

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 8**

#### **Environmental Fate**

Detailed summary of the risk assessment

Product code: SHA 105000 B

Product name: HIERRO

Chemical active substance:

Ferric phosphate, 10 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

#### **CORE ASSESSMENT**

Applicant: SHARDA Cropchem España

Submission date: November 2020

MS Finalisation date: July 2021; October 2021

## Version history

When	What
November 2020	Submission dRR by Applicant
July 2021	Assesment dRR by zRMS
October 2021	The Final Version of the RR

## Table of Contents

<b>8</b>	<b>Fate and behaviour in the environment (KCP 9).....</b>	<b>4</b>
8.1	Critical GAP and overall conclusions.....	5
8.2	Metabolites considered in the assessment.....	8
8.3	Rate of degradation in soil (KCP 9.1.1).....	8
8.3.1	Aerobic degradation in soil (KCP 9.1.1.1) .....	8
8.3.1.1	Ferric phosphate and its metabolites.....	8
8.3.2	Anaerobic degradation in soil (KCP 9.1.1.1).....	8
8.4	Field studies (KCP 9.1.1.2).....	8
8.4.1	Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1) ...	8
8.4.1.1	Ferric phosphate and its metabolites.....	8
8.4.2	Soil accumulation testing (KCP 9.1.1.2.2) .....	9
8.5	Mobility in soil (KCP 9.1.2) .....	9
8.5.1	Column leaching (KCP 9.1.2.1).....	9
8.5.2	Lysimeter studies (KCP 9.1.2.2).....	9
8.5.3	Field leaching studies (KCP 9.1.2.3) .....	9
8.6	Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3) .....	9
8.6.1	Ferric phosphate and its metabolites.....	9
8.7	Predicted Environmental Concentrations in soil (PEC <sub>soil</sub> ) (KCP 9.1.3) .....	9
8.7.1	Justification for new endpoints .....	9
8.7.2	Active substance and relevant metabolite.....	10
8.7.2.1	Ferric phosphate and its metabolites.....	10
8.7.2.2	PEC <sub>soil</sub> of HIERRO .....	10
8.8	Predicted Environmental Concentrations in groundwater (PEC <sub>gw</sub> ) (KCP 9.2.4) .....	11
8.8.1	Justification for new endpoints .....	11
8.8.2	Active substance and relevant metabolite (KCP 9.2.4.1) .....	11
8.9	Predicted Environmental Concentrations in surface water (PEC <sub>sw</sub> ) (KCP 9.2.5) .....	12
8.9.1	Justification for new endpoints .....	12
8.9.2	Active substance, relevant metabolite and the formulation (KCP 9.2.5).....	12
8.9.3	PEC <sub>sw/sed</sub> of HIERRO .....	12
8.10	Fate and behaviour in air (KCP 9.3, KCP 9.3.1) .....	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 new Annex II studies .....</b>	<b>15</b>
<b>Appendix 3</b>	<b>Additional information provided by the applicant (e.g. detailed modelling data).....</b>	<b>15</b>

## **8                    Fate and behaviour in the environment (KCP 9)**

## Critical GAP and overall conclusions

### Critical use pattern of the formulated product

[illegible]

Minor uses according to Article 51 (zonal uses)													
Minor uses according to Article 51 (interzonal uses)													

\* 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

#### Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

**Table 8.1-2: Assessed (critical) uses during approval of Ferric phosphate concerning the Section Environmental Fate**

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn, G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
-	Germany	All edible and non-edible crops	F	Pest slugs and snails	Strew, each row	At beginning of infestation	4	-	Not applicable (because ready-to-use bait)	0.12	Not applicable (because ready-to-use bait)	Not necessary	
-	Germany	Vegetables <b>such as</b> turnip cabbage, chinese cabbage, kale	F,G	Slugs Snails	broadcast	At infestation	6	14	Not applicable (because ready-to-use bait)	0.81	Not applicable (because ready-to-use)	Not applicable	-

		cabbage (green cabbage), head cabbage (including Savoy cabbage and Brussels sprout), cauliflower, broccoli, lettuce, spinach, beetroot, common beans etc.									bait)		
-	-	<b>Fruits</b> such as pome and stone fruits as well as soft fruits like strawberries	F	Slugs Snails	broadcast	At infestation	6	14	Not applicable (because ready-to-use bait)	0.81	Not applicable (because ready-to-use bait)	Not applicable	-
-	-	<b>Potatoes</b>	F	Slugs Snails	broadcast	At infestation	6	14	Not applicable (because ready-to-use bait)	0.81	Not applicable (because ready-to-use bait)	Not applicable	-
-	-	<b>Ornamentals</b>	F,G	Slugs Snails	broadcast	At infestation	6	14	Not applicable (because ready-to-use bait)	0.81	Not applicable (because ready-to-use bait)	Not applicable	-

\* 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

## 8.2 Metabolites considered in the assessment

**Table 8.2-1: Metabolites of Ferric phosphate potentially relevant for exposure assessment**

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
None				

## 8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

### 8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

#### 8.3.1.1 Ferric phosphate and its metabolites

Not applicable.

