

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SHA 105000 B

Product name(s): HIERRO

Chemical active substance: Iron phosphate 10.0 g/Kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España

Submission date: November 2020

MS Finalisation date: 07.2021; 10.2021; 08.2023

Version history

When	What
07.2021	Applicant updated document
07.2021	ZRMs evaluated dRR updated by Applicant.
10.2021	The Final Version of the RR
08.2023	Corrections made due to comments received from the Ministry of Agriculture and Rural Development

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Comments of zRMS are in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are in grey). Corrections marked by yellow.
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synerg ist per ha ^(f)	zRMS Conclusion (efficacy)
					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			

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. ^(e)	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 con- trolled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synerg ist per ha (f)	zRMS Conclusion (efficacy)
					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	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	-	-	-	To be con- firmed by cMS In PL: accept- ed.
2	CEU	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	-	-	-	To be con- firmed by cMS In PL – only root and tuber field crop are accepted in line to art. 33. Leafy vegeta- bles can be accepted only in line to article 51.
3	CEU	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	-	-	-	To be con- firmed by cMS. In Poland in label can be accepted: cereals, oilseed rape, sunflower, corn, sor- ghum, soy- beans. Pulses can be accept- ed only in line to Article 51.
4	CEU	Grapevine	F	Slugs and Snails	Spread to soil surface	From seed- ling/planting until	a) 4 b) 4	14	a) 50.0 b) 200.0	a) 0.5 b) 2.0	-	-	-	To be con- firmed by

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synerg ist per ha (f)	zRMS Conclusion (efficacy)
					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			
						BBCH 81								cMS. In PL-use accepted.
5	CEU	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	-	-	-	Not ac- ceptable. In PL – only in line to article 51 can be accepted.
6	CEU	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	-	-	-	To be con- firmed by cMS. In PL- only in line to article 51 can be accepted.

* 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

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product **Iron phosphate 1.0% GB (HIERRO; Product code: SHA 105000 B)** containing the active substance Iron phosphate, which has been included into Annex I of Council Directive 91/414/EEC under Inclusion Directive 2001/87/EC and implemented under Regulation (EU) No 540/2011.

The SANCO report for Iron phosphate (SANCO/3030/99 rev. 4) is considered to provide the relevant review information or a reference to where such information can be found.

For the implementation of the uniform principles of Annex VI, the conclusions of the review reports on the active substances iron phosphate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17th June 2011 and 29th September 2006, respectively, shall be taken into account. Consideration of active substances for Annex I inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of iron phosphate relating to efficacy.

The results are presented separated by crops to have a better overview of the effectiveness of the product. As Iron phosphate 1.0% GB is a molluscicide and his efficacy is independent of the crop, the results could be presented grouped. The product's mode of action produces an attraction of the slugs and snails, for that reason the efficacy is indepent of the kinf of crop where the product is applied.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

The detailed assessment of the individual trial and study data is located in the following report:

Report: KCP 6.0/001 Biological Assessment Dossier Iron phosphate 1.0% GB, Central
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Description of active substance iron phosphate

Iron phosphate was introduced several years ago for the control of slugs and snails on crops as cereals, vegetables, orchards, industrial crops among others.

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

Today, Iron phosphate is registered and commercialised in several formulations around the world.

Table 3.2-1: Current approvals of iron phosphate in the EU Central zone as well as connected EPPO zones where trials were conducted

Country	Product	Active ingredient	Approval number
Austria	Ferramol Schneckenkorn	Iron phosphate 9.9 g/kg	2605-0
Belgium	Derrex	Iron phosphate 3 g/kg	9904P/B
France	Ferramol	Iron phosphate 9.9 g/kg	2020003
Germany	Ferramol Schneckenkorn	Iron phosphate 9.9 g/kg	034496-00
	Derrex	Iron phosphate 29.7 g/kg	027086-00
Greece	Ferramol GB	Iron phosphate 1 g/kg	5022
Italy	Ferramol	Iron phosphate 1 g/kg	012172
Poland	Ferramol GR	Iron phosphate 9.9 g/kg	R-4/2014wu
	Slimax Agro	Methaldehyde 30 g	R-238/2014

Country	Product	Active ingredient	Approval number
	Lima Oro 3 GB	Methaldehyde 30 g	R-195/2015
Spain	Ferramol	Iron phosphate 1 g/kg	24670
United Kingdom	Derrex	Iron phosphate 29.7 g/kg	15351

Mode of action

Iron phosphate is a stomach poison in slugs and snails. It damages their digestive tissue. With enough exposure, they stop eating altogether and slowly die. The exact mode of action is not clearly understood.

Iron phosphate is an iron salt of phosphoric acid.

Table 3.2-2: Details of the formulation and the active substance

Proposed trade name	Iron phosphate 1.0% GB
A.S. content:	Iron phosphate 10 g/kg
Formulation type:	GB
Synonyms:	-
Active substance	Iron phosphate
IUPAC name:	Ferric phosphate
Chemical group:	iron salt of phosphoric acid
Mode of action:	Iron phosphate is a stomach poison in slugs and snails. It damages their digestive tissue. With enough exposure, they stop eating altogether and slowly die. The exact mode of action is not clearly understood.

For further physico-chemical properties, please refer to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Description of the plant protection product

Iron phosphate 1.0% GB is a Granular bait (GB) formulation containing 10.0 grams per kilogram (g/Kg) Iron phosphate for use Slugs and Snails in fruit crops, bulb vegetables, leafy vegetables, fresh herbs, root and tuber vegetables, fruit vegetables, legumes, straight vegetables, strawberry, cereals, ornamentals, oilseed rape and sugar beet.

According to the GAP, the proposed application rate of Iron phosphate 1.0% GB in fruit crops, bulb vegetables, leafy vegetables, fresh herbs, root and tuber vegetables, fruit vegetables, legumes, straight vegetables, strawberry, cereals, ornamentals, oilseed rape and sugar beet is 50.0 kg per hectare (Kg/ha), with up to 4 applications per season in all crops included in GAP table. This will deliver 500 g Iron phosphate per hectare per application.

The data presented in this dossier fully support the label claim of Iron phosphate 1.0% GB for the control of Slugs and Snails.

Table 3.2-3: Simplified table of currently registered uses and requested uses for the product code.

Crop / disease	Application method	Max. individual application rate (kg f.p./ha) [kg a.s./ha]	Max. number of applications	Application timing (e.g. BBCH)
Fruit crops / Slugs and Snails	Granular bait	(50.0) [500]	4	until BBCH 79

Crop / disease	Application method	Max. individual application rate (kg f.p./ha) [kg a.s./ha]	Max. number of applications	Application timing (e.g. BBCH)
Vegetable crops / Slugs and Snails	Granular bait	(50.0) [500]	4	until BBCH 81
Field crops / Slugs and Snails	Granular bait	(50.0) [500]	4	until BBCH 89
Grapevine / Slugs and Snails	Granular bait	(50.0) [500]	4	until BBCH 81
Ornamentals / Slugs and Snails	Granular bait	(50.0) [500]	4	until BBCH 69
Hop / Slugs and Snails	Granular bait	(50.0) [500]	4	until BBCH 82

Further details are in the table “All intended uses” in Part B - Section 0.

Description of the target pests

Key targets for this product are slugs and snails in all claimed crops. All the listed pests are present throughout or in parts of the Central zone and in relevant EPPO zones. The key targets for this product are described in detail in the Biological Assessment dossier.

Table 3.2-4: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name
DEROAG	<i>Deroceras agreste</i>	Grey field slug, field slug
HEXSP	<i>Helix aspersa</i>	Common snail

Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Fruit crops	CEU	CEU	Slugs; Snails	CEU	-
Vegetable crops	CEU	CEU	Slugs; Snails	CEU	-
Field crops	CEU	CEU	Slugs; Snails	CEU	-
Grapevine	CEU	CEU	Slugs; Snails	CEU	-
Ornamentals	CEU	CEU	Slugs; Snails	CEU	-
Hop		CEU	Slugs; Snails	CEU	-

Compliance with the Uniform Principles

Comprehensive field trials were conducted in Germany, United Kingdom, 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.

Information on trials submitted (3.1 Efficacy data)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

Table 3.2-6: Presentation of efficacy trials (efficacy trials, preliminary trials...)

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MAR	MED	N-E	S-E			
FRASS	Italy	MED + E		1			2017	GEP	
	Spain	MED + E		2			2017	GEP	
	Greece	MED + E		2			2017	GEP	
	United Kingdom	MED + E	1				2017	GEP	
	Germany	MED + E	1				2017	GEP	
	Poland	MED + E			2		2017	GEP	
	Total, Strawberry (eff.)		2	5	2	-			
LACSA	Italy	MED + E		1			2016	GEP	
	Spain	MED + E		2			2016	GEP	
	Greece	MED + E		2			2016	GEP	
	Total, Lettuce (eff.)		-	5	-	-			
TRAZW	Italy	MED + E		1			2016	GEP	
	Greece	MED + E		2			2016	GEP	
	France	MED + E		1			2016/7	GEP	
	United Kingdom	MED + E	2				2016	GEP	
	Czech Republic	MED + E	2				2016	GEP	
	Poland	MED + E			5		2018/19	GEP	
	Total, Winter wheat (eff.)		4	4	5	-			
SOLTU	Italy	MED + E		1			2016	GEP	
	Greece	MED + E		2			2016	GEP	
	Spain	MED + E		2			2016	GEP	
	United Kingdom	MED + E	2				2016	GEP	
	Germany	MED + E	1				2016	GEP	
	Poland	MED + E			3		2016	GEP	
	Total, Potato (eff.)		3	5	3	-			
MABSD	Italy	MED + E		1			2016	GEP	
	Greece	MED + E		2			2016	GEP	
	Spain	MED + E		2			2016	GEP	
	Germany	MED + E	1				2016	GEP	
	Czech Republic	MED + E	2				2016	GEP	

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MAR	MED	N-E	S-E			
	Total, Pome (eff.)		3	5	-	-			
HORVS	Spain	MED + E	2				2016	GEP	
	Total, Spring barley (eff.)		2	-	-	-			
BRSNW	United Kingdom	MED + E	2				2016	GEP	
	Germany	MED + E	1				2016	GEP	
	Czech Republic	MED + E	2				2016	GEP	
	Poland	MED + E			1		2016	GEP	
					5		2018/19	GEP	
	Total, Winter rape (eff.)		5	-	6	-			
HORVW	Poland	MED + E			1		2016	GEP	
	Total, Winter barley (eff.)		-	-	1	-			

Climatic zones

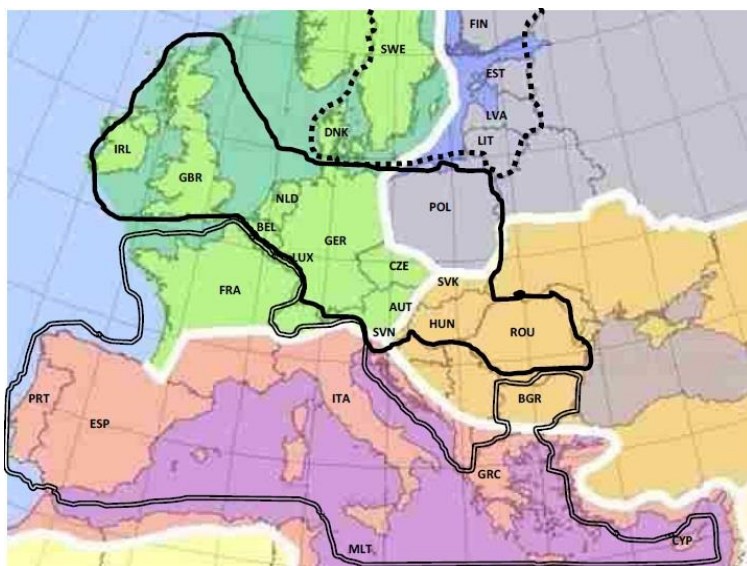
Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country¹.

