

Active substance (ISO Common Name)	Ferric phosphate
IUPAC	iron(3+);phosphate
Chemical structure	The chemical structure shows a central phosphorus atom (P) bonded to four oxygen atoms (O) in a tetrahedral arrangement. The phosphorus atom is enclosed in square brackets with a 3- charge. To the left of the brackets is an iron ion (Fe) with a 3+ charge.
Molecular formula	FePO ₄
Molar mass	150.82 g/mol (anhydrous)
Chemical group	Inorganic compound
Mode of action (if available)	Contact action, interferes with calcium metabolism in slug / snail stomach causing it to stop feeding
Systemic	Yes
Companies	Neudorff GmbH KG Bayer SAS
Rapporteur Member State (RMS)	Germany
Approval status	Approved Date of (01/01/2016) and reference to decision (REGULATION (EU) No 2015/1166). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1166&from=EN
Restriction	Restriction to uses as a molluscicide
Review Report	SANTE/10385/2015 Rev 1 29 May 2015
Current MRL regulation	Annexes Regulation (EC) No 396/2005 Reg. (EC) No 839/2008
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No
EFSA Journal : Conclusion on the peer review	Yes, EFSA Journal 2015;13(1):3973
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	No

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Summary on stability of residues studies reported in the EU

According to the Commission Regulation (EC) No 2015/1166, The Commission further considers that ferric phosphate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Ferric phosphate is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Ferric phosphate consists of compounds that are ubiquitous in the environment and that are essential for animal and plant functions. Additionally, ferric phosphate is a natural constituent of the human diet. The additional exposure of humans, animals and the environment by the uses approved under Regulation (EC) No 1107/2009 is expected to be negligible compared to exposure expected through realistic natural situations.

No MRLs are defined, Therefore no studies are required.

Conclusion on stability of residues during storage

Stability of residues studies are not relevant since the derivation of MRLs and consumer risk assessments are not appropriate for ferric and phosphate ions as naturally occurring and nutritionally-required compounds.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No data was submitted and required at EU level during the EU Review of Ferric phosphate

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Summary of plant metabolism studies reported in the EU

According to the Commission Regulation (EC) No 2015/1166, The Commission further considers that ferric phosphate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Ferric phosphate is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Ferric phosphate consists of compounds that are ubiquitous in the environment and that are essential for animal and plant functions. Additionally, ferric phosphate is a natural constituent of the human diet. The additional exposure of humans, animals and the environment by the uses approved under Regulation (EC) No 1107/2009 is expected to be negligible compared to exposure expected through realistic natural situations.

No MRLs are defined, Therefore no studies are required.

Conclusion on metabolism in primary crops

Plant metabolism studies are not relevant since the derivation of MRLs for animal products and consumer risk assessments are not appropriate for ferric and phosphate ions naturally occurring and nutritionally-required compounds.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

No new data submitted in the framework of this application.

Summary of plant metabolism studies reported in the EU

According to the Commission Regulation (EC) No 2015/1166, The Commission further considers that ferric phosphate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Ferric phosphate is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Ferric phosphate consists of compounds that are ubiquitous in the environment and that are essential for animal and plant functions. Additionally, ferric phosphate is a natural constituent of the human diet. The additional exposure of humans, animals and the environment by the uses approved under Regulation (EC) No 1107/2009 is expected to be negligible compared to exposure expected through realistic natural situations.

No MRLs are defined, Therefore no studies are required.

Conclusion on metabolism in rotational crops

Plant metabolism studies are not relevant since the derivation of MRLs for animal products and consumer risk assessments are not appropriate for ferric and phosphate ions naturally occurring and nutritionally-required compounds.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Summary on nature of residues in processed commodities

According to the Commission Regulation (EC) No 2015/1166, The Commission further considers that ferric phosphate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Ferric phosphate is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Ferric phosphate consists of compounds that are ubiquitous in the environment and that are essential for animal and plant functions. Additionally, ferric phosphate is a natural constituent of the human diet. The additional exposure of humans, animals and the environment by the uses approved under Regulation (EC) No 1107/2009 is expected to be negligible compared to exposure expected through realistic natural situations.

No MRLs are defined, Therefore no studies are required.

Conclusion on nature of residues in processed commodities

Processed commodities studies are not relevant since the derivation of MRLs for animal products and consumer risk assessments are not appropriate for ferric and phosphate ions naturally occurring and nutritionally-required compounds.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-2: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Not relevant.
Rotational crops covered	Not relevant.
Metabolism in rotational crops similar to metabolism in primary crops?	Not relevant.
Processed commodities	Not relevant.

