

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 6**

#### **Mammalian Toxicology**

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**

Applicant: SHARDA Cropchem España S.L.

Submission date: November 2020

MS Finalisation date: October 2021

## Version history

When	What
2021	Assessment by expert
September 2021	Application update
October 2021	Assessment after an update

## Table of Contents

<b>6</b>	<b>Mammalian Toxicology (KCP 7).....</b>	<b>5</b>
6.1	Summary .....	5
6.2	Toxicological Information on Active Substance(s) .....	7
6.3	Toxicological Evaluation of Plant Protection Product.....	7
6.4	Toxicological Evaluation of Groundwater Metabolites.....	8
6.5	Dermal Absorption (KCP 7.3) .....	8
6.5.1	Justification for proposed values - Ferric phosphate .....	8
6.6	Exposure Assessment of Plant Protection Product (KCP 7.2).....	9
6.6.1	Selection of critical use(s) and justification .....	9
6.6.2	Operator exposure (KCP 7.2.1) .....	9
6.6.2.1	Estimation of operator exposure .....	9
6.6.2.2	Measurement of operator exposure.....	10
6.6.3	Worker exposure (KCP 7.2.3) .....	11
6.6.3.1	Estimation of worker exposure .....	11
6.6.3.2	Refinement of generic DFR value (KCP 7.2).....	11
6.6.3.3	Measurement of worker exposure.....	11
6.6.4	Resident and bystander exposure (KCP 7.2.2) .....	11
6.6.4.1	Estimation of resident and bystander exposure .....	11
6.6.4.2	Measurement of resident and/or bystander exposure.....	12
6.6.5	Combined exposure .....	12
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation .....</b>	<b>13</b>
<b>Appendix 2</b>	<b>Detailed evaluation of the studies relied upon.....</b>	<b>15</b>
A 2.1	Statement on bridging possibilities.....	15
A 2.2	Acute oral toxicity (KCP 7.1.1) .....	15
A 2.3	Acute percutaneous (dermal) toxicity (KCP 7.1.2) .....	16
A 2.4	Acute inhalation toxicity (KCP 7.1.3) .....	16
A 2.5	Skin irritation (KCP 7.1.4).....	17
A 2.6	Eye irritation (KCP 7.1.5) .....	17
A 2.7	Skin sensitisation (KCP 7.1.6).....	18
A 2.8	Supplementary studies for combinations of plant protection products (KCP 7.1.7) .....	18
A 2.9	Data on co-formulants (KCP 7.4) .....	18
A 2.9.1	Material safety data sheet for each co- formulant.....	18
A 2.9.2	Available toxicological data for each co-formulant.....	18
A 2.10	Studies on dermal absorption (KCP 7.3) .....	18
A 2.11	Other/Special Studies .....	18
<b>Appendix 3</b>	<b>Exposure calculations .....</b>	<b>19</b>
A 3.1	Operator exposure calculations (KCP 7.2.1.1) .....	19
A 3.1.1	Calculations for Ferric phosphate .....	19
A 3.2	Worker exposure calculations (KCP 7.2.3.1) .....	21
A 3.3	Resident and bystander exposure calculations (KCP 7.2.2.1) .....	21
A 3.3.1	Calculations for Ferric phosphate .....	21

<b>Appendix 4</b>	<b>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) ..... 23</b>
-------------------	---

## 6 Mammalian Toxicology (KCP 7)

### 6.1 Summary

**Table 6.1-1: Information on SHA 105000 B/HIERRO \***

Product name and code	SHA 105000 B/HIERRO
Formulation type	Granular bait [Code: GB]
Active substance(s) (incl. content)	Ferric phosphate; 10 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 B/HIERRO 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 B/HIERRO 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)	P280
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

**Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for SHA 105000 B/HIERRO**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Broadcast application: certified by Manual application certified protective coverall + chemical resistant gloves during protective A mechanical applicator. None
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. safen- er/synergist (L/ha))  critical gap for operator, worker, resident or by- stander exposure based on [Expo- sure model]	Acceptability of exposure as- sessment			
			Method / Kind  (incl. applica- tion technique ***	Max. number (min. interval between applications)  a) per use b) per crop/ season	Max. applica- tion rate kg as/ha  a) a.s. 1 b) a.s. 2	Water L/ha  min / max			Operator	Worker	Residents	Bystander
1	Fruit crops (from seed- ling/planting until BBCH 79)	F	Spread to soil surface	4; 14	a) 0.5	-	-	Guidance on the assessment of exposure of opera- tors, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874				
2	Vegetable crops (from seed- ling/planting until BBCH 81)	F	Spread to soil surface	4; 14	a) 0.5	-	-					
3	Field crops (from seed- ling/planting until BBCH 89)	F	Spread to soil surface	4; 14	a) 0.5	-	-					
4	Grapevine (from seedling/planting until BBCH 81)	F	Spread to soil surface	4; 14	a) 0.5	-	-					
5	Ornamentals (from seed- ling/planting until BBCH 69)	F	Spread to soil surface	4; 14	a) 0.5	-	-					
6	Hop (from seedling/planting until BBCH 82)	F	Spread to soil surface	4; 14	a) 0.5	-	-					

\* 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

## 6.2 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
<b>Classification and proposed labelling</b>	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Not classified
Additional C&L proposal	-
<b>Agreed EU endpoints</b>	
AOEL systemic	0.4 mg/kg bw/d (corrected for 50% oral absorption)
Reference	EFSA Journal 2015;13(1):3973
<b>Conditions to take into account/critical areas of concern with regard to toxicology</b>	
According to EFSA Journal 2015;13(1):3973 for Ferric phosphate	None

## 6.3 Toxicological Evaluation of Plant Protection Product

The assessment of all acute toxicological properties of Iron phosphate 1% GB is derived from the classification of the active compound and co-formulants.

### Justification for the proposed classification according the Regulation (EC) No 1272/2008:

Full details of the calculation methodology, co-formulants and their volumes in the product can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).  
Classification for Iron phosphate 1% GB was calculated based on classification of co-formulants. Based on those calculations for formulation, no classification is required for the oral, dermal and inhalation toxicity, skin irritation, eye irritation and skin sensitizer.

**Table 6.3-1: Additional toxicological information relevant for classification/labelling of SHA 105000 B/HIERRO**

	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	Ferric phosphate	Not classified	Reg.	-

	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)
properties of active substance(s) (relevant for classification of product)	1% (w/w)		1272/2008	
Toxicological properties of non-active substance(s) (relevant for classification of product)	-	-	-	-
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

## 6.4 Toxicological Evaluation of Groundwater Metabolites

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

## 6.5 Dermal Absorption (KCP 7.3)

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

**Table 6.5-1: Dermal absorption rates for active substances in SHA 105000 B/HIERRO**

	Ferric phosphate	
	Value	Reference
Concentrate	10%	EFSA Journal 2015;13(1):3973
Dilution	n/a	n/a

### 6.5.1 Justification for proposed values - Ferric phosphate

No data on dermal absorption for Ferric phosphate in SHA 105000 B/HIERRO is available. Justifications for default values according to EFSA Journal (2015;13(1):3973) 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	10%	No relevant dermal absorption of FePO <sub>4</sub> is expected (extremely low solubility in water and lipids). The oral absorption is an active energy dependent process which will not take place in the skin. A dermal absorption value of 10% is proposed as worst-case scenario.	Acceptable
Dilution	n/a	n/a	Acceptable

## 6.6 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 B/HIERRO
Formulation type	GB
Category	Molluscicide
Active substance(s) (incl. content)	<b>Ferric phosphate</b> 10 g/kg
AOEL systemic	0.4 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	<del>100%</del> 50%
Dermal absorption	Concentrate: 10% Dilution: -

### 6.6.1 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.

### 6.6.2 Operator exposure (KCP 7.2.1)

#### 6.6.2.1 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 B/HIERRO 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, field crops, grapevine, ornamentals, hop (max. 50 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 2014;12(10):3874 calculator version: 30/03/2015