Germany, United Kingdom and Czech Republic are located in the Maritime EPPO zone; Poland is located in the North-east EPPO zone; and Spain, Italy, Greece as well as S-France are located in the Mediterranean EPPO zone (Figure 3.2-1).

This document is prepared to support the submission of Iron phosphate 1.0% GB throughout the Central Registration zone, therefore data from the Maritime EPPO zone, the Mediterranean EPPO zone and the North-east EPPO zone are included.

¹ Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, E. Bouma, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)



Agronomic conditions

Cultural conditions and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between the countries in the Central and Southern EU.

The same Iron phosphate containing molluscicides are already registered and used in the countries where the trials were conducted to support the current application for registration. Please refer to Table 3.2-1 for the registration numbers in the different countries. In Central and South zone countries, Iron phosphate - containing molluscicides are used as a protective molluscicide, which should be applied during the growing season, before or shortly after outbreaks of the diseases claimed on the label are foreseen. Depending on the forecast and the diseases to be controlled, the important period may stretch from April to September.

(i) *Pest physiology*

The physiology of Slugs and Snails is similar throughout Central and Southern Europe. Although trials were performed in different countries, sites were selected to exert maximum pest pressure and to exacerbate treatment differences. No difference in the level of control was apparent between the different countries or regions in which the trials were conducted.

(iii) *Agronomic practices*

Agronomic practices for cultivating crops are similar throughout the Central zone as well as in the countries in the connected EPPO zones where trials were conducted. The levels of inorganic fertilizers and other crop inputs are also generally similar between the countries.

(iv) *Varieties*

Although crop varieties tend to differ between countries, observations on selectivity have not indicated any particular varietal sensitivity. The crop safety of Iron phosphate 1.0% GB has been tested on a wide range of varieties in efficacy- and selectivity trials. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance and yield data generated in one country is therefore relevant in other Member states. To increase the probability of high levels of disease in the trials, the varieties chosen in each country were the ones with the least resistance to the selected disease. Therefore, the results from each country can be considered as the worst case.

(v) *Trial methodology*

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(vi) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for agricultural production of the respective crops due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

It is not expected that a foliar applied fungicide will be affected in any way by soil type and so this factor can be ignored for the purposes of this dossier.

On the basis that the above factors do not influence the overall performance of Iron phosphate 1.0% GB, it is the applicant's contention that data from Germany, United Kingdom, Czech Republic, Spain, Italy, Greece, France and Poland is equally valid in demonstrating the products performance throughout the Central EU zone.

Efficacy trials were carried out with Iron phosphate 1.0% GB in comparison to the references Iron phosphate product (Ferramol, Lima Oro, Slimax Agro 3 GB, Derrex) in Germany, United Kingdom, Czech Republic, Spain, Italy, Greece, France and Poland. The trials were carried out on strawberry, lettuce, winter wheat, potato, apple, spring barley, oilseed rape and winter barley.

Table 3.2-7: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Iron phosphate formulation					
Ferramol	GR	Iron phosphate 10 g/kg	25 kg/ha 50 kg/ha	Spain Greece France United Kingdom Germany Czech Republic Poland	10 10 1 7 4 6 14
Lima Oro	GB	Iron phosphate 30 g/kg	7 kg/ha	Poland	2
Slimax Agro 3 GB	GB	Iron phosphate 30 g/kg	7 kg/ha	Poland	1
Derrex	GB	Iron phosphate 29.7 g/kg	7 kg/ha	Italy	5

Comments of zRMS:	<p>This document was prepared by Applicant for registration the HIERRO (product code: SHA 105000 B) containing iron phosphate (10.0 g/Kg). The formulation of this product is a granular bail (GB).</p> <p>All necessary information's about tested plant protection products, active substances, studied pests, reference products, etc. are correctly presented in this drr by Applicant.</p> <p>Iron phosphate is an iron salt of phosphoric acid. Iron phosphate for use slugs and snails in fruit crops, vegetable crops, field crops, grapevine, ornamentals, and hop. Iron phosphate is a stomach poison in slugs and snails. It damages their digestive tissue. With enough exposure, they stop eating altogether and slowly die. The exact mode of action is not clearly understood.</p> <p>In Poland, few plants protection product containing iron phosphate are already registered. Control of slugs and snails in conventional farming is not problematic, because a number of molluscicides are registered (e.g. 20 preparations registered</p>
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	<p>in winter rape and 10 preparations in winter wheat), while the use of these agents is not allowed in organic farming. The only preparation allowed for use in organic farming by non-professional users is Ferramol GR, containing ferric phosphate</p> <p>The product – HIERRO (product code: SHA 105000 B) containing iron phosphate by Sharda Cropchem España S.L. has not been previously evaluated in any country according to Uniform Principles.</p> <p>Poland is a ZRMs.</p>
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3.2.1 Preliminary tests (KCP 6.1)

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.

Comments of zRMS:	Iron phosphate has been registered in several Member States for several years. The ZRMs considers that preliminary data are not needed in this case for HIERRO (SHA 105000 B). Iron phosphate is known and use since over 30 years.
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3.2.2 Minimum effective dose tests (KCP 6.2)

Field trials were established to determine the minimum effective dose for the control of the targets claimed in this dossier. In the following, summaries of the performance of Iron phosphate 1.0% GB on the key diseases in strawberry, lettuce, winter wheat, potato, apple, spring barley, oilseed rape and winter barley are presented. It is not necessary to demonstrate the minimum effective dose on all target diseases but only those that are considered key and therefore drive the overall dose rate when a formulation such as Iron phosphate is used.

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).

The results are presented separated by crops to have a better overview of the effectiveness of the product. As Iron phosphate 1.0% GB is a molluscicide and his efficacy is independent of the crop, the results could be presented grouped. The product’s mode of action produces an attraction of the slugs and snails, for that reason the efficacy is indepent of the kinf of crop where the product is applied.

According to the presented results, the dose rate of 50.0 kg/ha per application, for control of slugs and snails in fruit crops, bulb vegetables, leafy vegetables, fresh herbs, root and tuber vegetables, fruit vegetables, legumes, straight vegetables, strawberry, cereals, ornamentals, oilseed rape and sugar beet provided the optimal overall control and should be considered as effective against the pests, for which activity of Iron phosphate 1.0% GB is claimed. As pests often occur throughout a season, up to four applications per season of Iron phosphate 1.0% GB at the proposed rate should be used to efficiently control all pathogens claimed on the label.

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.

The results obtained with Iron phosphate 1.0% GB applied for the control of slugs and snails in strawberry are presented in

Target: DEROAG	No. of trials	Untreated Mean % (range)	Mean % Control from two trials in the Maritime EPPO Zone at a range of doses of Iron phosphate 1.0% GB					
			25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Strawberry								
Mean % control, one observation on MOLLUS per trial, COUNT at 7 DAT	1	16.8	82.1	-	88.1	-	94.0	-

Table 3.2.2-2 Table 3.2.2-1

Target: DEROAG	No. of trials	Untreated Mean % (range)	Mean % Control from two trials in the Maritime EPPO Zone at a range of doses of Iron phosphate 1.0% GB					
			25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Strawberry								
Mean % control, one observation on MOLLUS per trial, COUNT at 7 DAT	1	16.8	82.1	-	88.1	-	94.0	-

Table 3.2.2-2 Minimum effective dose of Iron phosphate 1.0% GB – Mediterranean zone

Target: DEROAG	No. of trials	Untreated Mean % (range)	Mean % Control from five in the Mediterranean EPPO Zone at a range of doses of Iron phosphate 1.0% GB					
			25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Strawberry								
Mean % control, one observation on LEAF/MOLLIV per trial, COUNT at 6-21 DAT	3	5.9 (3.8-10.0)	90.0	70.0-100	91.7	75.0-100	93.3	80.0-100
Mean % control, one observation on LEAATT per trial, DAMAGE at 156 DAT	2	20.7 (15.0-26.3)	30.6	22.9-38.2	53.0	45.8-60.2	82.6	81.3-83.8

Table 3.2.2-3 for results obtained in the Maritime EPPO zone, Mediterranean EPPO zone and the North-east EPPO zone).

The data from the trials proves that the minimum effective dose rate of Iron phosphate 1.0% GB to control slugs and snails in strawberry is 50.0 Kg/ha, with up to four applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Table 3.2.2-1 Minimum effective dose of Iron phosphate 1.0% GB – Maritime zone

Target: DEROAG	No. of trials	Untreated Mean % (range)	Mean % Control from two trials in the Maritime EPPO Zone at a range of doses of Iron phosphate 1.0% GB					
			25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Strawberry								
Mean % control, one observation on MOLLUS per trial, COUNT at 7 DAT	1	16.8	82.1	-	88.1	-	94.0	-

Table 3.2.2-2 Minimum effective dose of Iron phosphate 1.0% GB – Mediterranean zone

Target: DEROAG	No. of trials	Untreated Mean % (range)	Mean % Control from five in the Mediterranean EPPO Zone at a range of doses of Iron phosphate 1.0% GB					
			25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Strawberry								
Mean % control, one observation on LEAF/MOLLIV per trial, COUNT at 6-21 DAT	3	5.9 (3.8-10.0)	90.0	70.0-100	91.7	75.0-100	93.3	80.0-100
Mean % control, one observation on LEAATT per trial, DAMAGE at 156 DAT	2	20.7 (15.0-26.3)	30.6	22.9-38.2	53.0	45.8-60.2	82.6	81.3-83.8

Table 3.2.2-3 Minimum effective dose of Iron phosphate 1.0% GB – North-east zone

Target: DEROAG	No. of trials	Untreated Mean % (range)	Mean % Control from two trials in the North-east EPPO Zone at a range of doses of Iron phosphate 1.0% GB					
			25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Strawberry								
Mean % control, one observation on INSECT per trial, COUNT at 14 DAT	1	5.3	100	-	100	-	100	-
Mean % control, one observation on LEAF per trial, DAMAGE at 15 DAT	1	8.0	50.4	-	48.8	-	72.7	-

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.

The results obtained with Iron phosphate 1.0% GB applied for the control of slugs and snails in lettuce are presented in Table 3.2.2-4 for results obtained in the Mediterranean EPPO zone, Maritime EPPO zone and the North-east EPPO zone).

The data from the trials proves that the minimum effective dose rate of Iron phosphate 1.0% GB to control slugs and snails in lettuce is 50.0 Kg/ha, with up to four applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Table 3.2.2-4 Minimum effective dose of Iron phosphate 1.0% GB – Mediterranean zone

Target: Slugs and snails	No. of trials	Mean % Control from five in the Mediterranean EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated Mean % (range)	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Lettuce								
Mean % control, one observation on MOLLUS per trial, COUNT at 6 DAT	1	10.0	77.5	-	72.5	-	85.0	-
Mean % control, one observation on LEAATT-LEAF per trial, DAMAGE at 9-13 DAT	4	14.3	64.4	51.6-87.3	64.3	51.0-81.7	86.8	59.4-100

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.

The results obtained with Iron phosphate 1.0% GB applied for the control of slugs and snails in winter wheat are presented in Table 3.2.2-5 **Minimum effective dose of Iron phosphate 1.0% GB – Maritime zone**

Target: DEROAG	No. of trials	Mean % Control from five in the Maritime EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated Mean % (range)	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Winter wheat								
Mean % control, one observation on Plant per trial, COUPLA at 8-37 DAT	2	12.1 (2.2-12.1)	56.8	30.7-82.8	64.7	42.0-87.4	81.8	68.2-95.4
Mean % control, one observation on MOLLUS per trial, COUNT at 5-29 DAT	2	7.3 (4.5-10.0)	46.7	10.0-83.3	74.5	60.0-88.9	97.2	94.4-100
Mean % control, one observation on MOLLIV per trial, DAMAGE at 5 DAT	1	30.0	97.3	-	96.7	-	98.3	-

Table 3.2.2-6 Table 3.2.2-5 and Table 3.2.2-7 for results obtained in the Maritime EPPO zone, the Mediterranean EPPO zone and the North-east EPPO zone).

