

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: SHA 105000 B

Product name(s): HIERRO

Chemical active substance:

Ferric phosphate, 10.0 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: November 2020

Update: 03.2023, 05.2023

MS Finalisation date: 07.2021; 10.2021, 05.2023; 08.2023

Version history

When	What
11.2020	Submission dRR by Applicant
07.2021	Assesment dRR by zRMS
10.2021	The Final Version of the RR
03.2023	Update by Applicant - Part B5 (RI determination and analytical method validation for RI) and equivalency report
05.2023	Update by Applicant - Part B5 (update of RI determination and analytical method validation for RI)
05.2023	Assessment of Applicant's update (equivalence and RI determination and analytical methods validation for RI) by zRMS
08.2023	Corrections made due to comments received for B3 from the Ministry of Agriculture and Rural Development

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

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

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	-	-
Central zone	Poland	Hungary, Romania
Southern zone	Malta	Spain, Greece
Inter-zonal	-	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Ferric phosphate

Table 0.1-2: Summary of regulatory history of CAS No: 10045-86-0

Status	
Approved in EU	Yes
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 2015/1166 Commission Implementing Regulation (EU) No 540/2011
RMS	Germany Co-RMS: Poland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/01/2016

Status	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	-
Date of final Commission (re-registration) deadline (Step 2)	31/12/2016
Current expiration of approval	31/12/2030
Low risk substance or Candidate for Substitution?	Low-risk active substance

Issues that need to be considered as part of the EU approval are listed below.

On the basis of the representative uses evaluated (as listed in Appendix II), no issues have been identified as requiring particular and short term attention from all Member States.

The SANCO report for Ferric phosphate (SANTE/10385/2015 Rev 1) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 15/12/2014 (EFSA Journal 2015;13(1):3973).

Table 0.1-3: Information on minimum purity of Ferric phosphate

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
Ferric phosphate 703 g/kg equivalent to 260 g/kg iron and 144 g/kg phosphorus.	778.2 g/kg Equivalence report available: on-going RMS Comments: The equivalence source assessment of active substance (ferric phosphate) has not been completed and is available on CIRCA. RMS: PL The report should be provided before product registration

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The endpoints used in the evaluation are in line with EU endpoints.

0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

Phys-chem section:

The evaluation of the application for HIERRO resulted in the decision to grant the authorization. Shelf life – 2 years.

Recommended packaging: HDPE and PP bottles are accepted.

No chemical or physical hazards have been identified.

Toxicology section:

HIERRO (Iron Phosphate 1% GB) is unclassified. Risk for operator, worker and resident is ac-

ceptable.

Fate section: No risk for groundwater is expected after application of Iron phosphate 1% GB.

Ecotox section: No risk for groundwater is expected after application of Iron phosphate 1% GB

Metabolism and residues

Data Gap: none

Efficacy section:

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

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

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

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

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

Field crops: on cereals and winter oilseed rape uses are supported. According to EPPO standard PP1/95 (4) extrapolation from TRZAW (and HORVW) to all cereals is acceptable. Extrapolation to all field crops (except potato) is also possible, however, sufficient data on BRSNN are available only from the Maritime and N-E EPPO zone. In the Polish label we can accept only cereals and winter oilseed rape. In Polish label, sunflower and soybean can be accepted on the basis on possibility extrapolation results from oilseed rape to other oleo species. Sugar beet, sorghum and pulses without trials cannot 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.



Uses to be considered **safe** on the basis of EU methodology:

Fate section: 1-6
Ecotox section: 1-6
Residues section: 1-6
Efficacy section: 1-4, 6

Uses to be considered **non-safe** on the basis of EU methodology:

Fate section: none
Ecotox section: none
Residues section: none
Efficacy section: 5

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

Ecotox Section: Tier 1 calculations of the risk assessment should be provided by the applicant for completeness.

The following text is to be shortened or to be amended as necessary.

MRLs are not established.

Appendix 1 ALL intended uses

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

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

Formulation type: GB (Ganular bait)

Active substance 1: Iron phosphate

Conc. of as 1: 10 g/Kg

Active substance 2:

Conc. of as 2:

Safener: -

Conc. of safener: -

Synergist: -

Conc. of synergist: -

Applicant: SHARDA Cropchem España

Professional use:

Zone(s): central

Non professional use:

Verified by MS: yes/no

Field of use: Molluscicide

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

Minor uses according to Article 51 (interzonal uses)													
7													
8													

- | | | |
|-------------------------------|--|--|
| Remarks table heading: | <ul style="list-style-type: none"> (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008 (c) g/kg or g/l | <ul style="list-style-type: none"> (d) Select relevant (e) Use number(s) in accordance with the list of all intended GAPS in Part B, Section 0 should be given in column 1 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use. |
| Remarks columns: | <ul style="list-style-type: none"> 1 Numeration necessary to allow references 2 Use official codes/nomenclatures of EU Member States 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure) 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. | <ul style="list-style-type: none"> 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application 8 The maximum number of application possible under practical conditions of use must be provided. 9 Minimum interval (in days) between applications of the same product 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products. 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”. 13 PHI - minimum pre-harvest interval 14 Remarks may include: Extent of use/economic importance/restrictions |