

# **FINAL REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**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**

**Update: 03.2023, 05.2023**

**MS Finalisation date: July 2021; 10.2021; 05.2023; 08.2023;**

**11.2023**

## Version history

When	What
November 2020	Submission dRR by Applicant
July 2021	Assesment dRR by zRMS
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
08.2023	Corrections made due to comments received for B3 from the Ministry of Agriculture and Rural Development
11.2023	zRMS verification of co-formulants in PPP

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# PART A

## RISK MANAGEMENT

### 1 Details of the application

#### 1.1 Application background

This application is submitted by Sharda Cropchem España S.L. for approval of Iron phosphate 1% GB, an Ganular bait formulation containing 10 g/kg of Ferric phosphate for use as molluscicide on fruit crops, vegetables crops, field crops, grapevine, ornamentals, hop in Central Europe.

zRMS: Poland

#### 1.2 Letters of Access

Not applicable. Letter of access not needed.

#### 1.3 Justification for submission of tests and studies

This dossier relies on new tests and studies, providing data and information specific to the formulation HIERRO as required by the EU regulations.

#### 1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No.1107/2009 as provided for in the list of references in Appendix 4.

### 2 Details of the authorization decision

#### 2.1 Product identity

Product code	SHA 105000 B
Product name in MS	HIERRO (Iron phosphate 1% GB)
Authorization number	
Function	molluscicide
Applicant	Sharda Cropchem España S.L.
Active substance(s) (incl. content)	Ferric phosphate; 10.0 g/kg
Formulation type	Ganular bait [Code: GB]
Packaging	HDPE: 0.5, 0.75, 2.5, 5.5 L PP: 7.4, 13.75 L

Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

## 2.2 Conclusion

**Efficacy section:** use on ornamental plants, hop and grapevine, pulses and leafy vegetables can be accepted only according to Article 51. According to Article 33 only use on root and tuber vegetable, fruit strawberry and other fruit crops (in the field), grapevine and field crops (cereals, oilseed rape, sunflower, corn, sorghum, soybeans) can be accepted.

**Toxicology section:** HIERRO (Iron Phosphate 1% GB) is unclassified. Risk for operator, worker and resident is acceptable

**Residues section :** The evaluation of the application for Iron phosphate 1% GB resulted in the decision to grant the authorization.

**Fate section:**

The evaluation of the application for Iron phosphate 1% GB resulted in the decision to grant the authorization.

**Ecotox section:**

The evaluation of the application for Iron phosphate 1% GB resulted in the decision to grant the authorization..

**From a toxicological point of view:**

The composition of the assessed product HIERRO has been verified in terms of Regulation 2023/574 of March 2023 and does not contain any neutral, prohibited ingredients in plant protection products that have been identified in accordance with Annex III to Regulation (EC) No 1107/2009.

**From fate and behavior and ecotoxicology point of view:**

According to the Regulation 2021/383 and others available data all co-formulants have been accepted for use in HIERRO.

None co-formulat has been identified as having endocrine disrupting properties in accordance with Regulation (EU) No 528/2012.

Co-formulants does not affect the deterioration of the eco-toxicological properties of the product HIERRO.

No impact is expected on the overall classification of HIERRO.

## 2.3 Substances of concern for national monitoring

Not relevant.

## 2.4 Classification and labelling

### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	-
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	-
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	-
	-

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-
-	-

See Part C for justifications of the classification and labelling proposals.

### 2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	-

### 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
	Broadcast application: certified protective coverall M/L and A. Manual application: certified protective coverall + chemical resistant gloves during A.
P280	Wear protective gloves, protective clothing.
Worker protection:	
-	-
Integrated pest management (IPM)/sustainable use:	
respective code if available	e.g. The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.
Environmental protection	
respective code if available	-
Other specific restrictions	
respective code if available	are there any other national requirements

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	

## 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
-	-	-

## 2.6 Intended uses (only NATIONAL GAP)

GAP rev. 0, date: 2018-May-28th

PPP (product name/code): Iron phosphate 1 %GB

Formulation type: GB (Ganular bait)

Active substance 1: Ferric phosphate

Conc. of as 1: 10 g/Kg

Active substance 2:

Conc. of as 2:

Safener: -

Conc. of safener: -

Synergist: -

Conc. of synergist: -

Applicant: SHARDA Cropchem España

Professional use:

Zone(s): Central

Non professional use:

Verified by MS: yes/no

Field of use: Molluscicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					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		

Zonal uses (field or outdoor uses, certain types of protected crops)*													
1	CEU PL	Fruit crops Strawberry and other fruit crops (in the field).	F	Slugs and Snails	Spread to soil surface	From seed-ling/planting until BBCH 79	a) 4 b) 4	14	a) 50.0 b) 200.0	a) 0.5 b) 2.0	-	-	60-70 granular baits per m2 per application
2	CEU PL	Vegetable crops	F	Slugs and Snails	Spread to soil surface	From seed-ling/planting until BBCH 81	a) 4 b) 4	14	a) 50.0 b) 200.0	a) 0.5 b) 2.0	-	-	60-70 granular baits per m2 per application <b>Eff section:</b> in PL only root and tuber field crop are accepted in line to art. 33. Leafy vegetables can be accepted only in line to article 51.
3	CEU PL	Field crops	F	Slugs and Snails	Spread to soil surface	From seed-ling/planting until BBCH 89	a) 4 b) 4	14	a) 50.0 b) 200.0	a) 0.5 b) 2.0	-	-	60-70 granular baits per m2 per application <b>Eff. section:</b> In Poland in label can be accepted: cereals, oilseed rape, sunflower, corn, sorghum, soybeans.. Pulses can be accepted only to article 51.
4	CEU PL	Grapevine	F	Slugs and Snails	Spread to soil surface	From seed-ling/planting until BBCH 81	a) 4 b) 4	14	a) 50.0 b) 200.0	a) 0.5 b) 2.0	-	-	60-70 granular baits per m2 per application <b>Eff. section:</b> In PL-use accepted.
5	CEU PL	Ornamentals	F	Slugs and Snails	Spread to soil surface	From seed-ling/planting until BBCH 69	a) 4 b) 4	14	a) 50.0 b) 200.0	a) 0.5 b) 2.0	-	-	60-70 granular baits per m2 per application <b>Eff section:</b> in CEU and PL - only in line to Article 51 can be accepted.
6	CEU PL	Hop	F	Slugs and Snails	Spread to soil surface	From seed-ling/planting until BBCH 82	a) 4 b) 4	14	a) 50.0 b) 200.0	a) 0.5 b) 2.0	-	-	60-70 granular baits per m2 per application <b>Eff section:</b> in PL only in line to Article 51 can be accepted.
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													

Minor uses according to Article 51 (zonal uses)													
5													
6													
Minor uses according to Article 51 (interzonal uses)													
7													
8													

<b>Remarks table heading:</b>	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
<b>Remarks columns:</b>	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	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	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

\* Tier 1 calculations of the risk assessment for birds and mammals should be provided by the applicant for completeness according to B&M GD 2009.

## 3 Background of authorization decision and risk management

### 3.1 Physical and chemical properties (Part B, Section 2)

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.