The data from the trials proves that the minimum effective dose rate of Iron phosphate 1.0% GB to con-

trol slugs and snails in winter wheat is 50.0 Kg/ha, with up to four applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Table 3.2.2-5 Minimum effective dose of Iron phosphate 1.0% GB – Maritime zone

Target: DEROAG	No. of trials	Mean % Control from five in the Maritime EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated Mean % (range)	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Winter wheat								
Mean % control, one observation on PLANT per trial, COUPLA at 8-37 DAT	2	12.1 (2.2-12.1)	56.8	30.7-82.8	64.7	42.0-87.4	81.8	68.2-95.4
Mean % control, one observation on MOLLUS per trial, COUNT at 5-29 DAT	2	7.3 (4.5-10.0)	46.7	10.0-83.3	74.5	60.0-88.9	97.2	94.4-100
Mean % control, one observation on MOLLIV per trial, DAMAGE at 5 DAT	1	30.0	97.3	-	96.7	-	98.3	-

Table 3.2.2-6 Minimum effective dose of Iron phosphate 1.0% GB – Mediterranean zone

Target: DEROAG	No. of trials	Mean % Control from five in the Mediterranean EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated Mean % (range)	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Winter wheat								
Mean % control, one observation on MOLLIV per trial, COUNT at 7 DAT	1	10.0	72.5	-	80.0	-	85.0	-
Mean % control, one observation on LEAATT per trial, DAMAGE at 10 DAT	2	17.5 (15.0-20.0)	34.2	16.7-51.7	54.8	50.0-59.6	88.6	85.4-91.7
Mean % control, one observation on MOLLUS per trial, MORTAL at 12 DAT	1	0.0	4.0	-	8.0	-	14.0	-

Table 3.2.2-7 Minimum effective dose of Iron phosphate 1.0% GB – North-east zone

Target: DEROAG	No. of trials	Mean % Control from ten in the North-east EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated Mean % (range)	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Winter wheat								
Mean % control, one observation on ADULT per trial, COUNT at 3-5 DAT	5	11.8 (8.4-20.0)	82.7	66.3-88.8	89.4	82.7-95.0	95.1	89.4-100
Mean % control, one observation on PLANT per trial, DAMMOL at 3-5 DAT	5	17.7 (10.5-39.9)	59.2	41.0-87.0	79.5	71.0-90.7	89.5	87.0-93.7

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.

The results obtained with Iron phosphate 1.0% GB applied for the control of slugs and snails in potato are presented in

Target: DEROAG	No. of trials	Mean % Control from five in the Maritime EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated Mean % (range)	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Potato								
Mean % control, one observation on ADULT/MOLLIV per trial, COUNT at 7-17 DAT	3	7.2 (1.3-11.5)	73.7	69.6-80.0	87.1	80.0-95.7	98.3	97.1-100
Mean % control, one observation on Plant per trial, COUPLA at 7 DAT	2	15.4 (10.8-20.0)	73.4	68.6-78.1	87.9	80.2-95.6	90.4	81.4-99.4

Table 3.2.2-9 Table 3.2.2-8

Target: DEROAG	No. of trials	Mean % Control from five in the Maritime EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated Mean % (range)	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Potato								
Mean % control, one observation on ADULT/MOLLIV per trial, COUNT at 7-17 DAT	3	7.2 (1.3-11.5)	73.7	69.6-80.0	87.1	80.0-95.7	98.3	97.1-100
Mean % control, one observation on Plant per trial, COUPLA at 7 DAT	2	15.4 (10.8-20.0)	73.4	68.6-78.1	87.9	80.2-95.6	90.4	81.4-99.4

Table 3.2.2-9 Minimum effective dose of Iron phosphate 1.0% GB – Mediterranean zone

Target: DEROAG	No. of trials	Mean % Control from five in the Mediterranean EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated Mean % (range)	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Potato								
Mean % control, one observation on LEAF/LEAATT per trial, DAMAGE at 10-14 DAT	4	14.1 (4.4-21.3)	48.6	25.5-83.1	53.2	9.1-75.6	76.4	35.0-95.8
Mean % control, one	3	16.3	75.2	65.7-80.0	74.4	55.0-93.3	82.4	71.4-93.3

observation on MOLLIV per trial, COUNT at 2-14 DAT		(3.8-35.0)						
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Table 3.2.2-10 for results obtained in the Maritime EPPO zone, Mediterranean EPPO zone and the North-east EPPO zone.

The data from the trials proves that the minimum effective dose rate of Iron phosphate 1.0% GB to control slugs and snails in potato is 50.0 Kg/ha, with up to four applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Table 3.2.2-8 Minimum effective dose of Iron phosphate 1.0% GB – Maritime zone

Target: DEROAG	No. of trials	Mean % Control from five in the Maritime EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated Mean % (range)	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Potato								
Mean % control, one observation on ADULT/MOLLIV per trial, COUNT at 7-17 DAT	3	7.2 (1.3-11.5)	73.7	69.6-80.0	87.1	80.0-95.7	98.3	97.1-100
Mean % control, one observation on Plant per trial, COUPLA at 7 DAT	2	15.4 (10.8-20.0)	73.4	68.6-78.1	87.9	80.2-95.6	90.4	81.4-99.4

Table 3.2.2-9 Minimum effective dose of Iron phosphate 1.0% GB – Mediterranean zone

Target: DEROAG	No. of trials	Mean % Control from five in the Mediterranean EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated Mean % (range)	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Potato								
Mean % control, one observation on LEAF/LEAATT per trial, DAMAGE at 10-14 DAT	4	14.1 (4.4-21.3)	48.6	25.5-83.1	53.2	9.1-75.6	76.4	35.0-95.8
Mean % control, one observation on MOLLIV per trial, COUNT at 2-14 DAT	3	16.3 (3.8-35.0)	75.2	65.7-80.0	74.4	55.0-93.3	82.4	71.4-93.3

Table 3.2.2-10 Minimum effective dose of Iron phosphate 1.0% GB – North-east zone

Target: DEROAG	No. of trials	Mean % Control from five in the Maritime EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated Mean % (range)	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Potato								
Mean % control, one observation on Plant/LEAF per trial, DAMAGE at 3-8 DAT	3	18.5 (12.8-23.8)	39.2	35.0-47.0	29.1	8.8-43.5	55.5	46.0-60.6
Mean % control, one observation on Plant per trial, COUNT	2	32.4 (29.5-35.3)	46.5	37.0-56.0	53.0	50.0-56.0	59.5	55.0-64.0

at 8-10 DAT								
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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.

The results obtained with Iron phosphate 1.0% GB applied for the control of slugs and snails in apple are presented in

Target: DEROAG	No. of trials	Mean % Control from five in the Mediterranean EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
		Mean % (range)	Mean	Range	Mean	Range	Mean	Range
Apple								
Mean % control, one observation on ANIMAL per trial, COUNT at 3 DAT	1	1.8	85.7	-	85.7	-	100	-

Table 3.2.2-12 Table 3.2.2-11 for results obtained in the Maritime EPPO zone and the Mediterranean EPPO zone.

The data from the trials proves that the minimum effective dose rate of Iron phosphate 1.0% GB to control slugs and snails in apple is 50.0 Kg/ha, with up to four applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Table 3.2.2-11 Minimum effective dose of Iron phosphate 1.0% GB – Maritime zone

Target: DEROAG	No. of trials	Mean % Control from five in the Mediterranean EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
		Mean % (range)	Mean	Range	Mean	Range	Mean	Range
Apple								
Mean % control, one observation on ANIMAL per trial, COUNT at 3 DAT	1	1.8	85.7	-	85.7	-	100	-

Table 3.2.2-12 Minimum effective dose of Iron phosphate 1.0% GB – Mediterranean zone

Target: DEROAG	No. of trials	Mean % Control from five in the Mediterranean EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
		Mean % (range)	Mean	Range	Mean	Range	Mean	Range
Apple								
Mean % control, one observation on ADULT/MOLLIV per trial, COUNT at 7-22 DAT	3	5.5 (1.5-10.0)	69.7	65.0-77.5	55.0	45.0-70.0	86.7	80.0-100

Mean % control, one observation on LEAATT per trial, DAMAGE at 11 DAT	2	23.8 (22.5-25.0)	47.1	45.4-51.3	60.0	57.9-60.8	89.2	81.7-91.7
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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.

The results obtained with Iron phosphate 1.0% GB applied for the control of slugs and snails in Spring barley are presented in Table 3.2.2-13 for results obtained in the Mediterranean EPPO zone.

The data from the trials proves that the minimum effective dose rate of Iron phosphate 1.0% GB to control slugs and snails in Spring barley is 50.0 Kg/ha, with up to four applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Table 3.2.2-13 Minimum effective dose of Iron phosphate 1.0% GB – Mediterranean zone

Target: DEROAG	No. of trials	Mean % Control from five in the Mediterranean EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated Mean % (range)	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Spring barley								
Mean % control, one observation on LEAF per trial, DAMAGE at 5-14 DAT	2	2.3 (1.0-3.5)	88.3	76.5-100	92.2	84.4-100	94.3	88.5-100
Mean % control, one observation on PLANT per trial, COUNT at 5-14 DAT	2	4.4 (2.3-6.5)	83.4	66.7-100	88.9	77.8-100	88.9	77.8-100

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.

The results obtained with Iron phosphate 1.0% GB applied for the control of slugs and snails in oilseed rape are presented in Table 3.2.2-13 and

Target: DEROAG	No. of	Mean % Control from five in the Maritime EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
		Untreated Mean %	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range

	trials	(range)						
Oilseed rape								
Mean % control, one observation on ADULT/MOLLUS per trial, COUNT at 8-16 DAT	3	4.9 (1.3-10.0)	74.9	40.0-100	92.4	85.0-100	97.4	92.3-100
Mean % control, one observation on MOL-LIV-PLANT per trial, DAMAGE at 7-14 DAT	2	6.0 (3.5-8.5)	65.5	35.7-95.3	77.9	58.1-97.6	90.2	80.3-100

Table 3.2.2-14 for results obtained in the Maritime EPPO zone and the North-east EPPO zone.

The data from the trials proves that the minimum effective dose rate of Iron phosphate 1.0% GB to control slugs and snails in oilseed rape is 50.0 Kg/ha, with up to four applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Table 3.2.2-13 Minimum effective dose of Iron phosphate 1.0% GB – Maritime zone

Target: DEROAG	No. of trials	Untreated Mean % (range)	Mean % Control from five in the Maritime EPPO Zone at a range of doses of Iron phosphate 1.0% GB					
			25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Oilseed rape								
Mean % control, one observation on ADULT/MOLLUS per trial, COUNT at 8-16 DAT	3	4.9 (1.3-10.0)	74.9	40.0-100	92.4	85.0-100	97.4	92.3-100
Mean % control, one observation on MOL-LIV-PLANT per trial, DAMAGE at 7-14 DAT	2	6.0 (3.5-8.5)	65.5	35.7-95.3	77.9	58.1-97.6	90.2	80.3-100

Table 3.2.2-14 Minimum effective dose of Iron phosphate 1.0% GB – North-east zone

Target: DEROAG	No. of trials	Untreated Mean % (range)	Mean % Control from eleven in the North-east EPPO Zone at a range of doses of Iron phosphate 1.0% GB					
			25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean	Range	Mean	Range	Mean	Range
Oilseed rape								
Mean % control, one observation on PLANT per trial, COUPLA at 14 DAT	1	8.8	52.5	-	57.5	-	87.5	-
Mean % control, one observation on ADULT per trial, COUNT at 5-10 DAT	5	16.9 (9.9-20.0)	82.8	75.8-88.8	92.5	83.8-95.9	98.2	96.3-99.3
Mean % control, one observation on PLANT per trial, DAMMOL at 3-10 DAT	5	19.8 (4.9-35.0)	69.3	48.0-84.2	85.9	75.7-95.9	90.2	82.7-100

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 re-

sults 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.