**Table 6.6-3: Estimated operator exposure (longer term exposure)**

		Ferric phosphate	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Broadcast application of granules outdoors - vegetable crops, field crops			
Application rate		0.5 kg a.s./ha	
<b>Granule application</b> (PHED model; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.1041	<b>26</b>
	Certified protective coverall M/L and A	0.0178	<b>4.5</b>
Broadcast application of granules outdoors – fruit crops, grapevine, ornamentals, hop			
Application rate		0.5 kg a.s./ha	
<b>Granule application</b> (PHED model; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.0208	<b>5</b>
	Certified protective coverall M/L and A	0.0036	<b>0.9</b>
Manual application of granules outdoors - fruit crops, vegetable crops, field crops, grapevine, ornamentals, hop			
Application rate		0.5 kg a.s./ha	
<b>Granule application</b> (PHED model; 95 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	8.1208	<b>2030</b>
	Certified protective coverall + chemical resistant gloves during A	0.0851	<b>21</b>

**According to the EFSA AOEM Model, it can be concluded that the risk to the operator is acceptable without the use of PPE during application with a mechanical applicator.**

**However, use by hand spreading is acceptable, provided that a certified protective suit and chemical-resistant gloves are used. Implication for labelling: Gloves during manual application**

#### 6.6.2.2 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.

### **6.6.3 Worker exposure (KCP 7.2.3)**

#### **6.6.3.1 Estimation of worker exposure**

Since Iron phosphate 1.0% GB is 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.

### **Acceptable**

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

Not required.

#### **6.6.3.3 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.

### **6.6.4 Resident and bystander exposure (KCP 7.2.2)**

#### **6.6.4.1 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 6.6-4 shows the exposure model(s) used for estimation of resident exposure to Ferric phosphate. The outcome of the estimation is presented in Table 6.6-5 (longer term resident exposure). Detailed calculations are in Appendix 3.

**Table 6.6-4: Exposure models for intended uses**

Critical use(s)	Fruit crops, vegetable crops, field crops, grapevine, ornamentals, hop (max. 4 x 50.0 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 2014;12(10):3874 calculator version: 30/03/2015

**Table 6.6-5: Estimated resident exposure (longer term exposure)**

		Ferric phosphate	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Vehicle-mounted broadcast application of granules outdoors, manual application of granules outdoors <b>Buffer zone: 2-3(m)</b> Drift reduction technology: no DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 14 days			
Number of applications and application rate		4 x 0.5 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	-	-
	Vapour (75 <sup>th</sup> perc.)	0.0010700	0.27
	Deposits (75 <sup>th</sup> perc.)	0.0004767	0.12
		0.0003408	0.09
	Re-entry (75 <sup>th</sup> perc.)	-	-
	<b>Sum (mean)</b>	-	-
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	-	-
	Vapour (75 <sup>th</sup> perc.)	0.0002300	0.06
	Deposits (75 <sup>th</sup> perc.)	0.0000959	0.02
	Re-entry (75 <sup>th</sup> perc.)	-	-
	<b>Sum (mean)</b>	-	-

**According to the EFSA AOEM Model, it can be concluded there is no risk for residents and bystanders after accidental short-term exposure to HIERRO while maintaining the buffer zones of 2-3m.**

#### 6.6.4.2 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.

#### 6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

## 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 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	Y/N	Owner

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

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

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

## Appendix 2 Detailed evaluation of the studies relied upon

### A 2.1 Statement on bridging possibilities

Not relevant.