### 3.2 Efficacy (Part B, Section 3)

Iron phosphate 1.0% GB is a Granular bait (GB) formulation containing 10.0 grams per kilogram (g/Kg) Iron phosphate for use in fruit crops, vegetable crops, field crops, grapevine, ornamentals and hop.

It is used protectively and curatively to control slugs and snails.

In compliance with the GAP, the following dose rate is applied for registration:

- Up to four applications per season (From seedling/planting until BBCH 79) to control Slugs and Snails in fruit crops, target rate: 50.0 Kg/ha
- Up to four applications per season (From seedling/planting until BBCH 45) to control Slugs and Snails in Vegetables crops, target rate: 50.0 Kg/ha
- Up to four applications per season (From seedling/planting until BBCH 89) to control Slugs and Snails in Field crops, target rate: 50.0 Kg/ha
- Up to four applications per season (From seedling/planting until BBCH 82) to control Slugs and Snails in Grapevine, target rate: 50.0 Kg/ha
- Up to four applications per season (From seedling/planting until BBCH 69) to control Slugs and Snails in Ornamentals, target rate: 50.0 Kg/ha
- Up to four applications per season (From seedling/planting until BBCH 89) to control Slugs and Snails in Hop, target rate: 50.0 Kg/ha

This document serves the registration of Iron phosphate 1.0% GB in the Central zone of the EU. The objective of this document is to prove and support the label claims of the fungicidal efficacy and crop safety of Iron phosphate 1.0% GB in the GAP claimed crops.

Comprehensive field trials were conducted in United Kingdom, Germany, Czech Republic, Italy, Greece, Spain, France and Poland in 2016, 2017, 2018 and 2019. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

### 3.3 Efficacy data

#### Preliminary tests

The activity of Iron phosphate is well known; it has been marketed for the control a wide range of pests in e.g. fruits, cereals and vegetables for +30 years. Based on the knowledge about the active substances (more than 30 years) and the experiences with the actives in the GAP claimed crops at the proposed dose rates, the necessary application rates to obtain sufficient control of the pest organism are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

### **Minimum effective dose tests**

Iron phosphate 1.0% GB was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Iron phosphate 1.0% GB applied at 25.0 Kg/ha, 37.0 Kg/ha and 50.0 Kg/ha or was evaluated in strawberry (9), lettuce (5), winter wheat (13), potato (11), apple (8), spring barley (2), oilseed rape (11) and winter barley (1) trials, for the control of Slugs and -Snails. The dose rates tested reflects 50%, 75% and 100% of the recommended rate of Iron phosphate 1.0% GB, in accordance with the EPPO guideline PP 1/225(2) "Minimum effective dose". The dose rates are selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy was tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the Maritime EPPO zone (i.e. Czech Republic, United Kingdom and Germany), the Mediterranean EPPO zone (i.e Spain, Greece, S-France and Italy) and the North-east EPPO zone (i.e. Poland).

### **Control of slugs and snails in strawberry (CEU)**

To prove and to support the proposed dose rate of 50.0 Kg/ha Iron phosphate 1.0% GB [500 g Iron phosphate per hectare, per application] for the control of slugs and snails in strawberry, the assessment results from nine efficacy trials performed in the Maritime EPPO zone (2), the Mediterranean EPPO zone (5) and the North-east EPPO zone (2) are reported. The trials were conducted in United Kingdom (1), Germany (1), Italy (1), Greece (2), Spain (2) and Poland (2) in 2016 and 2017. Iron phosphate 1.0% GB was included in these trials at 50.0 Kg/ha to demonstrate the recommended dose rate as well as at two lower dose rates (25.0 Kg/ha and 37.0 Kg/ha [250 g Iron phosphate per hectare, per application and 370 g Iron phosphate per hectare, per application]). In the trials, specifically targeted for this pathogen, up to four applications were applied at growth stages from seedling/planting until BBCH 81.

It can be concluded that for consistent control of slugs and snails, the intended use rate of 50.0 Kg/ha, with up to four applications per season, is required.

### **Control of slugs and snails in lettuce (CEU)**

To prove and to support the proposed dose rate of 50.0 Kg/ha Iron phosphate 1.0% GB [500 g Iron phosphate per hectare, per application] for the control of slugs and snails in lettuce, the assessment results from 5 efficacy trials performed in the Mediterranean EPPO zone (5) are reported. The trials were conducted in Italy (1), Greece (2) and Spain (2) in 2016 and 2017. Iron phosphate 1.0% GB was included in these trials at 50.0 Kg/ha to demonstrate the recommended dose rate as well as at two lower dose rates (25.0 Kg/ha and 37.0 Kg/ha [250 g Iron phosphate per hectare, per application and 370 g Iron phosphate per hectare, per application]). In the trials, specifically targeted for this pathogen, up to four applications were applied at growth stages from seedling/planting until BBCH 45.

It can be concluded that for consistent control of slugs and snails, the intended use rate of 50.0 Kg/ha, with up to four applications per season, is required.

### **Control of slugs and snails in winter wheat (CEU)**

To prove and to support the proposed dose rate of 50.0 Kg/ha Iron phosphate 1.0% GB [500 g Iron phosphate per hectare, per application] for the control of slugs and snails in winter wheat, the assessment results from 8 efficacy trials performed in the Mediterranean EPPO zone (4) and the Maritime EPPO zone (4) are reported. The trials were conducted in Italy (1), Greece (2), France (1), United Kingdom (2) and Czech Republic (2) in 2016 and 2017. Iron phosphate 1.0% GB was included in these trials at 50.0 Kg/ha to demonstrate the recommended dose rate as well as at two lower dose rates (25.0 Kg/ha and 37.0 Kg/ha [250 g Iron phosphate per hectare, per application and 370 g Iron phosphate per hectare, per application]).

In the trials, specifically targeted for this pathogen, up to four applications were applied at growth stages from seedling/planting until BBCH 89.

It can be concluded that for consistent control of slugs and snails, the intended use rate of 50.0 Kg/ha, with up to four applications per season, is required.

#### **Control of slugs and snails in potato (CEU)**

To prove and to support the proposed dose rate of 50.0 Kg/ha Iron phosphate 1.0% GB [500 g Iron phosphate per hectare, per application] for the control of slugs and snails in potato, the assessment results from eleven efficacy trials performed in the Mediterranean EPPO zone (5), the Maritime EPPO zone (3) and the North-east EPPO zone (3) are reported. The trials were conducted in Italy (1), Greece (2), Spain (2), United Kingdom (2), Germany (1) and Poland (3) in 2016 and 2017. Iron phosphate 1.0% GB was included in these trials at 50.0 Kg/ha to demonstrate the recommended dose rate as well as at two lower dose rates (25.0 Kg/ha and 37.0 Kg/ha [250 g Iron phosphate per hectare, per application and 370 g Iron phosphate per hectare, per application]). In the trials, specifically targeted for this pathogen, up to four applications were applied at growth stages from seedling/planting until BBCH 69.

It can be concluded that for consistent control of slugs and snails, the intended use rate of 50.0 Kg/ha, with up to four applications per season, is required.