The results obtained with Iron phosphate 1.0% GB applied for the control of slugs and snails in winter barley are presented in Table 3.2.2-15 for results obtained in the North-east EPPO zone.

The data from the trials proves that the minimum effective dose rate of Iron phosphate 1.0% GB to control slugs and snails in winter barley is 50.0 Kg/ha, with up to four applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Table 3.2.2-15 Minimum effective dose of Iron phosphate 1.0% GB – North-east zone

Table 3.2.2-13 Minimum effective dose of Iron phosphate 1.0 % GB – North-east zone									
Target: DEROAG		No. of trials	Mean % Control from one in the Mediterranean EPPO Zone at a range of doses of Iron phosphate 1.0% GB						
			Untreated	25.0 Kg/ha		37.0 Kg/ha		50.0 Kg/ha	
			Mean % (range)	Mean	Range	Mean	Range	Mean	Range
Winter barley									
Mean % control, one observation on PLANT per trial, COUPLA at 5 DAT		1	15.3	42.2	-	16.3	-	44.4	-
Mean % control, one observation on LEAF per trial, DAMMOL at 5 DAT		1	36.3	78.5	-	42.0	-	78.5	-

Summary and conclusions on the minimum effective dose

In summary, reducing the application rate of Iron phosphate 1.0% GB from the proposed dose rate resulted in decreased efficacy against the pest of slugs and snails.

According to the presented results, the dose rate of 50.0 kg/ha per application, for control of slugs and snails in fruit crops, vegetable crops, field crops, grapevine, ornamentals and hop provided the optimal overall control and should be considered as effective against the pests, for which activity of Iron phosphate 1.0% GB is claimed. As pests often occur throughout a season, up to four applications per season of Iron phosphate 1.0% GB at the proposed rate should be used to efficiently control all pathogens claimed on the label.

Trials were conducted in strawberry, lettuce, winter wheat, potato, apple, spring barley, oilseed rape and winter barley. All these crops represent high row crops that are attacked in the autumn by slugs and snails, low to medium high row crop which are planted throughout the season (from spring to autumn). Other crops are attacked by slugs and snails throughout the season. Other crops are dense row crops which, are primarily fed on by snails and slugs in the autumn. In regard to feeding behavior of snails and slugs in the different crops, no difference is expected in the feeding behavior of snails and slugs in all crops tested compared to their feeding behavior in other crops. It is also expected that the attractiveness of the bait is the same in the different crops. With the crops chosen for the trials, molluscs are tried in different crop types (high, low or dense row crops) at different periods throughout the season, i.e. Spring, Summer and Autumn. As the results obtained in the trials showed, excellent control was obtained in any crop tested, at any application timing (whether in the spring, in the summer or in the autumn) and it is therefore expected that the crop chosen for the trials is of less importance. In conclusion, iron phosphate is applied in the same manner, in all crops, as a bait to attract the molluscs present in the crop, and as efficacy is consistently the same in the different crops, independently of the time of the year at which it is applied and of the crop tested, it can be concluded that the crop used for field trials is of lesser importance and results for all crops could be grouped as equivalent use.

This document clearly demonstrates – as will be demonstrated in the following sections – that the efficacy and crop safety of Iron phosphate 1.0% GB is equivalent to the standard Iron phosphate containing products to which it was compared. The applicant therefore wishes to cite the data on Iron phosphate now out of protection in additional support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal and national evaluators extrapolate from those data.

In conclusion, Iron phosphate is applied in the same manner, in all crops, as a bait to attract the molluscs present in the crop, and as efficacy has been consistently the same in the different crops, independently of the time of the year at which it is applied and of the crop tested even some of the crops tested represented a more challenging situation, it can be concluded that presented studies are sufficient to support uses present in GAP table and the applicant would therefore like to consider that the requirement is fulfilled.

Comments of zRMS:	<p>To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2).</p> <p>During field tests Applicant used different doses (25 kg/ha – 0,5N; 37,5 kg/ha – 0,75 N and 50 kg/ha – N) of molluscicide – HIERRO (product code: SHA 105000 B) containing iron phosphate (10.0 g/kg). So, in the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2).</p> <p>In total, Applicant submitted 60 trials 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). Trials were carried out in MED (strawberry, lettuce, winter wheat, potato, apple, spring barley), N-E EPPO zone (winter barley, winter oilseed rape, potato, strawberry), Maritime (strawberry, winter wheat, potato, apple, winter oilseed rape). Lack of trials for S-E EPPO zone.</p> <p>The data from submitted trials proves the minimum effective dose rate of HIERRO to control slugs and snails in strawberry, lettuce, winter wheat, potato, apple, spring barley, winter oilseed rape and winter barley is 50 kg/ha. As pests often occur throughout a season, up to four applications per season of Iron phosphate 1.0% GB at the proposed rate should be used to efficiently control all pathogens claimed on the label.</p> <p>Concerned Member States should consider the current authorization of a reference product (a.s. iron phosphate) in their own Member State when they are setting a minimum effective dose.</p>
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3.2.3 Efficacy tests (KCP 6.2)

Data from 60 efficacy trials conducted the Maritime EPPO zone (17; i.e. Germany (4), United Kingdom (7), Czech Republic (6)), in the Mediterranean EPPO zone (26, i.e. Italy (5), Greece (10), Spain (10) and France (1)) and the North-east EPPO zone (17; i.e. Poland) have been included in this biological assessment dossier to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone.

The results are presented separated by crops to have a better overview of the effectiveness of the product. As Iron phosphate 1.0% GB is a molluscicide and his efficacy is independent of the crop, the results could be presented grouped. The product's mode of action produces an attraction of the slugs and snails, for that reason the efficacy is indepent of the kinf of crop where the product is applied.

The 60 efficacy trials were conducted in strawberry (9), lettuce (5), winter wheat (13), potato (11), apple (8), spring barley (2), oilseed rape (11) and winter barley (1).

Additionally, it's important to remark that the effectiveness of pellet bait is dependent on it being sufficiently palatable in comparison with the treated crops for it to be consumed in lethal quantities.

In conclusion, iron phosphate is applied in the same manner, in all crops, as a bait to attract the molluscs present in the crop, and as efficacy has been consistently the same in the different crops, independently of the time of the year at which it is applied and of the crop tested even some of the crops tested represented a more challenging situation, it can be concluded that presented studies are sufficient to support uses present in GAP table and the applicant would therefore like to consider that the requirement is fulfilled.

Table 3.2-8: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (3), PP 1/181 (3), PP 1/135(3), PP 1/225 (2)
	Specific guidelines	EPPO PP 1/95 (4), PP 1/96 (3)
Experimental design	Plot design	RCBD (60)
	Plot size	0.03-9 m ²
	Number of replications	4 (60)
Crop	Trials per crop	Strawberry (9), Lettuce (5), Winter wheat (13), Potato (11), Apple (8), Spring barley (2), Oilseed rape (11) and Winter barley (1)
	Varieties per crop	Strawberry: Candonga, Kamaroza (2), Primoris, Fortuna, Florence, Sonata, Honeoye, Matis Lettuce: Canasta, Manchester, romana, Mariola (2) Winter wheat: Marcaurelio, Simeto (2), HYWIN, Evolution, Gallant, Rumor, Bardot, Sailor, Trapero, Memory, KWS Ozon, Kilimanjaro. Potato: Bisestile, Spunta (3), Quenebec, Kerrs Pink, Maris piper, Innovator, Satina, Vineta, Tajfun Apple: Red delicious, Gala backaeye, Granny smith, Starking, Uriarte, Elstar, golden delicious (2) Spring barley: Graphic, Quick Oilseed rape: Avatar, Ovace, Sherpa, Aтора, Exquisite, Chrobry, Mercedes, Saveo, SY Iowa. Winter barley: Wootan
	Sowing period	Strawberry: 4/09/14 to 28/10/16 Lettuce: 30/09/16 to 21/10/16 Winter wheat: 06/10/15 to 01/10/18 Potato: 21/03/16 to 16/05/17 Apple: 20 years to Feb. 2013 Spring barley: 01/05/16 Oilseed rape: 02/05/16 to 19/10/18 Winter barley: 26/09/16
Application	Application period	Strawberry: 23/05/16 – 30/08/17 Lettuce: 19/10/16 – 14/11/16 Winter wheat: 09/05/16 – 15/10/18 Potato: 06/05/16 – 22/08/17 Apple: 19/05/16 – 18/11/16 Spring barley: 23/05/16 – 01/07/16 Oilseed rape: 20/05/16 – 30/10/18 Winter barley: 08/10/16

	Crop stage (BBCH)* at application	Strawberry: BBCH 18-91 Lettuce: BBCH 19-42 Winter wheat: BBCH 03-77 Potato: BBCH 16-83 Apple: BBCH 67-91 Spring barley: BBCH 12-30 Oilseed rape: BBCH 01-18 Winter barley: BBCH 13
	Number of appl. Intervals between appl.	1 (55), 2 (3), 3 (1), 4 (1) 14-28
	Spray volumes	n.a.
Assessment	Assessment types	- Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate, this overall score was substituted or supplemented by assessments of individual symptoms.
	Assessment dates	As a rule 3 crop injury ratings
Other relevant information	Soil type	Volcanic soil, sand, clay loam, sandy silt loam, sandy loam, loam, silt clay, silt loam, clay sandy loam
	Organic matter content	1.4-4.1
	Natural / artificial inoculation...	Preferably disease-free conditions
	Field / Greenhouse...	Field

Reference products

In the efficacy trials with selectivity results, the performance of Iron phosphate 1.0% GB was measured against a commercially available reference products containing Iron phosphate (Ferramol, Lima Oro, Slimax Agro 3 GB, Derrex). The trials were carried out on strawberry, lettuce, winter wheat, potato, apple, spring barley, oilseed rape and winter barley.

Table 3.2-9: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Iron phosphate formulation					
Ferramol	GR	Iron phosphate 10 g/kg	25 kg/ha 50 kg/ha	Spain Greece France United Kingdom Germany Czech Republic Poland	10 10 1 7 4 6 14
Lima Oro	GB	Iron phosphate 30 g/kg	7 kg/ha	Poland	2
Slimax Agro 3 GB	GB	Iron phosphate 30 g/kg	7 kg/ha	Poland	1
Derrex	GB	Iron phosphate 29.7 g/kg	7 kg/ha	Italy	5

Control of slugs and snails in Strawberry

The efficacy trials were conducted to prove the following label claims:

Crop	Strawberry
Use rate	50 kg/ha iron phosphate 1.0% GB

Use frequency	4x
Application timing	depending on crop (see GAP table)
Target pest	Slugs and Snails

The effectiveness of applying Iron phosphate 1.0% GB against GAP claimed diseases in strawberry was evaluated in 9 trials, assessed for DAMAGE and COUNT. These trials were carried out in 2016 and 2017 in the Mediterranean EPPO zone (5; i.e. Spain (2), Greece (2) and Italy (1)) Maritime EPPO zone (2; i.e. Germany (1) and United Kingdom (1)), and the North-east EPPO zone (2; i.e. Poland). The objective was to confirm the performance of Iron phosphate 1.0% GB at the proposed dose rate of 50.0 Kg/ha (i.e. 500 g Iron phosphate per hectare). In the trials specifically targeted for this pest, one application was applied at growth stages ranging between BBCH 19 and BBCH 91.

In the trials, Iron phosphate 1.0% GB was tested alongside a locally approved Iron phosphate GB formulation.

Maritime zone

In the Maritime trials, slugs and snails was assessed at 2 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-11 therefore only contains one assessment per plant part from the Maritime trials assessed repeatedly.