### A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	<p><b>The acute oral toxicity of Iron phosphate 1% GB was estimated to be &gt; 2000 mg/kg.</b></p> <p><b>Therefore, according to the Regulation EC No. 1272/2008, Iron phosphate 1% GB is unclassified..</b></p>
-------------------	--

The classification of Iron phosphate 1% GB was performed by calculation. The assessment of all acute toxicological properties of Iron phosphate 1% 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 (10045-86-0)	<b>1.29</b>	>2000 mg/kg <sup>1)</sup>	>2000 mg/kg <sup>1)</sup>	*	Not Irritating <sup>1)</sup>	Not Irritating <sup>1)</sup>	Not sensitising <sup>1)</sup>
Coformulant 1	<b>xxx</b>	500 mg/kg <sup>2)</sup> H302	> 2000 mg/kg <sup>1)</sup>	1.5 mg/l <sup>2)</sup> , H332	Skin Irrit. 2, H315	Eye Irrit. 2, H319	Not sensitising <sup>1)</sup>
Coformulant 2	<b>xxx</b>	2100 mg/kg	> 2000 mg/kg <sup>1)</sup>	*	Not Irritating <sup>1)</sup>	Not Irritating <sup>1)</sup>	Not sensitising <sup>1)</sup>
Coformulant 3	<b>xxx</b>	>2000 mg/kg <sup>1)</sup>	>2000 mg/kg <sup>1)</sup>	*	Not Irritating <sup>1)</sup>	Not Irritating <sup>1)</sup>	Not sensitising <sup>1)</sup>
Coformulant 4	<b>xxx</b>	29700 mg/kg	>2000 mg/kg <sup>1)</sup>	*	Not Irritating <sup>1)</sup>	Not Irritating <sup>1)</sup>	Not sensitising <sup>1)</sup>
Coformulant 5	<b>xxx</b>	>2000 mg/kg <sup>1)</sup>	>2000 mg/kg <sup>1)</sup>	*	Not Irritating <sup>1)</sup>	Not Irritating <sup>1)</sup>	Not sensitising <sup>1)</sup>

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

<sup>1)</sup> As co-formulant is not classified

<sup>2)</sup> 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.

According to Regulation (EC) No 1272/2008 classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values:

$$\frac{100}{ATE_{mix}} = \sum_r \frac{C_i}{ATE_i}$$

or

$$\frac{100 - (\sum C_{unknown} \text{ if } > 10\%)}{ATE_{mix}} = \sum_r \frac{C_i}{ATE_i}$$

where:

$C_i$  = concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n

n = the number of ingredients

$ATE_i$  = Acute Toxicity Estimate of ingredient i.

The acute oral toxicity classification for Iron phosphate 1% GB was calculated:

$$ATE_{mix} = \frac{100}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100}{\frac{xxx\%}{500}} = 9615.38 \text{ mg/kg bw}$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Iron phosphate 1% GB can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

## Conclusion

The acute oral toxicity of Iron phosphate 1% GB was estimated to be > 2000 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Iron phosphate 1% GB is **not classified**. No signal word or hazard statement is required for this hazard.

### A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	<p><b>There is no co-formulant in the Iron phosphate 1% GB recipe classified as danger through dermal contact.</b></p> <p><b>According to the Regulation EC No. 1272/2008, Iron phosphate 1% GB is unclassified.</b></p>
-------------------	--

There is no co-formulant in the Iron phosphate 1% GB recipe classified as danger through dermal contact.

According to the Regulation EC No. 1272/2008, Iron phosphate 1% GB is **not classified**. No signal word or hazard statement is required for this hazard.

### A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	<p><b>The acute inhalation toxicity of Iron phosphate 1% GB was estimated to be &gt; 5 mg/l.</b></p> <p><b>Therefore, according to the Regulation EC No. 1272/2008, Iron phosphate 1% GB is unclassified..</b></p>
-------------------	--



The acute inhalation toxicity classification for Iron phosphate 1% GB was calculated:

$$ATE_{mix} = \frac{100}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100}{\frac{xxx\%}{1.5}} = 28.85 \text{ mg/l}$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute inhalation toxicity of Iron phosphate 1% GB can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

### Conclusion

The acute inhalation toxicity of Iron phosphate 1% GB was estimated to be > 5 mg/l.

Therefore, according to the Regulation EC No. 1272/2008, Iron phosphate 1% GB is **not classified**. No signal word or hazard statement is required for this hazard.

## A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	<b>According to the Regulation EC No. 1272/2008, Iron phosphate 1% GB is unclassified because under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.</b>
-------------------	--

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.