Residue pattern in processed commodities similar to pattern in raw commodities?	Not relevant.
Plant residue definition for monitoring	Not relevant.
Plant residue definition for risk assessment	Not relevant.
Conversion factor from enforcement to RA	Not relevant.

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Summary of plant metabolism studies reported in the EU

According to the Commission Regulation (EC) No 2015/1166, The Commission further considers that ferric phosphate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Ferric phosphate is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Ferric phosphate consists of compounds that are ubiquitous in the environment and that are essential for animal and plant functions. Additionally, ferric phosphate is a natural constituent of the human diet. The additional exposure of humans, animals and the environment by the uses approved under Regulation (EC) No 1107/2009 is expected to be negligible compared to exposure expected through realistic natural situations.

No MRLs are defined, Therefore no studies are required.

Conclusion on metabolism in livestock

Livestock metabolism studies are not relevant since the derivation of MRLs for animal products and consumer risk assessments are not appropriate for ferric and phosphate ions naturally occurring and nutritionally-required compounds.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-3: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Not relevant.
	Not relevant.
Time needed to reach a plateau concentration	Not relevant.
	Not relevant.
Animal residue definition for monitoring	Not relevant.
Animal residue definition for risk assessment	Not relevant.
Conversion factor	Not relevant.
Metabolism in rat and ruminant similar	Not relevant.
Fat soluble residue	Not relevant.

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Conclusion on the magnitude of residues in plants

Ferric phosphate is naturally occurring in the environment and the uptake of iron ions and phosphate ions by plants is actively controlled by the plants. The level of these compounds in plants is species dependent. In the unlikely event that a pellet gets lodged in a leaf it is likely that it will be removed by normal food processing e.g. washing and removal of outer leaves. If there is some exposure it will not be significant and there will be a large margin of safety on any reference values.

According to the available data, all the intended uses are considered acceptable, for outdoor uses.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Not required

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.

Conclusion on feeding studies

Soil application will not result in relevant residues of ferric and phosphate in animals. Consequently it is not necessary to conduct livestock feeding studies.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

7.2.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.

7.2.5.2 Conclusion on processing studies

No relevant residues of iron or phosphate are to be expected in plants after soil application of ferric phosphate. Therefore, processing studies on the transfer of residues into processed products are not necessary.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 0), no study dealing with magnitude of residues in succeeding crops is needed.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

No relevant residues of iron or phosphate are to be expected in plants after soil application of ferric phosphate. In addition iron and particularly phosphate are used as fertilizers. Therefore, additional relevant residues from the application of iron phosphate for the control of slugs will not occur in succeeding crops.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of Iron phosphate 1% GB. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment

7.2.8.2 Conclusion on consumer risk assessment

According to the Commission Regulation (EC) No 2015/1166, The Commission further considers that ferric phosphate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Ferric phosphate is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Ferric phosphate consists of compounds that are ubiquitous in the environment and that are essential for animal and plant functions. Additionally, ferric phosphate is a natural constituent of the human diet. The additional exposure of humans, animals and the environment by the uses approved under Regulation (EC) No 1107/2009 is expected to be negligible compared to exposure expected through realistic natural situations.

The consumer risk assessments is not appropriate for ferric and phosphate ions as naturally occurring and nutritionally-required compounds.

The proposed uses of Ferric phosphate in the formulation Iron phosphate 1% GB do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance ferric phosphate, EFSA Journal 2015;13(1):3973

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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
-	-	-	-	-	-

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
-	-	-	-	-	-

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
-	-	-	-	-	-

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 Detailed evaluation of the additional studies relied upon

A 2.1 Ferric phosphate

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.2 Storage stability of residues in animal products

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

A 2.1.2.1.2 Nature of residue in rotational crops

A 2.1.2.1.3 Nature of residues in processed commodities

A 2.1.2.2 Nature of residues in livestock

A 2.1.3 Magnitude of residues in plants

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

A 2.1.5.2 Processing studies on a core set of representative processes

A 2.1.6 Magnitude of residues in representative succeeding crops

A 2.1.7 Other/Special Studies

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Not required

A 3.2 IEDI calculations

Not required

A 3.3 IESTI calculations - Raw commodities

Not required

A 3.4 IESTI calculations - Processed commodities

Not required

Appendix 4 Additional information provided by the applicant

None