Table 3.2-10: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – Maritime zone

Maritime zone									
Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifenazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean					
				50.0 Kg/ha	1 N	>	=	<	
COUNT									
MOLLUS	7 DAT	1	16.8	94.0	89.6		1		=
DAMMOL									
FRUIT	5 DAT	1	7.3	93.1	96.6		1		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

Mediterranean zone

In the Mediterranean trials, slugs and snails was assessed at 5 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-11 therefore only contains one assessment per plant part from the Mediterranean trials assessed repeatedly.

Table 3.2-11: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – Mediterranean zone

Wheat-Rainfed Zone									
Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifenazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean					
				50.0 Kg/ha	1 N	>	=	<	
COUNT									
LEAF	6-21 DAT	3	5.9 (3.8-10.0)	93.3 (80.0-100)	91.7 (75.0-100)		3		=
DAMAGE									
LEAATT	156 DAT	2	20.7 (15.0-26.3)	82.6 (81.3-83.8)	84.3 (83.3-85.2)		2		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

North-east zone

In the North-east trials, slugs and snails was assessed at 2 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-12 therefore only contains one assessment per plant part from the North-east trials assessed repeatedly.

Table 3.2-12: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – North-east zone

North east zone									
Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifenazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean					
				50.0 Kg/ha	1 N	>	=	<	
COUNT									
INSECT	14 DAT	1	5.3	100	100		1		=
DAMAGE									
LEAF	5 DAT	1	8.0	72.7	64.8		1		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

Control of slugs and snails in Lettuce

The efficacy trials were conducted to prove the following label claims:

Crop	Lettuce
Use rate	50 kg/ha iron phosphate 1.0% GB
Use frequency	4x
Application timing	depending on crop (see GAP table)
Target pest	Slugs and Snails

The effectiveness of applying Iron phosphate 1.0% GB against GAP claimed diseases in lettuce was evaluated in 5 trials, assessed for DAMAGE and COUNT. These trials were carried out in 2016 in the Mediterranean EPPO zone (5; i.e. Spain (2), Greece (2) and Italy (1)). The objective was to confirm the performance of Iron phosphate 1.0% GB at the proposed dose rate of 50.0 Kg/ha (i.e. 500 g Iron phosphate per hectare). In the trials specifically targeted for this pest, one application was applied at growth stages ranging between BBCH 19 and BBCH 42.

In the trials, Iron phosphate 1.0% GB was tested alongside a locally approved Iron phosphate GB formulation.

Mediterranean zone

In the Mediterranean trials, slugs and snails was assessed at 5 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-13 therefore only contains one assessment per plant part from the Mediterranean trials assessed repeatedly.

Table 3.2-13: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – Mediterranean zone

Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifenazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean					
				50.0 Kg/ha	1 N	>	=	<	
COUNT									
MOLLUS	6 DAT	1	10.0	85.0	72.5		1		=
DAMAGE									
LEAATT	9-13 DAT	4	14.3 (2.0-27.5)	86.8 (59.4-100)	75.8 (35.2-96.4)		4		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

Control of slugs and snails in Winter wheat

The efficacy trials were conducted to prove the following label claims:

Crop	Winter wheat
Use rate	50 kg/ha iron phosphate 1.0% GB
Use frequency	4x
Application timing	depending on crop (see GAP table)
Target pest	Slugs and Snails

The effectiveness of applying Iron phosphate 1.0% GB against GAP claimed diseases in winter wheat was evaluated in 13 trials, assessed for COUNT, DAMAGE and MORTAL. These trials were carried out in 2016 and 2017 in the Mediterranean EPPO zone (4; i.e. France (1), Greece (2) and Italy (1)), Maritime EPPO zone and (4; i.e. Czech Republic (2) and United Kingdom (2)) and North-east EPPO zone and (5; i.e. Poland (5)). The objective was to confirm the performance of Iron phosphate 1.0% GB at the proposed dose rate of 50.0 Kg/ha (i.e. 500 g Iron phosphate per hectare). In the trials specifically targeted for this pest, one or four application were applied at growth stages ranging between BBCH 03 and BBCH 77.

In the trials, Iron phosphate 1.0% GB was tested alongside a locally approved Iron phosphate GB formulation.

Maritime zone

In the Maritime trials, slugs and snails was assessed at 5 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-14 therefore only contains one assessment per plant part from the Maritime trials assessed repeatedly.

Table 3.2-14: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – Maritime zone

Maritime zone									
Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifenazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean					
				50.0 Kg/ha	1 N	>	=	<	
COUPLA									
Plant	8-37 DAT	2	12.1 (2.2-22.0)	81.8 (68.2-95.4)	76.1 (60.2-92.0)		2		=
COUNT									
MOLLUV	5-37 DAT	2	7.3 (4.5-10.0)	97.2 (94.4-100)	86.7 (83.3-90.0)		2		=
DAMAGE									
MOLLIV	5 DAT	1	30.0	98.3	99.0		1		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

Mediterranean zone

In the Mediterranean trials, slugs and snails was assessed at 4 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-15 therefore only contains one assessment per plant part from the Mediterranean trials assessed repeatedly.

Table 3.2-15: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – Mediterranean zone

Mediterranean zone									
Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifentazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean		50.0 Kg/ha	1 N	>	=
COUNT									
MOLLIV	7 DAT	1	10.0	85.0	80.0		1		=
DAMAGE									
LEAATT	10 DAT	2	17.5 (15.0-20.0)	88.6 (85.4-91.7)	96.7 (93.8-100)		2		=
MORTAL									
MOLLUS	12 DAT	1	0.0	14.0	12.0		1		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

North-east zone

In the North-east trials, slugs and snails was assessed at 5 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-156 therefore only contains one assessment per plant part from the North-east trials assessed repeatedly.

Table 3.2-16: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – North-east zone

North-east zone									
Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifentazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean					
				50.0 Kg/ha	1 N	>	=	<	
COUNT									
ADULT	3-5 DAT	5	11.8 (8.4-20.0)	95.1 (89.4-100)	97.2 (94.1-98.8)		4	1	=
DAMMOL									
PLANT	3-5 DAT	5	17.7 (10.5-39.9)	89.5 (87.0-93.7)	90.4 (88.0-93.2)		4	1	=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

Control of slugs and snails in Potato

The efficacy trials were conducted to prove the following label claims:

Crop	Potato
Use rate	50 kg/ha iron phosphate 1.0% GB
Use frequency	4x

Application timing	depending on crop (see GAP table)
Target pest	Slugs and Snails

The effectiveness of applying Iron phosphate 1.0% GB against GAP claimed diseases in potato was evaluated in 11 trials, assessed for DAMAGE, COUPLA and COUNT. These trials were carried out in 2016 and 2017 in the Mediterranean EPPO zone (5; i.e. Spain (2), Greece (2) and Italy (1)) Maritime EPPO zone (3; i.e. Germany (1) and United Kingdom (2)), and the North-east EPPO zone (3; i.e. Poland). The objective was to confirm the performance of Iron phosphate 1.0% GB at the proposed dose rate of 50.0 Kg/ha (i.e. 500 g Iron phosphate per hectare). In the trials specifically targeted for this pest, one or two application were applied at growth stages ranging between BBCH 16 and BBCH 83.

In the trials, Iron phosphate 1.0% GB was tested alongside a locally approved Iron phosphate GB formulation.

Maritime zone

In the Maritime trials, slugs and snails was assessed at 3 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-17 therefore only contains one assessment per plant part from the Maritime trials assessed repeatedly.

Table 3.2-17: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – Maritime zone

Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifenazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean	Mean				
				50.0 Kg/ha	1 N	>	=	<	
COUNT									
MOLLUS	7-17 DAT	3	7.2 (1.3-11.5)	98.3 (97.1-100)	77.1 (60.0-88.6)		3		=
COUPLA									
Plant	7 DAT	2	15.4 (10.8-20.0)	90.4 (81.4-99.4)	82.4 (72.1-98.1)		2		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

Mediterranean zone

In the Mediterranean trials, slugs and snails was assessed at 5 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-18 **Błąd! Nie można odnaleźć źródła odwołania.** therefore only contains one assessment per plant part from the Mediterranean trials assessed repeatedly.

Table 3.2-18: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – Mediterranean zone

Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifenazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean	Mean				
				50.0 Kg/ha	1 N	>	=	<	
COUNT									
MOLLIV	2-21 DAT	3	16.3 (3.8-35.0)	82.4 (71.4-93.3)	71.8 (58.6-86.7)		3		=
DAMAGE									
LEAATT	2-21 DAT	4	14.1 (4.4-21.3)	76.4 (35.0-95.8)	72.5 (16.0-95.8)		4		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

North-east zone

In the North-east trials, slugs and snails was assessed at 4 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-19 therefore only contains one assessment per plant part from the North-east trials assessed repeatedly.

Table 3.2-19: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – North-east zone

Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifentazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean	Mean				
				50.0 Kg/ha	1 N	>	=	<	
DAMAGE									
PLANT	3-8 DAT	3	18.5 (12.8-23.8)	55.5 (46.0-60.6)	53.8 (39.0-67.3)		3		=
COUNT									
PLANT	8-10 DAT	2	32.4 (29.5-35.3)	59.5 (55.0-64.0)	56.0 (53.0-59.0)		2		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

Control of slugs and snails in Apple

The efficacy trials were conducted to prove the following label claims:

Crop	Apple
Use rate	50 kg/ha iron phosphate 1.0% GB
Use frequency	4x
Application timing	depending on crop (see GAP table)
Target pest	Slugs and Snails

The effectiveness of applying Iron phosphate 1.0% GB against GAP claimed diseases in apple was evaluated in 8 trials, assessed for DAMAGE MORTAL and COUNT. These trials were carried out in 2016 in the Mediterranean EPPO zone (5; i.e. Spain (2), Greece (2) and Italy (1)) and the Maritime EPPO zone (3; i.e. Germany (1) and Czech Republic (1)). The objective was to confirm the performance of Iron phosphate 1.0% GB at the proposed dose rate of 50.0 Kg/ha (i.e. 500 g Iron phosphate per hectare). In the trials specifically targeted for this pest, one application was applied at growth stages ranging between BBCH 67 and BBCH 95.

In the trials, Iron phosphate 1.0% GB was tested alongside a locally approved Iron phosphate GB formulation.

Maritime zone

In the Maritime trials, slugs and snails was assessed at 3 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-20 therefore only contains one assessment per plant part from the Maritime trials assessed repeatedly.

Table 3.2-20: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products –

Maritime zone

Maritime zone									
Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifenazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean					
				50.0 Kg/ha	1 N	>	=	<	
COUNT									
ANIMAL	3 DAT	1	0.8	100	100		1		=
MORTAL									
ADULT	10 DAT	2	0.0	33.8 (27.5-40.0)	47.5 (42.5-52.5)		2		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

Mediterranean zone

In the Mediterranean trials, slugs and snails was assessed at 5 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-21 therefore only contains one assessment per plant part from the Mediterranean trials assessed repeatedly.

Table 3.2-21: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – Mediterranean zone

Median Rank Zone									
Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifenazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean					
				50.0 Kg/ha	1 N	>	=	<	
COUNT									
ADULIV	7-22 DAT	3	5.5 (1.5-10.0)	86.7 (80.0-100)	54.7 (16.7-75.0)		3		=
DAMAGE									
LEAATT	11 DAT	2	23.8 (22.5-25.0)	89.2 (81.7-91.7)	90.2 (89.6-90.8)		2		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

Control of slugs and snails in Spring barley

The efficacy trials were conducted to prove the following label claims:

Crop	Spring barley
Use rate	50 kg/ha iron phosphate 1.0% GB
Use frequency	4x
Application timing	depending on crop (see GAP table)
Target pest	Slugs and Snails

The effectiveness of applying Iron phosphate 1.0% GB against GAP claimed diseases in spring barley was evaluated in 2 trials, assessed for DAMAGE and COUNT. These trials were carried out in 2016 in the Mediterranean EPPO zone (2; i.e. Spain (2)). The objective was to confirm the performance of Iron phosphate 1.0% GB at the proposed dose rate of 50.0 Kg/ha (i.e. 500 g Iron phosphate per hectare). In the trials specifically targeted for this pest, one application was applied at growth stages ranging between BBCH 12 and BBCH 30.