#### **Control of slugs and snails in apple (CEU)**

To prove and to support the proposed dose rate of 50.0 Kg/ha Iron phosphate 1.0% GB [500 g Iron phosphate per hectare, per application] for the control of slugs and snails in apple, the assessment results from eight efficacy trials performed in the Mediterranean EPPO zone (5) and the Maritime EPPO zone (3) are reported. The trials were conducted in Italy (1), Greece (2), Spain (2), Czech Republic (2) and Germany (1) in 2016. Iron phosphate 1.0% GB was included in these trials at 50.0 Kg/ha to demonstrate the recommended dose rate as well as at two lower dose rates (25.0 Kg/ha and 37.0 Kg/ha [250 g Iron phosphate per hectare, per application and 370 g Iron phosphate per hectare, per application]). In the trials, specifically targeted for this pathogen, up to four applications were applied at growth stages from seedling/planting until BBCH 95.

It can be concluded that for consistent control of slugs and snails, the intended use rate of 50.0 Kg/ha, with up to four applications per season, is required.

#### **Control of slugs and snails in spring barley (CEU)**

To prove and to support the proposed dose rate of 50.0 Kg/ha Iron phosphate 1.0% GB [500 g Iron phosphate per hectare, per application] for the control of slugs and snails in Spring barley, the assessment results from two efficacy trials performed in the Mediterranean EPPO zone (2) are reported. The trials were conducted in Spain (2) in 2016. Iron phosphate 1.0% GB was included in these trials at 50.0 Kg/ha to demonstrate the recommended dose rate as well as at two lower dose rates (25.0 Kg/ha and 37.0 Kg/ha [250 g Iron phosphate per hectare, per application and 370 g Iron phosphate per hectare, per application]). In the trials, specifically targeted for this pathogen, up to four applications were applied at growth stages from seedling/planting until BBCH 30.

It can be concluded that for consistent control of slugs and snails, the intended use rate of 50.0 Kg/ha, with up to four applications per season, is required.

#### **Control of slugs and snails in oilseed rape (CEU)**

To prove and to support the proposed dose rate of 50.0 Kg/ha Iron phosphate 1.0% GB [500 g Iron phosphate per hectare, per application] for the control of slugs and snails in oilseed rape, the assessment results from six efficacy trials performed in the Maritime EPPO zone (5) and the North-east EPPO zone (1) are reported. The trials were conducted in United Kingdom (2), Germany (1), Czech Republic (2) and Poland (1) in 2016. Iron phosphate 1.0% GB was included in these trials at 50.0 Kg/ha to demonstrate the

recommended dose rate as well as at two lower dose rates (25.0 Kg/ha and 37.0 Kg/ha [250 g Iron phosphate per hectare, per application and 370 g Iron phosphate per hectare, per application]). In the trials, specifically targeted for this pathogen, up to four applications were applied at growth stages from seedling/planting until BBCH 18.

It can be concluded that for consistent control of slugs and snails, the intended use rate of 50.0 Kg/ha, with up to four applications per season, is required.

### **Control of slugs and snails in winter barley (CEU)**

To prove and to support the proposed dose rate of 50.0 Kg/ha Iron phosphate 1.0% GB [500 g Iron phosphate per hectare, per application] for the control of slugs and snails in winter barley, the assessment results from one efficacy trials performed in the North-east EPPO zone (1) are reported. The trial was conducted in Poland (1) in 2017. Iron phosphate 1.0% GB was included in these trials at 50.0 Kg/ha to demonstrate the recommended dose rate as well as at two lower dose rates (25.0 Kg/ha and 37.0 Kg/ha [250 g Iron phosphate per hectare, per application and 370 g Iron phosphate per hectare, per application]). In the trials, specifically targeted for this pathogen, up to four applications were applied at growth stages from seedling/planting until BBCH 13.

It can be concluded that for consistent control of slugs and snails, the intended use rate of 50.0 Kg/ha, with up to four applications per season, is required.

### **Efficacy tests and conclusions regarding authorization of intended uses**

Details of experiment are presented above by Applicant. All used methodology is in accordance with GEP rules, in exception of EPPO 1/181 (4). However, Applicant has made the appropriate explanation for carrying out the survey only in one growing season for some uses (ex. strawberry, lettuce, potato, apple, spring barley), which was accepted by Evaluator.

Applicant submitted in total 60 trials showing the results in research into product efficacy carried out on strawberry (9 trials), lettuce (5 trials), winter wheat (13 trials), potato (11 trials), apple (8 trials), spring barley (2 trials), winter oilseed rape (11 trials) and winter barley (1 trial). Those efficacy trials were performed in MED (spring barley, apple, potato, winter wheat, lettuce, strawberry), Maritime (strawberry, winter wheat, potato, apple, winter oilseed rape), and N-E EPPO zone (winter barley, winter oilseed rape, potato, winter wheat, strawberry). Lack of trials for S-E EPPO zone.

Iron phosphate is a low-risk substance that is used even in organic farming. Therefore, in the opinion of the evaluator, the reduced number of tests should be sufficient. For example, in Poland the acceptable number of tests for major and minor crops is 2-3 efficacy tests. According to EPPO PP1/95 (4) extrapolation from BRSNN to other oilseed crops and field crops (except cereals and potato) is possible. Extrapolation to all field crops (except potato) is possible, since sufficient data on TRZAX are available, too.

In the opinion of Evaluator, enough trials were presented against:

- strawberry in MAR, MED and N-E EPPO zone,
- lettuce in MED EPPO zone,
- winter wheat in MED, MAR, and N-E EPPO zone,
- potato in MAR, MED and N-E EPPO zone,
- apple in MAR and MED EPPO zone,
- spring barley in MED EPPO zone. However, on the basis on possibility of extrapolation from winter wheat, this use can also be accepted in MAR and N-E EPPO zone,
- winter oilseed rape in MAR and N-E EPPO zone,
- winter barley in N-E EPPO zone. However, on the basis on possibility of extrapolation from winter wheat, this use can also be accepted in MAR and MED EPPO zone.

To demonstrate the effectiveness of the tested plant protection product at the recommended dose rate

against slugs and snail's application in studied crops was compared to the reference product included in the trials.

According to EPPO 1/95 (3) following organisms can be distinguished and studied in trials: (1) omnivorous species, e.g. (*Deroceras reticulatum*) (DERORE), (*Deroceras agreste*) (DEROAG), *Deroceras sturanyi* (DEROST), *Limax maximus* (LIMXMA), (*Arion rufus*) (ARIORU), *Arion lusitanicus* (ARIOLU); (2) species feeding on fresh leaves, dead leaves and fungi, e.g. *Arion distinctus* (ARIODI), *Arion sylvaticus* (ARIOSY), *Arion fasciatus* (ARIOFA), *Arion hortensis* (ARIOHO), (*Deroceras laeve*) (DEROLA), (*Tandonia rustica*) (MILXRU), *Arion circumscriptus* (ARIOCI); (3) root feeding species, e.g. *Limax flavus* (LIMXFL), *Tandonia budapestensis* (MILXBU), *Milax gagates* (MILXGA). Crop: any variety of any of the following plants vegetable, strawberry (FRAAN) or ornamental plant or ornamentals susceptible to slugs in open field crops or under cover. Tests may also be the test can also be conducted on a slug-infested bare field in which the test crop is planted.