### Conclusion

According to the Regulation EC No. 1272/2008, Iron phosphate 1% GB is **not classified**. No signal word or hazard statement is required for this hazard.

## A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	<b>According to the Regulation EC No. 1272/2008, Iron phosphate 1% GB is unclassified. because under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.</b>
-------------------	---

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.

### Conclusion

According to the Regulation EC No. 1272/2008, Iron phosphate 1% GB is **not classified**. No signal word or hazard statement is required for this hazard.

#### A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	<b>No co-formulant in the Iron phosphate 1% GB recipe classified as skin sensitiser. According to the Regulation EC No. 1272/2008, Iron phosphate 1% GB is unclassified</b>
-------------------	---

There is no co-formulant in the Iron phosphate 1% GB recipe classified as skin sensitiser.

According to the Regulation EC No. 1272/2008, Iron phosphate 1% GB is **not classified**. No signal word or hazard statement is required for this hazard.

#### A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No data available.

#### A 2.9 Data on co-formulants (KCP 7.4)

##### A 2.9.1 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).

##### A 2.9.2 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).

#### A 2.10 Studies on dermal absorption (KCP 7.3)

According to EFSA Journal 2015;13(1):3973, no relevant dermal absorption of FePO<sub>4</sub> is expected (extremely low solubility in water and lipids). The oral absorption is an active energy dependent process which will not take place in the skin. A dermal absorption value of 10% is proposed as worst-case scenario.

**Acceptable**

#### A 2.11 Other/Special Studies

No data submitted.

## Appendix 3 Exposure calculations

### A 3.1 Operator exposure calculations (KCP 7.2.1.1)

#### A 3.1.1 Calculations for Ferric phosphate

**Table A 1: Input parameters considered for the estimation of operator exposure (broadcast application)**

Formulation type	GB		Crop type	Vegetable crops, field crops
Application rate (AR)	0.5	kg a.s./ha	Application method	Broadcast application of granules
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	10	% (concentr.)	Indoor/outdoor	Outdoor
	-	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.4	mg/kg bw/d	Water soluble bag	No

**Table A 2: Estimation of longer term operator exposure towards Ferric phosphate according to EFSA guidance**

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			None	
Specific exposure value	0.3631718	µg/person	0.3631718	µg/person
Systemic exposure	0.0060529	mg/kg bw/d	0.0060529	mg/kg bw/d
Body			Certified protective coverall	
Specific exposure value	4.0598361	µg/person	0.0405984	µg/person
Systemic exposure	0.0676639	mg/kg bw/d	0.0006766	mg/kg bw/d
Inhalation			None	
Specific exposure value	0.5202546	µg/person	0.5202546	µg/person
Systemic exposure	0.0086709	mg/kg bw/d	0.0086709	mg/kg bw/d
Application				
Hands			None	
Specific exposure value	0.1020641	µg/person	0.1020641	µg/person
Systemic exposure	0.0017011	mg/kg bw/d	0.0017011	mg/kg bw/d
Body			Certified protective coverall	
Specific exposure value	1.1735757	µg/person	0.0117358	µg/person
Systemic exposure	0.0195596	mg/kg bw/d	0.0001956	mg/kg bw/d
Inhalation			None	
Specific exposure value	0.0296387	µg/person	0.0296387	µg/person
Systemic exposure	0.0004940	mg/kg bw/d	0.0004940	mg/kg bw/d
Total				
Total systemic exposure	0.1041424	mg/kg bw/d	0.0177911	mg/kg bw/d

% of AOEL	26.04	%	4.45	%
-----------	-------	---	------	---

**Table A 3: Input parameters considered for the estimation of operator exposure (broadcast application)**

Formulation type	GB		Crop type	Fruit crops, grapevine, ornamentals, hop
Application rate (AR)	0.5	kg a.s./ha	Application method	Broadcast application of granules
Area treated per day (A)	10	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	10	% (concentr.)	Indoor/outdoor	Outdoor
	-	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.4	mg/kg bw/d	Water soluble bag	No