In the trials, Iron phosphate 1.0% GB was tested alongside a locally approved Iron phosphate GB formu-

lation.

Mediterranean zone

In the Mediterranean trials, slugs and snails was assessed at 4 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-22 therefore only contains one assessment per plant part from the Mediterranean trials assessed repeatedly.

Table 3.2-22: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – Mediterranean zone

Mediteranean zone									
Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifenazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean					
				50.0 Kg/ha	1 N	>	=	<	
DAMAGE									
LEAF	14 DAT	2	2.3 (1.0-3.5)	94.3 (88.5-100)	94.2 (88.5-100)		2		=
COUNT									
PLANT	14 DAT	2	4.4 (2.3-6.5)	88.9 (77.8-100)	88.9 (77.8-100)		2		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

Control of slugs and snails in Oilseed rape

The efficacy trials were conducted to prove the following label claims:

Crop	Oilseed rape
Use rate	50 kg/ha iron phosphate 1.0% GB
Use frequency	4x
Application timing	depending on crop (see GAP table)
Target pest	Slugs and Snails

The effectiveness of applying Iron phosphate 1.0% GB against GAP claimed diseases in oilseed rape was evaluated in 6 trials, assessed for DAMAGE, COUPLA and COUNT. These trials were carried out in 2016 in the Maritime EPPO zone (5; i.e. Germany (1), Czech Republic (2) and United Kingdom (2)), and the North-east EPPO zone (1; i.e. Poland). The objective was to confirm the performance of Iron phosphate 1.0% GB at the proposed dose rate of 50.0 Kg/ha (i.e. 500 g Iron phosphate per hectare). In the trials specifically targeted for this pest, one to three applications were applied at growth stages ranging between BBCH 01 and BBCH 18.

In the trials, Iron phosphate 1.0% GB was tested alongside a locally approved Iron phosphate GB formulation.

Maritime zone

In the Maritime trials, slugs and snails was assessed at 5 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-23 therefore only contains one assessment per plant part from the Maritime trials assessed repeatedly.

Table 3.2-23: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products –

Maritime zone

Maritime zone									
Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifenazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean					
				50.0 Kg/ha	1 N	>	=	<	
COUNT									
MOLLUS	8-16 DAT	3	4.9 (1.3-10.0)	97.4 (92.3-100)	100 (100-100)		3		=
DAMAGE									
MOLLIV	7-14 DAT	2	6.0 (3.5-8.5)	90.2 (80.3-100)	84.7 (69.4-100)		2		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

North-east zone

In the North-east trials, slugs and snails was assessed at 6 trials, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-24 therefore only contains one assessment per plant part from the North-east trials assessed repeatedly.

Table 3.2-24: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – North-east zone

Part assessed Days after Treatment. (DAT) No. of trials			Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifenazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean					
				50.0 Kg/ha	1 N	>	=	<	
COUPLA									
Plant	14 DAT	1	8.3	43.0	34.2		1		=
COUNT									
Adult	5-10 DAT	5	16.9 (9.9-20.0)	98.2 (96.3-99.3)	96.7 (93.9-99.3)		2	3	=, <
DAMMOL									
Plant	3-10 DAT	5	19.8 (4.9-35.0)	90.2 (82.7-100)	91.7 (85.7-97.0)		2	3	=, <

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

Control of slugs and snails in Winter barley

The efficacy trials were conducted to prove the following label claims:

Crop	Winter barley
Use rate	50 kg/ha iron phosphate 1.0% GB
Use frequency	4x
Application timing	depending on crop (see GAP table)
Target pest	Slugs and Snails

The effectiveness of applying Iron phosphate 1.0% GB against GAP claimed diseases in winter barley was evaluated in 1 trials, assessed for COUPLA and DAMMOL. These trials were carried out in 2017 in the North-east EPPO zone (1; i.e. Poland). The objective was to confirm the performance of Iron phosphate 1.0% GB at the proposed dose rate of 50.0 Kg/ha (i.e. 500 g Iron phosphate per hectare). In the

trials specifically targeted for this pest, one application was applied at growth stages ranging between BBCH 13.

In the trials, Iron phosphate 1.0% GB was tested alongside a locally approved Iron phosphate GB formulation.

North-east zone

In the North-east trials, slugs and snails was assessed at 1 assessments, which were considered valid. In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-25 therefore only contains one assessment per plant part from the North-east trials assessed repeatedly.

Table 3.2-25: Efficacy of Iron phosphate 1.0% GB in comparison to standard registered products – North-east zone

North-east zone									
Part assessed	Days after Treatment. (DAT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Iron phosphate 1.0% GB is >, < or =, compared to the bifenazate reference product = : ± 5% control			Overall
				Iron phosphate 1.0% GB at:	Iron phosphate ref. prod. at				
				Mean					
				50.0 Kg/ha	1 N	>	=	<	
COUPLA									
PLANT	5 DAT	1	17.8	44.4	33.2		1		=
DAMMOL									
LEAF	5 DAT	1	36.3	78.5	67.0		1		=

The individual trial results show that Iron phosphate 1.0% GB gave good control of slugs and snails, as good as the achieved by the Iron phosphate formulated reference product.

Summary and conclusion

As the data obtained from trials conducted in strawberry, lettuce, winter wheat, potato, apple, spring barley, oilseed rape and winter barley studies show, the level of control of slugs and snails from Iron phosphate 1.0% GB is equivalent to that of the Iron phosphate reference product used in the trials.

The studies conducted in 2016, 2017, 2018 and 2019 presented in this dossier were used to register Iron phosphate 1.0% GB in central zone and now are registered in various countries (Lima Oro, Ferramol, Slimax Agro 3 GB, Derrex). These products can be used as supportive standards since now are registered in central zone countries.

Trials were conducted in strawberry, lettuce, winter wheat, potato, apple, spring barley, oilseed rape and winter barley. All these crops represent high row crops that are attacked in the autumn by slugs and snails, low to medium high row crop which are planted throughout the season (from spring to autumn). Other crops are attacked by slugs and snails throughout the season. Other crops are dense row crops which, are primarily fed on by snails and slugs in the autumn. In regard to feeding behaviour of snails and slugs in the different crops, no difference is expected in the feeding behaviour of snails and slugs in all crops tested compared to their feeding behaviour in other crops.

According EPPO PP 1/95(4) SLUGS, APPENDIX 1 extrapolation of evidence of control between crops and situations for mellet molluscicide products, Oilseed rape, wheat and potato and key crops for field crops and lettuce, strawberry and key crops for horticultural field leafy and fruit crops. According Appendix 1 extrapolation is permitted to all field crops and horticultural leafy vegetables and fruit crops.

It is also expected that the attractiveness of the bait is the same in the different crops. With the crops chosen for the trials, molluscs are tried in different crop types (high, low or dense row crops) at different periods throughout the season, i.e. Spring, Summer and Autumn. As the results obtained in the trials showed, excellent control was obtained in any crop tested, at any application timing (whether in the spring, in the summer or in the autumn) and it is therefore expected that the crop chosen for the trials is of

less importance. In conclusion, iron phosphate is applied in the same manner, in all crops, as a bait to attract the molluscs present in the crop, and as efficacy is consistently the same in the different crops, independently of the time of the year at which it is applied and of the crop tested, it can be concluded that the crop used for field trials is of lesser importance and results for all crops could be grouped as equivalent use.

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.

The standard products, which contain the same active ingredients have been registered for many years in Central Europe countries for the control of slugs and snails, and have demonstrated a good control of the pests claimed in the GAP table.

Therefore, we believe that presented studies are sufficient to demonstrate the similarity between our product and standards.

Applicant would like to refer to the EPPO standard PP 1/226(3) where is indicated that full number of trials in different years is required “particularly for plant protection products or active substances which not have been on the market in the EPPO region in which authorization is sought”. It is important to remark that the EPPO standard is referring to the region where registration is sought and not to a specific country, thus applicant considers that presence of standards has to be evaluated taking into account the registers in the whole Central Zone. The same EPPO PP 1/226(3) indicates that reduced number of trials can be presented “where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance on closely related pests or against the same pests on different crops”. Iron phosphate formulations have been registered in Central Zone and in countries where trials were conducted for various years like Ferramol GR (reg nr R-4/2014) registered in Poland in 2014, Ferramol (reg nr 4406-3) registered in the Czech Republic in 2015, Ferramol Scheneckenkorn (reg nr 034496-00) registered in Germany since 2018. According to this, formulation has been widely proved in Central Zone where registration is sought, thus applicant considers that number of trials are enough to register formulation.

Trials were conducted in oilseed rape, cereals, potato, strawberry, lettuce (only Mediterranean) and apple. According Appendix 1 to EPPO PP 1/95(4) Slugs, for request on authorised use in All situations (both edible and non edible) may be supported by substantial data package following key representative crops and slug species. These key representative crops are oilseed rape, cereals, potato, lettuce, strawberry and ornamentals. Applicant has presented a total of 60 trials conducted on all key crops with exception of ornamentals to demonstrate efficacy of all groups of crops. According Appendix 1 to EPPO PP 1/95(4) group of trials on key crops can be presented to demonstrate efficacy of the product and applicant can request uses on all situations (edible and non edible crops).

In regard to feeding behaviour of snails and slugs in the different crops, no difference was observed for all crops tested. It is also expected that the attractiveness of the bait is the same in the different crops. With the crops chosen for the trials, molluscs are tried in different crop types (high, low or dense row crops) at different periods throughout the season, i.e. Spring, Summer and Autumn. As the results obtained in the trials showed, excellent control was obtained in any crop tested, at any application timing (whether in the spring, in the summer or in the autumn) and it is therefore expected that the crop chosen for the trials is of less importance. In conclusion, iron phosphate is applied in the same manner, in all crops, as a bait to attract the molluscs present in the crop, and as efficacy is consistently the same in the different crops, independently of the time of the year at which it is applied and of the crop tested, it can be concluded that the crop used for field trials is of lesser importance and the applicant would therefore like to consider that the requirement is fulfilled.