According to EPPO 1/96 (3) following pest can be studied: field anthill (*Deroceras (Deroceras agreste)* (DEROAG), spotted seatroot (*Deroceras reticulatum*) (DERORE), *Deroceras sturanyi* (DEROST), *Arion distinctus* (ARIODI), *Arion hortensis* (ARIOHO), *Arion rufus* (ARIORU), *Arion lusitanicus* (ARIOLU), *Arion sylvaticus* (ARIOSY) are found in crops the most common, but other species can also be found. Cultivated plant: any variety of cereal, oilseed, legume oilseeds, pulses, potato (SOLTU) and turnip (BRSRR) or other according to the intended use. use.

During efficacy studies following pest species were studied:

- strawberry: ARIOLU (N-E), DERORE (MAR), ARIOCI (MAR), 1LIMAF (MED), NAROCO (MED), THEBI (MED)
- lettuce: 1LIMAF, NAROCO, DEROAG
- winter wheat: DERORE (N-E, MAR), LIMXCI (MAR), HRLIXSP (MED), 1LIMAF (MED), NAROCO (MED)
- potato: ALIORU (N-E), DERORE (N-E, MAR), ARIOLU (N-E), ARIOCI (MAR), 1LIMAF (MED), NAROCO (MED), DERARG (MED),
- apple: DERORE (MAR), ARIOSP (MAR), 1LIMAF (MED), CYCHCA (MED), DEROAG (MED)
- spring barley: DEROAG (MED)
- winter oilseed rape: AROLU (N-E), DERORE (N-E, MAR), LIMXCI (MAR)
- winter barley: ARIOLU (N-E)

All relevant species were assessed, therefore extrapolation to all slug species is possible. Extrapolation to minor damaging snails seems acceptable. Final decision is left to cMS.

Only slugs were assessed. Extrapolation to snails seems acceptable.

Applicant recommended use up to max 4 application per season. However, only in MED EPPO zone 4 applications were studied on strawberry, lettuce, winter wheat, potato, apple, and spring barley. In the opinion of Evaluator for Maritime and N-E EPPO zone only one application per season was proven by efficacy studies (3 or 4 application were not studied during efficacy trials, 3 applications were studied during selectivity trials performed in Poland). However, considering the low harmfulness to plants and high effectiveness against slugs, a maximum of 4 applications per season should be still recommended. Most registered products recommend a maximum of 4 applications per season, including the reference standards. Molluscicides cannot be used as a single treatment, as they can occur at different stages of development at the same time. Eggs and juveniles have a good chance of survival. There are also limitations on the timing of the treatment, on the products that can be used, and on the cost of chemical control. The greatest effectiveness of control is achieved when the snails grow up. Treatments sometimes must be repeated several times. It is good if the treatment covers as much of the slug-infested area as possible. Otherwise, the worms will be replaced by migrating worms from neighbouring areas that have not been treated with chemicals.

According to **EPPO PP 1/95 (4)** often authorization is sought for molluscicides on a broad range of crops, rather than an individual or a small number of named crops. Generating appropriate data that

*encompasses both major/ most susceptible crops, and major slug species with representative biology, can permit subsequent extrapolation to all crops and all slug species.....*

Crop	Species	Permissible Author-ised Uses	Multi-crop data pack-ages	Permissible Author-ised use
<b>Field Crops (including combinable crops*, root/tuber but not leafy vegetable crops)</b>				
Oilseed rape BRSNN	<i>Deroceras reticulatum</i> DERORE and <i>Arion vulgaris</i> ARIOVU. Plus some data on other common <i>Deroceras</i> DEROSP, <i>Arion</i> ARIOSP species	All oilseed crops and field crops (except cereals and potato)	Oilseed rape and wheat†	All field crops (except potato)
Wheat TRZAX		All cereal crops		
Potato SOLTU	Keeled slug species e.g. <i>Milax</i> MILXSP, <i>Tandonia</i> TANDSP, <i>Boettgerilla</i> sp. BOEGSP	All root and tuber field crops attacked by keeled slug species	Oilseed rape and wheat† and potato	All combinable* field crops, sugar beet, potato and other root/tuber field crops
Horticultural Field Leafy Crops, Horticultural Protected Crops (including Brassica vegetables), Ornamentals‡				
Lettuce LACSA or Chinese cabbage BRSPK; and Brussels sprouts BRSOB or kale BRSOA. Plus one other crop type, from cauliflower BRSOB or broccoli BRSOK or head cabbage BRSOL	<i>D. reticulatum</i> DERORE and <i>A. vulgaris</i> ARIOVU. Plus some data on other common <i>Deroceras</i> DEROSP, <i>Arion</i> ARIOSP, <i>Limax</i> species LIMXSP	All leafy vegetables	Lettuce or Chinese cabbage and Strawberry	All leafy vegetables, fruit
Strawberry FRAAN		All fruit crops		
Susceptible ornamental plant e.g. <i>Tagetes</i> TAGSS e.g. <i>Cymbidium</i> CMFSS, <i>Alstroemeria</i> ALTAU, <i>Gerbera</i> GEBJA, <i>Chrysanthemum</i> CHYIN		All ornamentals (field and protected)	Lettuce or Chinese cabbage and Strawberry and Susceptible ornamental species	All leafy vegetables, fruit, ornamentals

\*All types of crops gathered by use of a combine harvester separating out edible parts of the plant (seeds/beans) e.g. cereals, oilseeds, legumes (beans, peas, lupines), and vetches.

†Oilseed rape, should have a comprehensive data set which forms the greater proportion of the data package.

‡Trials on lettuce/Chinese cabbage, strawberry, and ornamentals may be conducted as semi-field barriered small plot trials, rather than full scale field trials. See 1/289 The design and use of Molluscicide field small plot cage (barriered) trials for further details.

§Full details on use of semi-field barriered small plot trials are given in PP 1/289.

**Vegetable crops:** Only trials on lettuce were carried out in MED trials. According to EPPO standard PP1/95 (4) extrapolation from lettuce to other leafy vegetables is not possible since trials in Brassica vegetable crops are missing. However, taking into account the field trials in BRSNW, representing a highly slug palatable Brassica crop, extrapolation to all vegetable Brassica crops, or even to all vegetable crops, may be acceptable. However, since this approach is not completely EPPO conform, the final decision is left to cMS. In Poland leafy vegetable crops should be excluded from label because trials from MED EPPO zone are not acceptable for Poland for field use. This use in Poland can be accepted according to Article 51 only. Vegetable crops like root and tuber field crops attacked by keeled slug species can be accepted on the basis on extrapolated results from potato.

**Fruit crop:** To extrapolate to all fruit crops, trials on strawberry should have been carried out. Applicant submitted trials carried out on apple in MAR (DE-1, CZ-2) and MED (IT-1, GR-2, ED-2) and on strawberries in MAR (UK, DE), MED (IT-1, ES-2, GR-2) and N-E (PL-2). So, in the opinion of Evaluator this use can be accepted in Poland, MAR EPPO zone, MED and N-E. However, each cMS should decide if use on fruit crop can be accepted. The entry on the label of the product for orchard crops could have the following wording (since the term "fruit crops" is not practiced): *strawberry and other fruit crops (in the field)*.