According to EFSA conclusions (EFSA Journal 2015;13(1):3973), Ferric phosphate is an inorganic salt with a very low solubility in water ( $1.86 \times 10^{-12}$  g FePO<sub>4</sub>/L at 25°C). As such the insolubility of ferric phosphate and the adsorption to soil particles ensures that breakdown is a slow process while the granule itself remains in situ on application to soil. A major source of dissipation in the environment is likely to be due to ingestion over time by target pests.

### 8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Not applicable.

According to EFSA conclusions (EFSA Journal 2015;13(1):3973), Ferric phosphate is an inorganic salt with a very low solubility in water ( $1.86 \times 10^{-12}$  g FePO<sub>4</sub>/L at 25°C). As such the insolubility of ferric phosphate and the adsorption to soil particles ensures that breakdown is a slow process while the granule itself remains in situ on application to soil. A major source of dissipation in the environment is likely to be due to ingestion over time by target pests.

## 8.4 Field studies (KCP 9.1.1.2)

### 8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

#### 8.4.1.1 Ferric phosphate and its metabolites

Not applicable.

According to EFSA conclusions (EFSA Journal 2015;13(1):3973), Ferric phosphate is an inorganic salt with a very low solubility in water ( $1.86 \times 10^{-12}$  g FePO<sub>4</sub>/L at 25°C). As such the insolubility of ferric phosphate and the adsorption to soil particles ensures that breakdown is a slow process while the granule itself remains in situ on application to soil. A major source of dissipation in the environment is likely to be due to ingestion over time by target pests.



#### **8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)**

Not applicable.

According to EFSA conclusions (EFSA Journal 2015;13(1):3973), Ferric phosphate is an inorganic salt with a very low solubility in water ( $1.86 \times 10^{-12}$  g FePO<sub>4</sub>/L at 25 °C). As such the insolubility of ferric phosphate and the adsorption to soil particles ensures that breakdown is a slow process while the granule itself remains in situ on application to soil. A major source of dissipation in the environment is likely to be due to ingestion over time by target pests.

### **8.5 Mobility in soil (KCP 9.1.2)**

Not applicable.

Specific data addressing adsorption/desorption and mobility in soil were not submitted. Due to the fact that the active substance is practically insoluble in water and that both iron and phosphate ions are ubiquitous components of soils occurring in amounts much greater than those applied a risk of ground water contamination resulting from application of HIERRO according to the GAP is not expected.

#### **8.5.1 Column leaching (KCP 9.1.2.1)**

Not applicable.

#### **8.5.2 Lysimeter studies (KCP 9.1.2.2)**

Not applicable.

#### **8.5.3 Field leaching studies (KCP 9.1.2.3)**

Not applicable.

### **8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)**

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

#### **8.6.1 Ferric phosphate and its metabolites**

Not applicable.

### **8.7 Predicted Environmental Concentrations in soil (PEC<sub>soil</sub>) (KCP 9.1.3)**

#### **8.7.1 Justification for new endpoints**

Not relevant as there is no deviation to the EU agreed endpoints.

## 8.7.2 Active substance and relevant metabolite

**Table 8.7-1: Input parameters related to application for PEC<sub>soil</sub> calculations**

Use No.	1	2*	3	4	5	6
Crop	Fruit crops	Vegetable crops	Field crops	Grape-vine	Ornamentals	Hop
Application rate (g as/ha)	500					
Number of applications/interval	4 / 14					
Crop interception (%) <sup>1</sup>	40	0		40	0	
Depth of soil layer (relevant for plateau concentration) (cm)	5	20		5	20	

\*Worst case

**Table 8.7-2: Input parameter for active substance and relevant metabolites for PEC<sub>soil</sub> calculation**

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/Reference
Ferric phosphate	150.82	-	Since no degradation is assumed, a cumulative PEC <sub>soil</sub> for multiple application (4 x 500 g as/ha) was calculated. No time weighted average values for short term or long term were calculated.	y/EFSA Journal 2015;13(1):3973