Comments of zRMS:	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, Appli-
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	<p>cant 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.</p> <p>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.</p> <p>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.</p> <p><u>In the opinion of Evaluator, enough trials were presented against:</u></p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p>According to EPPO 1/95 (3) following organisms can be distinguished and studied in trials: (1) omnivorous species, e.g. (<i>Deroceras reticulatum</i>) (DERORE), (<i>Deroceras agreste</i>) (DEROAG), <i>Deroceras sturanyi</i> (DEROST), <i>Limax maximus</i> (LIMXMA), (<i>Arion rufus</i>) (ARIORU), <i>Arion lusitanicus</i> (ARIOLU); (2) species feeding on fresh leaves, dead leaves dead leaves and fungi, e.g. <i>Arion distinctus</i> (ARIODI), <i>Arion sylvaticus</i> (ARIOSY), <i>Arion fasciatus</i> (ARIOFA), <i>Arion hortensis</i> (ARIOHO), (<i>Deroceras laeve</i>) (DEROLA), (<i>Tandonia rustica</i>) (MILXRU), <i>Arion circumscriptus</i> (ARIOCI); (3) root feeding species, e.g. <i>Limax flavus</i> (LIMXFL), <i>Tandonia budapestensis</i> (MILXBU), <i>Milax gagates</i> (MILXGA). Crop: any variety of any of the following plants vegetable, strawberry (FRAAN) or ornamental plant 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.</p> <p>According to EPPO 1/96 (3) following pest can be studied: field anthill (<i>Deroceras</i> (<i>Deroceras agreste</i>) (DEROAG), spotted seatroot (<i>Deroceras reticulatum</i>) (DERORE), <i>Deroceras sturanyi</i> (DEROST), <i>Arion distinctus</i> (ARIODI), <i>Arion</i></p>
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<p><i>hortensis</i> (ARIOHO), <i>Arion rufus</i> (ARIORU), <i>Arion lusitanicus</i> (ARIOLU), <i>Arion sylvaticus</i> (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.</p> <p><u>During efficacy studies following pest species were studied:</u></p> <ul style="list-style-type: none"> • 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) <p>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.</p> <p>Only slugs were assessed. Extrapolation to snails seems acceptable.</p> <p>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.</p> <p>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.....</p>			
Crop	Species	Permissible Author-ised Uses	Multi-crop data packages
Field Crops (including combinable crops*, root/tuber but not leafy vegetable crops)			
Oilseed rape BRSNN	<i>Deroceras reticulatum</i> DERORE and <i>Arion vulgaris</i> ARIOVU. Plus	All oilseed crops and field crops (except cereals and	Oilseed rape and wheat†

		some data on other common <i>Deroceras</i> DERO SP, <i>Arion</i> ARI-OSP species	potato) All cereal crops		
	Wheat TRZAX				
	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 combin crops, sugar beet, other root/tuber f
Horticultural Field Leafy Crops, Horticultural Protected Crops (including Brassica vegetables), Ornamentals‡					
	Lettuce LACSA or Chinese cabbage BRSPK; and Brussels sprouts BRSPF or kale BRSPA. Plus one other crop type, from cauliflower BRSPB or broccoli BRSPC or head cabbage BRSPD	<i>D. reticulatum</i> DERO-RE and <i>A. vulgaris</i> ARIOVU. Plus some data on other common <i>Deroceras</i> DERO SP, <i>Arion</i> ARIOSP, <i>Limax</i> species LIMXSP	All leafy vegetables	Lettuce or Chinese cabbage and Strawberry	All leafy 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 fruit, ornam
<p>*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.</p> <p>†Oilseed rape, should have a comprehensive data set which forms the greater proportion of the data package.</p> <p>‡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 Mol-luscicide field small plot cage (barriered) trials for further details.</p> <p>§Full details on use of semi-field barriered small plot trials are given in PP 1/289.</p> <p>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 EP-PO confirm, 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.</p> <p>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.</p> <p>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</p>					

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. **In PL pulses can be accepted only in line to Article 51.** Each cMS should decide about acceptable species in label. ~~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 equiv-

	alent dose rate.
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3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

The following dossier section follows EPPO standard PP 1/213(3) *Resistance risk analysis* in particular point 6. *Registration requirements* of the standard.

Introduction

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.

3.3.1 Active ingredient

Iron phosphate is a stomach poison in slugs and snails. It damages their digestive tissue. With enough exposure, they stop eating altogether and slowly die. The exact mode of action is not clearly understood.

Iron phosphate is an iron salt of phosphoric acid. It is a key component of mollusc control strategies throughout Europe due to their persistent broad-spectrum control. The risk of mollusc resistance is considered low.

3.3.2 Mechanism of resistance

Resistance is known in various mollusc species. To date, no reports have been published where Iron phosphate resistance has been observed.

Even though resistance appears not to be a problem in the EU, it is of course not a guarantee that it does not exist somewhere in Europe and caution should be taken when using Sharda Iron phosphate formulations in the recommended crops at the recommended dose rates.

3.3.3 Evidence of resistance

There are no evidence of Iron phosphate resistance in molluscs.

3.3.4 Cross-resistance

No cross-resistance has been reported between other active ingredient (iron phosphate) with activity against molluscs.

3.3.5 Sensitivity data

Slugs and snails vary in their sensitivity towards molluscicides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. Iron phosphate has been tested and used worldwide for more than 30 years and it is therefore difficult to find unexposed mollusc populations. No true base line sensitivity data can therefore be established.

3.3.6 Use pattern

In the EU Central zone, iron phosphate is proposed for use against slugs and snails in a range of crops, all listed in the GAP table in Appendix 2. The baits are consistently applied at 50 kilograms product per hectare (kg/ha), with one to 4 applications per season in Iron phosphate 1.0% GB, depending on the concentration of applied product and corresponding to a maximum of 500 g ai/ha.

3.3.7 Resistance Risk Assessment of Unrestricted Use pattern

Agronomic practice

In terms of agronomic practice the selection pressure on the intended targets for Sharda Iron phosphate formulations is higher in some crops compared to others. This can be due to the prevalence of continuous cropping in e.g. fruit orchards or short rotation intervals between successive cereal crops. In contrast, other crops tend to be grown on a longer rotation cycle.

The plant protection product

For optimum molluscs control, Iron phosphate is applied at the rates recommended on the proposed label. These have been shown to be the minimum effective dose for the major target slugs and snails (Section 6.1.2).

Unrestricted Use pattern

In the absence of any potential resistance risk and in the absence of any other restrictions on the GAP (residues, toxicology etc.) the unrestricted use pattern for Iron phosphate would be season long usage with an unrestricted number of applications.

Resistance risk assessment of unrestricted use pattern

Overall it is clear that the unrestricted use of Iron phosphate presents an unacceptable resistance risk and therefore modifiers as part of a Management Strategy are proposed.

3.3.8 Test methods

There are several monitoring methods approved.

3.3.9 Acceptability of the Resistance risk

Without any precautions the resistance risk is unacceptable. However, taking the right precautions and following Good Agricultural Practise, the risk is acceptable. Should resistant populations arise, control could be achieved through use of alternative products.

3.3.10 Management Strategy

As the unmodified use pattern is considered unacceptable, a number of modifiers are proposed which are entirely in accordance with the general recommendations.

- Use in alternation with fungicides with a different mode of action
- Use as recommended on the label. Do not use reduced doses.
- Application should be as a protective application.
- Use other measures such as resistant varieties, good agronomic practice

3.3.11 Implementation of the management strategy

Information on the management of resistance and the specific Resistance Management Strategy for Iron phosphate 1.0% GB is disseminated by a number of routes including, but not exclusively:

- Product label has a clear statement regarding resistance risk and the management strategy
- Pack inserts- for general information or to address a particular issue in a specific geographical area where it to occur.
- Leaflets available at, and distributed by distributors/wholesalers/merchants
- Information released by national and local advisory services re. monitoring
- Training for distributors/wholesalers/merchants and farmer groups
- Links from company web sites to local Resistance working groups for information and advice

3.3.12 Monitoring, reporting and reaction to changes in performance

Monitoring of field performance

Where field performance is significantly less than expected (relative to field trial results presented in section 6.1.3) and where no other explanation can be found for the reduced performance e.g. application errors, then samples may be taken for sensitivity testing. Where testing is carried out it will be conducted at laboratories experienced in carrying out such testing and using methods recommended by the authorities.

Analysis of performance-related complaints

Where no other reason for a failure in performance can be identified, samples may be taken for testing as described above.

Where resistance is confirmed as the cause for loss of field performance this will be reported to the authorities on an annual basis or as required.

Containment plan

The above recommendations will be adjusted as needed depending on the success of the proposed strategy. In the event that practical field resistance should occur on any significant scale, Sharda's plan for containing the further development or spread of resistance includes a number of possible actions on a temporary or permanent basis, including but not exclusively:

- Recommendations to use only fungicides from alternative mode of action groups for the remainder of the growing season
- Reduction in number of applications
- Recommendation to use only in a programme e.g. before or after an application of a fungicide from a different mode of action group.

Normally any action taken would be in consultation with the relevant authorities.

Comments of zRMS:	<p>An EPPO confirm analysis of the resistance risk was carried out. Evaluator accepted strategy against resistance developing.</p> <p>Resistance is known in various mollusc species. To date, no reports have been published where Iron phosphate resistance has been observed.</p> <p>Even though resistance appears not to be a problem in the EU, it is of course not a guarantee that it does not exist somewhere in Europe and caution should be taken when using Sharda Iron phosphate formulations in the recommended crops at the recommended dose rates.</p> <p>Nevertheless, the risk of this product to accelerate the development of resistant slug or snail populations is considered low. The proposed resistance risk management strategy is acceptable. Final assessment of the resistance risk has to be carried out on member state level since the agronomic factors influencing the risk of resistance development tend to vary between the Member States.</p>
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3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

3.4.1.1 Materials and methods

Reference products

In the efficacy trials with selectivity results, the performance of Iron phosphate 1.0% GB was measured against a commercially available reference products containing Iron phosphate (Ferramol, Lima Oro, Slimax Agro 3 GB, Derrex). The trials were carried out on strawberry, lettuce, winter wheat, potato, apple, spring barley, oilseed rape and winter barley.

Table 3.4-1: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Iron phosphate formulation					

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Ferramol	GR	Iron phosphate 10 g/kg	25 kg/ha 50 kg/ha 100 kg/ha	Spain	10
				Greece	10
				France	1
				United Kingdom	7
				Germany	4
				Czech Republic	4
				Poland	25
Lima Oro	GB	Iron phosphate 30 g/kg	7 kg/ha	Poland	2
Slimax Agro 3 GB	GB	Iron phosphate 30 g/kg	7 kg/ha	Poland	1
Derrex	GB	Iron phosphate 29.7 g/kg	7 kg/ha	Italy	5

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.

3.4.1.2 Strawberry

Crop phytotoxicity was evaluated in efficacy trials where Iron phosphate 1.0% GB was applied at one or two applications at the rate of 50.0 Kg/ha in strawberry. The 50.0 Kg/ha dose rate corresponds to 100% of the max. proposed dose rate in Central EU countries. Crop phytotoxicity was assessed in all trials at various intervals from first application and up to termination of the trial.

Phytotoxicity in strawberry trials, Maritime EPPO zone

A total of 2 efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in strawberry. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 2 efficacy trials treated with Iron phosphate 1.0% GB in the Maritime EPPO zone.

Phytotoxicity in strawberry trials, Mediterranean EPPO zone

A total of 5 efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in strawberry. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 5 efficacy trials treated with Iron phosphate 1.0% GB in the Mediterranean EPPO zone.

Phytotoxicity in strawberry trials, North-east EPPO zone

A total of 2 efficacy and 3 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in strawberry. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 2 efficacy and 3 selectivity trials treated with Iron phosphate 1.0% GB in the North-east EPPO zone.

3.4.1.3 Lettuce

Crop phytotoxicity was evaluated in efficacy trials where Iron phosphate 1.0% GB was applied at one applications at the rate of 50.0 Kg/ha in lettuce. The 50.0 Kg/ha dose rate corresponds to 100% of the max. proposed dose rate in Central EU countries. Crop phytotoxicity was assessed in all trials at various intervals from first application and up to termination of the trial.

Phytotoxicity in winter wheat trials, Mediterranean EPPO zone

A total of 5 efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in lettuce. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 5 efficacy trials treated with Iron phosphate 1.0% GB in the Mediterranean EPPO zone.

3.4.1.4 Winter wheat

Crop phytotoxicity was evaluated in efficacy trials where Iron phosphate 1.0% GB was applied at one or four applications at the rate of 50.0 Kg/ha in winter wheat. The 50.0 Kg/ha dose rate corresponds to 100% of the max. proposed dose rate in Central EU countries. Crop phytotoxicity was assessed in all trials at various intervals from first application and up to termination of the trial.

Phytotoxicity in winter wheat trials, Maritime EPPO zone

A total of 4 efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in winter wheat. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 4 efficacy trials treated with Iron phosphate 1.0% GB in the Maritime EPPO zone.