**Ornamental:** To extrapolate to all ornamental crops, trials in specific highly palatable ornamentals should have been carried out. Therefore, according to EPPO, not further extrapolation is possible. The corresponding uses cannot be supported. Missing trials for ornamentals. This use should be excluded. For Poland, this use is not acceptable, according to Polish extrapolating tables Applicant should presented at least 2-3 trials carried out on gerbera or funkia. Then, extrapolation for other ornamental plants would be possible. Also, due to EPPO and PP 1/95 (4) without any trial carried out on ornamental species should be excluded. This use in Poland can be accepted according to Article 51 only.

**Hop:** lack of trials. This use cannot be supported. According to EPPO tables, only against mites or aphids, extrapolation from fruit crop and apple is possible. This use should be excluded form Polish label. Each cMS should decide if use on hop without any trials can be accepted. This use in Poland can be accepted according to Article 51 only.

**Grapevine:** lack of trials. ~~This use should be excluded from Polish label.~~ cMS should decide if this use can be acceptable by results from other crops. This use in Poland can be accepted according to ~~Article 51 only~~ EPPO 1/95. EPPO Guideline 1/95 indicates that, in this case, the indicator crop is strawberry, and on the basis of tests on this crop it is possible to register for the group of crops referred to as "fruit crops." There is no annotation here that additional tests are required for vines, etc. Therefore, according to our opinion, the entry on the label of the product for orchard crops could have the following wording (since the term "fruit crops" is not practiced): *strawberry and other fruit crops (in the field)*.

**Field crops:** on cereals and winter oilseed rape uses are supported. According to EPPO standard PP1/95 (4) extrapolation from TRZAW (and HORVW) to all cereals is acceptable. Extrapolation to all field crops (except potato) is also possible, however, sufficient data on BRSNN are available only from the Maritime and N-E EPPO zone. In the Polish label we can accept only cereals (and winter oilseed rape. In Polish label, sunflower and soybean can be accepted on the basis on possibility extrapolation results from oilseed rape to other oleo species. Sugar beet, ~~sorghum~~ and pulses without trials can not be accepted. Each cMS should decide about acceptable species in label. In PL pulses can be accepted only in line to Article 51. ~~In Poland minor crops, ex. sorghum can be accepted only on the basis on Article 51.~~ In our opinion for Poland, taking into account the results of tests of the agent in cereals and rapeseed, as well as the above-mentioned EPPO guideline and extrapolation table, here per analogiam to "other cereal species" (annex to the findings of the harmonization meetings) extrapolation and to corn and sorghum seems reasonable, given also the s.cz. status of the agent - low risk.

In the trials conducted can be observed that the product tested showed a good control of the slugs and snails at different levels of pest pressure and developed a same behaviour compared to the standard products registered in Central Europe countries.

In the trials conducted can be observed that the product tested showed a good control of the slugs and snails at different levels of pest pressure and developed a same behaviour compared to the standard products registered in Central Europe countries.

HIERRO (SHA 105000 B) applied at the proposed dose rate of 50 kg/ha provides a very high level of control of slugs and snails, in all EPPO zones (S-E was not studied). Compared to the reference product, the efficacy obtained with Iron phosphate 1.0% GB is comparable.

Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the reference product (a.s. iron phosphate) in their own Member State.

It is recommended to authorize the product HIERRO (SHA 105000 B) in the extent of the authorization of the reference product (a.s. iron phosphate) at the equivalent dose rate.

### 3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds, molluscs and fungi. It usually becomes evident after the repeated use of a particular pesticide selects the

naturally-occurring resistant strains within the wild population and allows them to multiply over several seasons until they become dominant in the population and pose a control problem.

The molluscicide-resistant population develops because the sensitive population is suppressed and the rare molluscicide-resistant individual can multiply and occupy the biological niche previously filled by the sensitive population. An increase in the frequency of such resistant strains may result in loss of disease control. As a general principle, resistance develops at different rates depending on the pathogen type, nature of the epidemic (or disease severity) and use pattern of the molluscicide.

Reports of the appearance of resistant strains in laboratory studies do not necessarily imply that any loss of control is expected in the field. Likewise, the appearance of less-sensitive strains in the field does not always result in failure of disease control. When the frequency of resistant individuals is low and/or the level of resistance is moderate, molluscicide applications in most cases will provide satisfactory control.

To avoid the misinterpretation of potential and/or possible resistance cases, the term resistance be limited to situations where the conditions in both (a) and (b) below are met:

(a) the development of resistance leads to failure of control under practical field conditions following application of a molluscicide correctly and according to the label and

(b) a demonstration that a loss of control is due to the presence of pathogenic strains with reduced molluscicide sensitivity.

### **3.3.2 Adverse effects on treated crops**

#### **Phytotoxicity to host crop**

As Iron phosphate 1.0% GB is a molluscicide, no specific studies are required as long as in the efficacy trials no negative effects are observed. The crop safety of applying Iron phosphate 1.0% GB at a recommended dose rate in strawberry, lettuce, winter wheat, potato, apple, spring barley, oilseed rape and winter barley was evaluated in 69 trials (15 MAR, 26 MED and 28 N-E). In the efficacy trials, Iron phosphate 1.0% GB was applied at 50.0 Kg/ha and in the selectivity trials, Iron phosphate 1.0% GB was applied at 100.0 Kg/ha.

The trials were conducted in the Maritime EPPO zone (15; i.e. Germany (4), United Kingdom (7), Czech Republic (4)), the Mediterranean EPPO zone (26, i.e. Italy (5), Greece (10), Spain (10) and France (1)) and the North-east EPPO zone (28; i.e. Poland) EPPO zones in 2016, 2017, 2018 and 2019 to evaluate the crop safety of Iron phosphate 1.0% GB in strawberry, lettuce, winter wheat, potato, apple, spring barley, oilseed rape and winter barley.

#### **Effects on yield and quality**

No studies of yield and quality of the crops had been recorded. According EPPO PP 1/135 (4) Phytotoxicity assessments, Table 1 selectivity trials are not required for Insecticides. Observations for phytotoxic effects should be made in the direct efficacy (effectiveness) trials. No phytotoxicity was observed in any efficacy trial, thus no selectivity trials are required. Additionally, Table 1 indicate that yield in selectivity trials is not required for Insecticides. Data is only required for active substances on major uses where no information on effects on yield is available. Iron phosphate is a well known active substance and has been registered in Europe for more than 30 years so active substance effects are well known. As per all previous references, results for yield are not required.

#### **Effect on transformation processes**

There are no indications that the use of Iron phosphate will have influence on possible transformation processes. It is therefore expected that application of Iron phosphate 1.0% GB, when applied in accordance with good agricultural practices will not cause any unacceptable adverse effects on transformation processes.

Furthermore, the residue data (see Part B Section 4 Annex Point IIIA 8.3) clearly demonstrate that, at the proposed application rates, no Iron phosphate nor its metabolites above the LOQ (= limit of quanti-

fication) are found in any of the tested crops. In case of undetectable residues no special studies are required according to the EPPO guideline PP 1/243(1).