### 8.7.2.1 Ferric phosphate and its metabolites

**Table 8.7-3: PEC<sub>soil</sub> for Ferric phosphate**

PEC <sub>soil</sub> (mg/kg)	Vegetable crops			
	Single application		Multiple applications	
	Actual	TWA	Actual	TWA
Initial	0.667	-	<b>2.667</b>	-
Plateau concentration	Not applicable	-		-

### 8.7.2.2 PEC<sub>soil</sub> of HIERRO

Since HIERRO is rapidly broken down into its constituent parts on contact with soil and/or crop material, it is appropriate to calculate the PEC<sub>s</sub> following a single application only, using the following equation:

$$PEC_s(mg/kg) = \frac{\text{Application rate (g/ha)} \times (1-F)}{100 \times \text{Soil depth (cm)} \times \text{Soil dry bulk density (g/cm}^3\text{)}}$$

**Table 8.7-4: PEC<sub>soil</sub> for HIERRO on Cereals**

Preparation	Application rate (g/ha)	Crop interception (%)	PEC <sub>act</sub> (mg/kg)
HIERRO	4 x 50 000	0	266.7

**zRMS comments:**

zRMS agree with PECs calculation.

Maximum PEC<sub>soil</sub> value for ferric phosphate was **2.667** mg/kg, following the highest application rate of 200 g Ferric phosphate/ha.

## 8.8 Predicted Environmental Concentrations in groundwater (PEC<sub>gw</sub>) (KCP 9.2.4)

### 8.8.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

### 8.8.2 Active substance and relevant metabolite (KCP 9.2.4.1)

According to EFSA conclusions (EFSA Journal 2015;13(1):3973), Ferric phosphate is practically insoluble in water. Iron and phosphate ions are ubiquitous components of soils occurring in amounts much greater than those applied according to the GAP. A risk of ground water contamination resulting from application of ferric phosphate is not expected.

According to the very low solubility of the active substance in water ( $1.86 \times 10^{-12}$  g FePO<sub>4</sub>/L at 25 °C), which differs by orders of magnitude from the relevant criterion of water quality for water intended for human consumption (indicator parameter 200 µg/L set for iron by Council Directive 98/83/EC) the calculation of PEC<sub>gw</sub> values is considered not relevant. It can be concluded that for the active substance FePO<sub>4</sub> due to its very limited water solubility, groundwater concentrations will be < 0.1µg/L as required for pesticide active substances by European Parliament and Council Directive 2006/118/EC.

**zRMS comments:**

The submitted justification was accepted. Ferric pyrophosphate is practically insoluble in water, and iron and phosphorus ions are commonly found in the environment and all living organisms. The use of plant protection products with ferric pyrophosphate will not pose a risk of ground water contamination.

## 8.9 Predicted Environmental Concentrations in surface water (PEC<sub>sw</sub>) (KCP 9.2.5)

### 8.9.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

### 8.9.2 Active substance, relevant metabolite and the formulation (KCP 9.2.5)

According to EFSA conclusions (EFSA Journal 2015;13(1):3973). Due to the very low solubility no PEC surface water calculations need to be performed for ferric phosphate. For the aquatic risk assessment, the maximum solubility in water ( $1.86 \times 10^{-12}$  g FePO<sub>4</sub>/L) can be used.

### 8.9.3 PEC<sub>sw</sub>/sed of HIERRO

As the Iron phosphate is a granular application no drift is expected. Therefore, no calculations have been done for surface water and sediment.

#### zRMS comments:

zRMS agree with the argumentations submitted by the applicant.

The EFSA 2015 concluded: due to the very low solubility no PEC surface water calculations were performed for ferric phosphate. For the aquatic risk assessment the maximum solubility in water ( $1.86 \times 10^{-12}$  g/L) can be used.

No modelling of risk of contamination of surface water is required in this case, as the a.s. has a very low water solubility and ferric and phosphate ions occur naturally. No further calculation is required.

## 8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Ferric phosphate
Direct photolysis in air	Not applicable
Quantum yield of direct phototransformation	Not applicable
Photochemical oxidative degradation in air	Not applicable
Volatilisation	Non volatile
Metabolites	None

The vapour pressure at 20 °C of the active substance Ferric phosphate is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Ferric phosphate due to volatilization with subsequent deposition should not be considered.

#### zRMS comments:

Agreed, and in accordance with EFSA's conclusion on ferric phosphate. The fate of ferric phosphate in air does not need to be assessed further.

## 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**

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

**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 Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

## **Appendix 2    Detailed evaluation of the new Annex II studies**

None

## **Appendix 3    Additional information provided by the applicant (e.g. detailed modelling data)**

None