Phytotoxicity in winter wheat trials, Mediterranean EPPO zone

A total of 4 efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in winter wheat. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 4 efficacy trials treated with Iron phosphate 1.0% GB in the Mediterranean EPPO zone.

Phytotoxicity in winter wheat trials, North-east EPPO zone

A total of 5 efficacy and 4 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in winter wheat. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 5 efficacy and 4 selectivity trials treated with Iron phosphate 1.0% GB in the North-east EPPO zone.

3.4.1.5 Potato

Crop phytotoxicity was evaluated in efficacy trials where Iron phosphate 1.0% GB was applied at one or two applications at the rate of 50.0 Kg/ha in potato. The 50.0 Kg/ha dose rate corresponds to 100% of the max. proposed dose rate in Central EU countries. Crop phytotoxicity was assessed in all trials at various intervals from first application and up to termination of the trial.

Phytotoxicity in potato trials, Maritime EPPO zone

A total of 3 efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in potato. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 3 efficacy trials treated with Iron phosphate 1.0% GB in the Maritime EPPO zone.

Phytotoxicity in potato trials, Mediterranean EPPO zone

A total of 5 efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in potato. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 5 efficacy trials treated with Iron phosphate 1.0% GB in the Mediterranean EPPO zone.

Phytotoxicity in potato trials, North-east EPPO zone

A total of 3 efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in potato. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 3 efficacy trials treated with Iron phosphate 1.0% GB in the North-east EPPO zone.

3.4.1.6 Apple

Crop phytotoxicity was evaluated in efficacy trials where Iron phosphate 1.0% GB was applied at one applications at the rate of 50.0 Kg/ha in apple. The 50.0 Kg/ha dose rate corresponds to 100% of the max. proposed dose rate in Central EU countries. Crop phytotoxicity was assessed in all trials at various intervals from first application and up to termination of the trial.

Phytotoxicity in apple trials, Maritime EPPO zone

A total of 3 efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in apple. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 3 efficacy trials treated with Iron phosphate 1.0% GB in the Maritime EPPO zone.

Phytotoxicity in apple trials, Mediterranean EPPO zone

A total of 5 efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in apple. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 5 efficacy trials treated with Iron phosphate 1.0% GB in the Mediterranean EPPO zone.

3.4.1.7 Spring barley

Crop phytotoxicity was evaluated in efficacy trials where Iron phosphate 1.0% GB was applied at one applications at the rate of 50.0 Kg/ha in spring barley. The 50.0 Kg/ha dose rate corresponds to 100% of the max. proposed dose rate in Central EU countries. Crop phytotoxicity was assessed in all trials at various intervals from first application and up to termination of the trial.

Phytotoxicity in spring barley trials, Mediterranean EPPO zone

A total of 2 efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in spring barley. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 2 efficacy trials treated with Iron phosphate 1.0% GB in the Mediterranean EPPO zone.

3.4.1.8 Oilseed rape

Crop phytotoxicity was evaluated in efficacy trials where Iron phosphate 1.0% GB was applied at one to two applications at the rate of 50.0 Kg/ha in oilseed rape. The 50.0 Kg/ha dose rate corresponds to 100% of the max. proposed dose rate in Central EU countries. Crop phytotoxicity was assessed in all trials at various intervals from first application and up to termination of the trial.

Phytotoxicity in oilseed rape trials, Maritime EPPO zone

A total of 5 efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in oilseed rape. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 5 efficacy trials treated with Iron phosphate 1.0% GB in the Maritime EPPO zone.

Phytotoxicity in oilseed rape trials, North-east EPPO zone

A total of 6 efficacy and 4 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in oilseed rape. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 6 efficacy and 4 selectivity trials treated with Iron phosphate 1.0% GB in the North-east EPPO zone.

3.4.1.9 Winter barley

Crop phytotoxicity was evaluated in efficacy trials where Iron phosphate 1.0% GB was applied at one applications at the rate of 50.0 Kg/ha in winter barley. The 50.0 Kg/ha dose rate corresponds to 100% of the max. proposed dose rate in Central EU countries. Crop phytotoxicity was assessed in all trials at various intervals from first application and up to termination of the trial.

Phytotoxicity in winter barley trials, North-east EPPO zone

A total of 5 efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Iron phosphate 1.0% GB when applied as recommended in winter barley. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 5 efficacy trials treated with Iron phosphate 1.0% GB in the North-east EPPO zone.

3.4.1.10 Overall conclusion

Fruit crops, vegetable crops, field crops, grapevine, ornamentals and hop claimed on the label. The claims of crop safety on fruit crops, vegetable crops, field crops, grapevine, ornamentals and hop are supported with a total of 69 strawberry, lettuce, winter wheat, potato, apple, spring barley, oilseed rape and winter barley trials in Germany, United Kingdom, Czech Republic, Greece, Spain, France and Poland trials in 2016, 2017, 2018 and 2019. In all trials, Iron phosphate 1.0% GB applied at the proposed label recommended rates proved to be crop safe and did not significantly affect the crop adversely when applied at a range of growth stages within and occasionally beyond the label recommended range.

As the data on strawberry, lettuce, winter wheat, potato, apple, spring barley, oilseed rape and winter barley show, the crop safety and efficacy of Iron phosphate 1.0% GB is equivalent to that of the Iron phosphate formulated reference products tested in the trials. As comparability between the formulations has been demonstrated, the applicant therefore wishes to cite the original registrant's data on Iron phosphate now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Table 3.4-2: Phytotoxicity (of product)

Number of trials with...		Efficacy trials (58 trials)		Selectivity trials (11 trials)	
		Test product	Standard	Test product	Standard
		50.0 Kg/ha	1N	100.0 Kg/ha	2N
Maximum of phytotoxicity recorded during the trials	0% to 5%	58	58	11	11
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	58	58	11	11
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

Comments of zRMS:	The applicant's conclusion on crop safety can be agreed: HIERRO (SHA 105000 B) applied at the recommended dose rate was perfectly safe in the assessed crops (FRASS, SOLTU, MABSD, BRNSW, TRZAW, HORVS, LACSA, HORVW) and did not cause phytotoxicity in any of the trials. Safety of the product was assessed during 60 efficacy trials and 11 selectivity trials. However, selectivity trials were carried out only in N-E EPPO zone in Poland. During those trials (strawberry-3 trials, winter oilseed rape – 4 trials, winter wheat – 4 trials) dose N (50 kg/ha and 2 N – 100 kg/ha) was studied. No negative effect was observed during trials. All results were comparable to standard reference products used during trials.
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3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

No studies of yield 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 phosphite 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.

Comments of zRMS:	The applicant's conclusion on crop safety can be agreed. The control of insects feeding from leaves, seeds and other plant parts is expected to positively impact the harvested mass of treated crops. So, no negative influence of the product HIERRO (SHA 105000 B) on the yield of treated plants or plant product is to be expected when applied at the proposed label rate. Also, 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.
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3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

No studies of 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 phosphosphate 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.

Comments of zRMS:	No assessments of yield quality data are available. The control of insects feeding from leaves, seeds and other plant parts is expected to positively impact the quality of plants and plant products. The zRMS considers that the adverse effects on the quality of plants or plant products are low when HIERRO (SHA 105000 B) is applied at the proposed label rate and used according to the label recommendations. Also, 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.
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3.4.4 Effects on transformation processes (KCP 6.4.4)

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 quantification) 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.

Comments of zRMS:	The applicant demonstrated that residues are undetectable (Part B Section 4). It is not expected that HIERRO (SHA 105000 B) at the proposed label rate will have adverse effects on transformation processes.
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3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

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 greenhouses.

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.

Comments of zRMS:	Applicant's statement can be agreed. A detailed evaluation of the adverse effect on parts of plants used for propagating purposes can be waived.
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The product complies with the Uniform Principles.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

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.

Comments of zRMS:	No assessment following the EPPO Standard PP 1/207 'Effects on succeeding crops' was carried out. This assessment can be waived since iron phosphate has no herbicidal activity. Applicant's statement can be agreed. HIERRO (SHA 105000 B) did not cause any symptoms of phytotoxicity. It is not probable that this product would cause damage to succeeding crops at the recommended rate.
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3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

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.

Comments of zRMS:	No assessment following the EPPO Standard PP 1/256 'Effects on adjacent crops' was carried out. This assessment can be waived since iron phosphate has no herbicidal activity. Applicant's statement can be agreed. There should not be any negative effect on adjacent crops when HIERRO (SHA 105000 B) is used as recommended.
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3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

From the experimentation carried out with Iron phosphate 1.0% GB in 2016, 2017, 2018 and 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.

The product complies with the Uniform Principles.

Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

Comments of zRMS:	In efficacy trials no adverse effect on beneficial and other non-target organisms were seen. Reference should be made to Section 9 (Ecotoxicology). Applicant's statement can be agreed. Moreover, for details concerning adverse effects on beneficial and other non-target organisms see Part B9 of the dossier (eco-toxicological data).
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3.5.4 Tank cleaning

Relevant information on tank cleaning is included in dRR Part B124. Please refer to this section for complete evaluation.

Comments of zRMS:	Statement accepted.
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3.6 Other/special studies

No other studies were conducted

3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified and the trials were conducted according to GEP guidelines.

Table 3.7-1: List of test facilities

Testing facility	Zone	Country	Year and trial type					
			2016	2017	2018		2019	
			Efficacy		Efficacy	Selectivity	Efficacy	Selectivity

Strawberry								
Agrigeos Srl	MED	IT	1					
NOVACERT	MED	GR	2					
Biotek Agriculture España S.L.	MED	ES	2					
SGS	MAR	UK	1					
Field Research Support	MAR	DE	1					
Fertico Sp.	NE	PL		1		3		
ANADIAG	NE	PL	1					
Total, Strawberry			8	1		3		
Lettuce								
Agrigeos Srl	MED	IT	1					
NOVACERT	MED	GR	2					
Biotek Agriculture España S.L.	MED	ES	2					
Total, Lettuce			5					
Winter wheat								
Agrigeos Srl	MED	IT	1					
NOVACERT	MED	GR	2					
PROMOVERT	MED	FR		1				
SGS	MAR	UK	2					
Zkusebni stanice Rymarov s.r.o.	MAR	CZ	1					
Research Institute for Fodder Crops, Ltd.	MAR	CZ	1					
State Research Institute	NE	PL					4	3
Fertico Sp.	NE	PL			1	1		
Total, Winter wheat			7	1	1	1	4	3
Potato								
Agrigeos Srl	MED	IT	1					
NOVACERT	MED	GR	2					
Biotek Agriculture España S.L.	MED	ES	2					
SGS	MAR	UK	2					
Field Research Support	MAR	DE		1				
Fertico Sp.	NE	PL		2				
ANADIAG	NE	PL		1				
Total, Potato			7	4				
Apple								
Agrigeos Srl	MED	IT	1					
NOVACERT	MED	GR	2					
Biotek Agriculture España S.L.	MED	ES	2					
Field Research Support	MAR	DE	1					
Research and Breeding Institute of Pomology Holovousy, Ltd.	MAR	CZ	2					
Total, Apple			8					
Spring barley								
Biotek Agriculture España S.L.	MED	ES	2					
Total, Spring barley			2					
Oilseed rape								
SGS	MAR	UK	2					
Field Research Support	MAR	DE	1					
Zkusebni stanice Rymarov s.r.o.	MAR	CZ	1					
Research Institute for Fodder Crops, Ltd.	MAR	CZ	1					
ANADIAG	NE	PL	1					
Fertico Sp.	NE	PL			3	1		
State Research Institute	NE	PL					2	3
Total, Oilseed rape			6		3	1	2	3
Winter barley								
ANADIAG	NE	PL	1					
Total, Winter barley			1					

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
CP 6.0-001	Anonymous	2020	Biological Assessment Dossier: Iron phosphate 1.0% GB (10.0 g/kg Iron phosphate) – EU Central zone Sharda Cropchem España -, - Unpublished	N	SHA