Finally, it should be noted that Iron phosphate has been used for a long time as a molluscicide in the GAP claimed crops. Since the market introduction no effects on transformation processes have been recorded for any of these products, nor do Iron phosphate containing products have any label restrictions concerning their use on crops destined for processing.

### **Impact on treated plants or plant products to be used for propagations**

Not applicable. Iron phosphate 1.0% GB a molluscicide used against slugs and snails in a range of crops cultivated in the field as well as in green-houses.

Currently there are no label restrictions regarding the use of Iron phosphate on crops destined for propagation and there seems no reason to suppose that Iron phosphate 1.0% GB will perform any differently to those products in this respect.

### **3.3.3 Observations on other undesirable or unintended side-effects**

#### **Impact on succeeding crops.**

Use of Iron phosphate 1.0% GB according to the proposed GAP does not represent a hazard to rotational crops and does not justify specific label restrictions. Iron phosphate 1.0% GB is not persistent in soil nor is it taken up by succeeding crops. In addition, based upon practical experiences with use of iron phosphate products in practice it is concluded that Iron phosphate 1.0% GB applied as recommended will not cause any detrimental effects on succeeding crops.

In the event of crop failure following treatment, there is no restriction on the timing of sowing/planting succeeding crop.

#### **Impact on other plants including adjacent crops**

Studies on the toxicity to non-target terrestrial plants have not been carried out with Iron phosphate. No data is provided in the respective EU DAR and related documents.

No trials assessing the risk for adjacent crops were submitted. At that point it has to be considered that Iron phosphate 1.0% GB can be applied by hand or by tractor granules applicator. In case of application by tractor granules applicator the granules can be spread out of intended area and consequently they can have a contact with adjacent crops.

However Iron phosphate products have been on the market for many years in the form of granular baits without any report relating to the negative effects on adjacent crops. Due to it is assumed that no detrimental effects on adjacent crops are expected when Iron phosphate 1.0% GB is applied at the recommended dose.

#### **Effects on beneficial and other non-target organisms**

From the experimentation carried out with Iron phosphate 1.0% GB in 2016 to 2019, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 9.

### 3.4 Methods of analysis (Part B, Section 5)

#### 3.4.1 Analytical method for the formulation

#### Methods suitable for the determination of Ferric phosphate in plant protection product Iron phosphate 1% GB

	Ferric phosphate
Author(s), year	B. Krzysiak-Warzała, 2017
Principle of method	XRF
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	6 points 0.06 – 0.70% of Fe $Y = 0.0575x - 0.0299$ $R = 0.99894$
Precision – Repeatability Mean n = 3 (%RSD)	%RSD = 1.84– 9.38%
Accuracy n = 5 (% Recovery)	%Recovery = 96.99-98.57%
Interference/ Specificity	No interference

#### Conclusion

Sufficiently sensitive and selective analytical method for the active substance is available. The analytical method for determination of iron phosphate phosphate in the test item Iron Phosphate 1.0 GB was validated.

No methods to show the determination of relevant impurities in the plant protection product have been provided.

Study is on going.

#### Method suitable for the determination of the relevant impurities in plant protection product (PPP)

	Cadmium	Lead	Mercury
Author(s), year	Mr. K. Vasu, 2023		
Principle of method	ICP-MS	ICP-MS	ICP-MS
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	6 points 0.0003 – 0.0060 mg/L $Y = 941\ 610.6x - 33.282$ $r^2 = 0.9933$	6 points 0.0003 – 0.0060 mg/L $Y = 13\ 719\ 973.24x - 2294.576$ $r^2 = 0.9913$	6 points 0.00006 - 00030 mg/L $Y = 11\ 211\ 371x - 34.01$ $r^2 = 0.9916$
Precision – Repeatability Mean n = 5 (%RSD)	%RSD = 3.0367 %RSD <sub>R</sub> = 41.12 %RSD <sub>r</sub> = 27.55 Hr = 0.11 ≤ 1	%RSD = 3.4468 %RSD <sub>R</sub> = 40.96 %RSD <sub>r</sub> = 27.44 Hr = 0.13 ≤ 1	%RSD = 4.0167 %RSD <sub>R</sub> = 73.74 %RSD <sub>r</sub> = 49.41 Hr = 0.08 ≤ 1
Accuracy n = 3 at each level (% Recovery)	T1 - 0.001 mg/L of Cadmium: Mean marginal recovery: 100.72%  T2 - 0.0020 mg/L of	T1 - 0.001 mg/L of Lead: Mean marginal recovery: 94.42%  T2 - 0.0020 mg/L of Lead: Mean marginal recovery:	T1 - 0.00004 mg/L of Mercury: Mean marginal recovery: 102.14%  T2 - 0.00007 mg/L of

	<b>Cadmium</b>	<b>Lead</b>	<b>Mercury</b>
	Cadmium: Mean marginal recovery: 109.84%  T3 - 0.0045 mg/L of Cadmium: Mean total recovery: 113.57%  Total mean recovery: 108.04%	113.13%  T3 - 0.0045 mg/L of Lead: Mean total recovery: 114.53%  Total mean recovery: 107.36%	Mercury: Mean marginal recovery: 95.33%  T3 - 0.0002 mg/L of Mercury: Mean marginal recovery: 111.28%  Total mean recovery: 102.92%
<b>Interference/ Specificity</b>	No interference, the method is specific		
<b>LOQ LOD</b>	LOD=0.000014 mg/kg LOQ=0.00018 mg/kg	LOD=0.000023 mg/kg LOQ=0.00022 mg/kg	LOD=0.000005 mg/kg LOQ=0.000037 mg/kg
<b>Comment</b>	No comments		

Sufficiently sensitive and selective analytical method for the determination of relevant impurities Cadmium, Lead and Mercury in the test item Ferric Phosphate 1% GB is available. The analytical method for determination of relevant impurities was validated according to SANCO/3030/99 rev. 5.

### 3.4.2 Analytical methods for residues

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

Analytical methods for determination of residues are not required.

## 3.5 Mammalian toxicology (Part B, Section 6)

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

### 3.5.1 Acute toxicity

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.

### 3.5.2 Operator exposure

Operator exposure to HIERRO was not evaluated as part of the EU review of Ferric phosphate for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential operator exposure have been undertaken for HIERRO using EFSA AOEM Model and dermal absorption value (10% concentrate).

Conclusions:

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:

**Implication for labelling:** Gloves during manual application.

### 3.5.3 Worker exposure

Since Iron phosphate 1% 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.

### 3.5.4 Bystander and resident exposure

Bystander and resident exposure to HIERRO was not evaluated as part of the EU review of Ferric phosphate for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential residents and bystander's exposures have been undertaken for Ferric phosphate using EFSA AOEM Model and dermal absorption value (10% concentrate).

**Conclusion:** According to the EFSA AOEM Model, it can be concluded that there is no undue risk to any bystander after accidental short-term exposure nor to any resident exposure to HIERRO while maintaining the buffer zone 2-3 m.

**Implication for labelling:** None

## 3.6 Residues and consumer exposure (Part B, Section 7)

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.