**Table A 4: Estimation of longer term operator exposure towards Ferric phosphate according to EFSA guidance**

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			None	
Specific exposure value	0.0726344	µg/person	0.0726344	µg/person
Systemic exposure	0.0012106	mg/kg bw/d	0.0012106	mg/kg bw/d
Body			Certified protective coverall	
Specific exposure value	0.8119672	µg/person	0.0081197	µg/person
Systemic exposure	0.0135328	mg/kg bw/d	0.0001353	mg/kg bw/d
Inhalation			None	
Specific exposure value	0.1040509	µg/person	0.1040509	µg/person
Systemic exposure	0.0017342	mg/kg bw/d	0.0017342	mg/kg bw/d
Application				
Hands			None	
Specific exposure value	0.0204128	µg/person	0.0204128	µg/person
Systemic exposure	0.0003402	mg/kg bw/d	0.0003402	mg/kg bw/d
Body			Certified protective coverall	
Specific exposure value	0.2347151	µg/person	0.0023472	µg/person
Systemic exposure	0.0039119	mg/kg bw/d	0.0000391	mg/kg bw/d
Inhalation			None	
Specific exposure value	0.0059277	µg/person	0.0059277	µg/person
Systemic exposure	0.0000988	mg/kg bw/d	0.0000988	mg/kg bw/d
Total				
Total systemic exposure	0.0208285	mg/kg bw/d	0.0035582	mg/kg bw/d
% of AOEL	5.21	%	0.89	%

**Table A 5: Input parameters considered for the estimation of operator exposure (manual application)**

Formulation type	GB		Crop type	Fruit crops, vegetable crops, field crops, grapevine, ornamentals, hop
Application rate (AR)	0.5	kg a.s./ha	Application method	Manual application of granules

Area treated per day (A)	1	ha	Application equipment	Manual
Dermal absorption (DA)	10	% (concentr.)	Indoor/outdoor	Outdoor
	-	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.4	mg/kg bw/d	Water soluble bag	No

**Table A 6: Estimation of longer term operator exposure towards Ferric phosphate according to EFSA guidance**

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			None	
Specific exposure value	0.0000000	µg/person	0.0000000	µg/person
Systemic exposure	0.0000000	mg/kg bw/d	0.0000000	mg/kg bw/d
Body			Certified protective coverall	
Specific exposure value	0.0000000	µg/person	0.0000000	µg/person
Systemic exposure	0.0000000	mg/kg bw/d	0.0000000	mg/kg bw/d
Inhalation			None	
Specific exposure value	0.0000000	µg/person	0.0000000	µg/person
Systemic exposure	0.0000000	mg/kg bw/d	0.0000000	mg/kg bw/d
Application				
Hands			Chemical resistant gloves	
Specific exposure value	142.6600431	µg/person	1.4266004	µg/person
Systemic exposure	2.3776674	mg/kg bw/d	0.0237767	mg/kg bw/d
Body			Certified protective coverall	
Specific exposure value	344.3537658	µg/person	3.4435377	µg/person
Systemic exposure	5.7392294	mg/kg bw/d	0.0573923	mg/kg bw/d
Inhalation			None	
Specific exposure value	0.2338665	µg/person	0.2338665	µg/person
Systemic exposure	0.0038978	mg/kg bw/d	0.0038978	mg/kg bw/d
Total				
Total systemic exposure	8.1207946	mg/kg bw/d	0.0850667	mg/kg bw/d
% of AOEL	2030.20	%	21.27	%

### A 3.2 Worker exposure calculations (KCP 7.2.3.1)

Not relevant.