### 3.6.1 Residues

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

### 3.6.2 Consumer exposure

The consumer risk assessments is not required.

### **3.7 Environmental fate and behaviour (Part B, Section 8)**

Concentration of Iron phosphate 1% GB in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentration (PEC values) in soil, surface water, sediment and ground water are provided.

#### **3.7.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)**

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. Maximum PEC<sub>soil</sub> value for Ferric phosphate was 2.667 mg/kg.

#### **3.7.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)**

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 < 0.1 µg/L as required for pesticide active substances by European Parliament and Council Directive 2006/118/EC.

#### **3.7.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)**

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/L) can be used.

#### **3.7.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)**

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.

### **3.8 Ecotoxicology (Part B, Section 9)**

#### **3.8.1 Effects on terrestrial vertebrates**

Based on a weight-of-evidence approach, nature of the active substance, absence of mortality at the highest tested dose in the acute study and information from literature, a low risk for birds from the use of HIERRO can be concluded.

Based on a weight-of-evidence approach, nature of the active substance, absence of mortality at the highest tested dose in the acute study and information from literature, a low risk for mammals from the use of

HIERRO can be concluded.

### **3.8.2 Effects on aquatic species**

According to active substance characteristics, the type of formulation and the weight of evidence, an unacceptable risk for aquatic organisms is not expected after the application of HIERRO according to the proposed use.

### **3.8.3 Effects on bees**

Exposure of honeybees is considered highly unlikely in the case of application of HIERRO since the formulation is a granular bait product applied directly to the soil, and because of its use pattern, there should be no significant exposure of honeybee by either contact or oral exposure. In addition, HIERRO is a solid, non-volatile and non-dusty and the active substance is practically insoluble. Therefore, there is no relevant exposure for honeybees

However, hazard quotients were calculated for oral exposure (Q<sub>ho</sub>) and contact exposure (Q<sub>hc</sub>) to ferric phosphate and all hazard quotients (HQ) were considerably less than 50, therefore a low risk to bees is expected from the application of HIERRO at all proposed label rates. No chronic study for adult bees and chronic study for larvae is required.

### **3.8.4 Effects on other arthropod species other than bees**

The in-field and off-field risk posed to non-target arthropods from the use of HIERRO is considered to be acceptable.

### **3.8.5 Effects on soil organisms**

There is no risk for earthworms and non-target soil organisms after exposure to HIERRO when applied according to the proposed GAP.

The risk to soil microorganisms from the proposed uses of HIERRO is considered to be acceptable.

### **3.8.6 Effects on non-target terrestrial plants**

No unacceptable effects are expected on non-target flora after application of HIERRO.

### **3.8.7 Effects on other terrestrial organisms (Flora and Fauna)**

The formulation HIERRO are applied as ready for use bait, resulting in a minimal potential for exposure to non-target terrestrial organisms.

Furthermore, ferric phosphate is included in the Food and Agriculture Organisation of the United Nations list of permitted nutrient supplements in food as made in an amendment (FAO, 1986). In fact, both the iron and the phosphate ions occur in food naturally because they are an inherent part of plant and animal metabolism. Iron is a micronutrient and phosphorus is a macronutrient, both of which are essential to

plant growth and development. Both the ferric and phosphate ions of ferric phosphate are, therefore, essential in plant and animal metabolism.

However, the Tier 1 calculations of the risk assessment should be provided by the applicant to completeness of the risk assessment for birds and mammals according to B&M GD ,2009.

The risk to other terrestrial organisms (Flora and Fauna) of HIERRO is therefore considered to be acceptable.

### **3.9 Relevance of metabolites (Part B, Section 10)**

Not relevant. No metabolites are predicted to occur in groundwater at concentrations above 0.1 µg/L.

## **4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)**

Not relevant. Iron phosphate 1% GB does not contain active substances considered as candidate for substitution.

## **5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization**

## **Appendix 1 Copy of the product authorization**

MS assessor to insert details of the product authorization for MS country.

## Appendix 2 Copy of the product label

### Skuteczność:

Chmiel, rośliny ozdobne i winorośl, rośliny warzywne liściaste mogą być zaakceptowane tylko jako uprawy małoobszarowe w trybie art. 51. Z roślin rolniczych – burak cukrowy, sorgo i rośliny strączkowe są nieakceptowane. ~~Sorgo oraz~~ małoobszarowe rośliny strączkowe mogą być uwzględnione w etykiecie tylko w trybie Art. 51.

Zapis rośliny owocowe został wykreślony, zastąpiono go zapisem: *truskawka i inne rośliny sadownicze (w uprawie polowej)*.

Podsumowując następujące zastosowania są akceptowalne w głównej części etykiety: truskawka i inne rośliny sadownicze (w uprawie polowej); zboża, rzepak ozimy, słonecznik, kukurydza, sorgo, soja i winorośl oraz rośliny warzywne okopowe i bulwiaste.

**Pozostałości:** brak uwag

**Toksykologia:** brak uwag

Zezwolenie MRiRW nr R - 11/2020 z dnia 31.01.2020 r.

### Posiadacz zezwolenia:

Sharda Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa, tel.: 22 886 9328 lub 17 240 13 07, e-mail: eu.sales@shardaintl.com

### Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

Sharda Cropchem Ltd. Prime Business Park, Dashrathlal Joshi Road Vile Parle (West), Mumbai – 400 056, Indie, tel.: + 91 22 6678 2800 lub +48 17 240 13 07, e-mail: eu.sales@shardaintl.com.

### Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

(...)

## HIERRO

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

fosforan żelaza (związek z grupy nieorganicznych związków fosforu) – 10 g/kg (1 %)

### Zezwolenie MRiRW nr R - z dnia r.

EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska należy postępować zgodnie z instrukcją użycia.
P280	Stosować rękawice ochronne/odzież ochronną.

### OPIS DZIAŁANIA

MOLUSKOCYD, przeznaczony do zwalczania ślimaków nagich w formie granul. Mechanizm działania substancji czynnej środka - fosforanu żelaza, polega na redukcji wydzielania śluzu przez ślimaki. Po spożyciu granul ślimaki zwykle chowają się w glebie/podłożu, gdzie obumierają, dlatego dowodów skutecz-

ności środka w postaci obumarłych ślimaków jest niewiele. Ze względu na to, że efekty stosowania środka mogą nie być widoczne od razu, jego skuteczność należy mierzyć pośrednio - mniejszym rozmiarem szkód wyrządzonych przez szkodniki, odżywiający się roślinami uprawnymi. Rezultaty stosowania środka można zatem ocenić głównie na podstawie ograniczenia szkód w uprawach

## STOSOWANIE ŚRODKA

Środek jest przeznaczony do stosowania poprzez rozrzucenie ręczne lub za pomocą mechanicznego aplikatora do środków w postaci granulatu.

### ~~Rośliny owocowe~~ **Truskawka i inne rośliny sadownicze (w uprawie polowej)**

**Maksymalna / zalecana dawka dla jednorazowego zastosowania:** 50,0 kg/ha.

Termin stosowania: od siewu/sadzenia do fazy osiągnięcia przez owoce 90% typowej wielkości (BBCH 79).

**Maksymalna liczba zabiegów w sezonie wegetacyjnym:** 4

Odstęp między zabiegami: co najmniej 14 dni.

### Rośliny warzywne **okopowe i bulwiaste**

**Maksymalna / zalecana dawka dla jednorazowego zastosowania:** 50,0 kg/ha.

Termin stosowania: od siewu/sadzenia do fazy BBCH 81.

**Maksymalna liczba zabiegów w sezonie wegetacyjnym:** 4

Odstęp między zabiegami: co najmniej 14 dni.

### Zboża, rzepak ozimy, ~~burak cukrowy~~, słonecznik, kukurydza, **sorgo**, soja, ~~warzywa strączkowe~~

**Maksymalna / zalecana dawka dla jednorazowego zastosowania:** 50,0 kg/ha.

Termin stosowania: od siewu/sadzenia do fazy BBCH 89.

**Maksymalna liczba zabiegów w sezonie wegetacyjnym:** 4

Odstęp między zabiegami: co najmniej 14 dni.

### **Winorośl**

**Maksymalna / zalecana dawka dla jednorazowego zastosowania:** 50,0 kg/ha.

Termin stosowania: od siewu/sadzenia do fazy BBCH 81.

**Maksymalna liczba zabiegów w sezonie wegetacyjnym:** 4

Odstęp między zabiegami: co najmniej 14 dni.

### **Rośliny ozdobne**

**Maksymalna / zalecana dawka dla jednorazowego zastosowania:** 50,0 kg/ha.

Termin stosowania: od siewu/sadzenia do fazy BBCH 69.

**Maksymalna liczba zabiegów w sezonie wegetacyjnym:** 4

Odstęp między zabiegami: co najmniej 14 dni.

### **Chmiel**

~~Maksymalna / zalecana dawka dla jednorazowego zastosowania: 50,0 kg/ha.~~

~~Termin stosowania: od siewu/sadzenia do fazy BBCH 82.~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 4~~

~~Odstęp między zabiegami: co najmniej 14 dni.~~

## ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie dotyczy

1. Podczas aplikacji należy zachować ostrożność, aby granulat nie pozostał na liściach, kwiatach lub innych częściach roślin zwłaszcza w uprawie warzyw i roślin ozdobnych.
2. Środek jest najbardziej skuteczny w ochronie roślin jednorocznych, kiedy jest stosowany bezpośrednio po siewie/sadzeniu.
3. Najwyższą skuteczność osiąga się, wykonując zabieg przed wystąpieniem szkód.
4. W przypadku upraw roślin jednorocznych zaleca się jako regułę użycie środka przed zaobserwowaniem szkód.
5. Konieczne może być powtórzenie aplikacji, zwłaszcza w przypadku spożycia przez ślimaki granulatu lub pojawienia się kolejnych pokoleń szkodników.
6. Nie należy stosować środka łącznie z nawozami.

## ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony i które zwróciły się o taką informację.

Stosować rękawice ochronne i odzież ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin podczas stosowania środka. Należy unikać niepotrzebnego kontaktu ze środkiem. Nieprawidłowe stosowanie środka może spowodować szkody dla zdrowia.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji): Nie dotyczy

## ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg. Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

## WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

– w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,

– w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

### **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe. W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę

Okres ważności - 2 lata  
Data produkcji - .....  
Zawartość netto - .....  
Nr partii - .....

### **Appendix 3 Letter of Access**

No letter of Access to protected data are required.

## Appendix 4 Lists of data considered for national authorization

### 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.2.1 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	Y	Data/study report never submitted before to Poland	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	Y	Data/study report never submitted before to Poland	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	Y	Data/study report never submitted before to Poland	SHARDA CROPCHEM LIMITED
CP 6.0-001	Anonymous	2020	Biological Assessment Dossier: Iron phosphate 2.97% GB (29.7 g/kg Iron phosphate) – EU central zone Sharda Cropchem España -, - Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA CROPCHEM LIMITED
KCP 5.1.1	B. Krzysiak-Warzała	2017	Iron phosphate 1.0% GB: Analysis of active substances content and physicochemical properties of initial preparation and	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			preparation after accelerated storage procedure (CIPAC MT 46.3) Report No. 18/2017/BA-AD GLP Unpublished				LIMITED
KCP 5.1.1-3	Mr. K. Vasu	2023	Method validation and determination of relevant impurities Leas, Mercury and Cadmium in Iron Phosphate 1% GB, Report No.: 13033/2023 Bioscience Research Foundation GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA CROPCHEM LIMITED
KCP 10.2.1-01	XXXXXX	2019	Iron phosphate 2.9% GB: Fish, acute toxicity test with rainbow trout. Study code: XXXXXXXX GLP, Unpublished	Y	Y	Data/study report never submitted before to Poland	SHARDA CROPCHEM LIMITED
KCP 10.2.1-02	Halappa, R.	2019	Iron phosphate 2.9% GB. <i>Daphnia magna</i> , acute immobilisation test. Study code: G14346. Eurofins. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA CROPCHEM LIMITED
KCP 10.2.1-03	Halappa, R.	2019	Ferric Phosphate 2.9% GB: Alga, Growth Inhibition Test. Study code: G14345. Eurofins. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA CROPCHEM LIMITED
KCP 10.3.2.1-01	Angayarkanni, V.	2020	A laboratory test for evaluating the effects of Ferric phosphate 2.9% GB on the carabid beetle, <i>Poecilus cupreus</i> L. (Coleoptera, Carabidae). Study code: 6121/2019. Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA CROPCHEM LIMITED
KCP 10.3.2.1-02	Angayarkanni, V.	2020	A laboratory test for evaluating the effects of Ferric phosphate 2.9% GB on the rove beetle, <i>Aleochara bilineata</i> (Gyllenhal). Study code: 6193/2019. Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA CROPCHEM LIMITED
KCP 10.4.1.1	Halappa, R.	2019	Iron phosphate 2.9% GB: Earthworm Reproduction Test. Study code: G14350. Eurofins. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA CROPCHEM LIMITED
KCP 10.4.2.1-01	Rajeshwari, S.	2019	Effect of Ferric phosphate 2.9% GB on the reproductive output of the predatory soil mite <i>Hypoaspis (Geolaelaps) aculeifer</i> Canestrini (Acari: Laelapidae) in artificial soil. Study code: 6077/2019. Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA CROPCHEM LIMITED

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.4.2.1-02	Murali, K.	2019	Effect of Ferric phosphate 2.9% GB on reproduction of the collembolans ( <i>Folsomia candida</i> ) in artificial soil. Study code: 6076/2019. Bioscience Research Foundation. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA CROPCHEM LIMITED
KCP 10.5-01	Anand, H. S.	2019	Soil microorganisms: nitrogen transformation test of Iron phosphate 1.0% GB. Study code: G14362. Eurofins. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA CROPCHEM LIMITED
KCP 10.5-02	Anand, H. S.	2019	Soil microorganisms: carbon transformation test of iron phosphate 1.0% GB. Study code: G14361. Eurofins. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	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	Data protection claimed Y/N	Justification if data protection is claimed	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-

**List of data relied on and 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>Data protection claimed</b> <b>Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
-	-	-	-	-	-	-	-