### A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

#### A 3.3.1 Calculations for Ferric phosphate

**Table A 7: Input parameters considered for the estimation of longer term resident exposure**

Intended use(s)	Fruit crops, vegetable crops, field crops, grapevine, ornamentals, hop, broadcast and manual application of granules		Drift reduction (DR)		%
Application rate (AR)	0.5	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm <sup>2</sup> /h (adult)
				2600	cm <sup>2</sup> /h (child)
Minimum water volume (V)	-	L/ha	Drift on surface (D) - 75 <sup>th</sup> perc.	3.00	%
Buffer strip	2-3	m	Drift on surface (D) - mean	3.00	%
Number of applications (NA)	4		Turf Transferable Residues (TTR)	5	%
Interval between applications	14	days	Exposure duration dermal (H <sub>D</sub> )	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H <sub>I</sub> )	24	h
Multiple application factor (MAF)	2.6		Exposure duration entry into treated crops (H <sub>E</sub> )	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m <sup>3</sup>
	10	kg/person (children)			
Dermal absorption (DA)	10	% ('worst case')	Dislodgeable foliar residue (DFR)	3	µg/cm <sup>2</sup> /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.4	mg/kg bw/d	Surface Area of Hands (SA)	20	cm <sup>2</sup>
Spray drift dermal (SD) - 75 <sup>th</sup> perc.	-	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	-	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 <sup>th</sup> perc.	-	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR <sub>OM</sub> )	20	%
	-	mL spray dilution (child)			
Spray drift dermal (SD) - mean	-	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm <sup>2</sup> /d
	-	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	-	mL spray dilution (adult)	TC entry into treated crops - 75 <sup>th</sup> perc.	7500	cm <sup>2</sup> /h (adult)
	-	mL spray dilution (child)		2250	cm <sup>2</sup> /h (child)
Inhalation rate (IR)	16.57	m <sup>3</sup> /d (adult)	TC entry into treated crops - mean:	5980	cm <sup>2</sup> /h (adult)
	8.31	m <sup>3</sup> /d (child)		1794	cm <sup>2</sup> /h (child)

**Table A 8: Estimation of longer term resident exposure towards Ferric phosphate according to EFSA guidance**

Adult			Child		
Spray drift (75 <sup>th</sup> perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	-	mg/kg bw/d	Systemic exposure	-	mg/kg bw/d

% of AOEL:	-	%	% of AOEL:	-	%
<b>Vapour (75<sup>th</sup> perc.)</b>					
(VC x IR x IA) / BW					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AOEL:	0.06	%	% of AOEL:	0.27	%
<b>Surface deposits (75<sup>th</sup> perc.)</b>					
<b>Dermal</b>					
AR x MAF x D x TTR x TC x H <sub>D</sub> x DA / BW					
Systemic exposure	0.0000959	mg/kg bw/d	Systemic exposure	0.0002048	mg/kg bw/d
<b>Hand to mouth</b>					
AR x MAF x D x TTR x SE x SA x Freq x H <sub>D</sub> x OA / BW					
			Systemic exposure	0.0000748	mg/kg bw/d
<b>Object to mouth</b>					
AR x MAF x D x DR <sub>OM</sub> x IgR x OA / BW					
			Systemic exposure	0.0001970	mg/kg bw/d
<b>Total</b>					
Systemic exposure	0.0000959	mg/kg bw/d	Systemic exposure	0.0004767	mg/kg bw/d
% of AOEL:	0.02	%	% of AOEL:	0.12	%
<b>Entry into treated crops (75<sup>th</sup> perc.)</b>					
<b>Dermal</b>					
AR x MAF x TC x H <sub>D</sub> x DFR x DA / BW					
Systemic exposure	-	mg/kg bw/d	Systemic exposure	-	mg/kg bw/d
<b>Hand to mouth</b>					
AR x MAF x 100% x TTR x SE x SA x Freq x H <sub>D</sub> x OA / BW					
	-		Systemic exposure	-	mg/kg bw/d
<b>Object to mouth</b>					
AR x MAF x 100% x DR <sub>OM</sub> x IgR x OA / BW					
	-		Systemic exposure	-	mg/kg bw/d
<b>Total</b>					
Systemic exposure	-	mg/kg bw/d	Systemic exposure	-	mg/kg bw/d
% of AOEL:	-	%	% of AOEL:	-	%
<b>All pathways (mean)</b>					
Systemic exposure	-	mg/kg bw/d	Systemic exposure	-	mg/kg bw/d
% of AOEL:	-	%	% of AOEL:	-	%

## 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)

Not relevant.