

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 105000 B

Product name(s): HIERRO

Chemical active substance:

Ferric phosphate, 10 g/Kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España

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Version history

When	What
July 2021	Finalisation of the assessment by zRMS
September 2021	Applicant update
October 2021	FINAL VERSION of RR after commenting period

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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I**	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ synergist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber 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			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	CEU	Fruit crops	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	-	-								
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	-	-								
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	-	-								
4	CEU	Grapevine	F	Slugs and Snails	Spread to soil surface	From seed- ling/planting until BBCH 81	a) 4 b) 4	14	a) 50.0 b) 200.0	a) 0.5 b) 2.0	-	-								
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	-	-								
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	-	-								
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				
Minor uses according to Article 51 (field uses)																				

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21			
Minor uses according to Article 51 (interzonal uses)																							

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 “Conclusion”

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

Remarks table:

- (1) Numeration necessary to allow references
- (2) Use official codes/nomenclatures of EU
- (3) For crops, the EU and Codex classifications (both) should be used; where 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
- (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

9.1.1 Overall conclusions

zRMS comment:

In the EFSA Conclusion on the peer-review of the pesticide risk assessment of the active substance ferric phosphate (EFSA Journal 2015;13(1):3973); Ferric phosphate was identified as a low risk active substance. No confirmatory data requirements were set and no issues were highlighted for MS consideration. No critical areas of concern were identified but there was one issue that could not be finalised:

- The risk characterisation to aquatic organisms from exposure to the representative formulated products could not be finalised, due to the uncertainty in the potential for and nature of the exposure. Low risks to all other groups of non-target organisms were demonstrated in the EU review. No ecotoxicologically relevant metabolites were identified.

In summary, the zRMS concludes that there is no unacceptable risk to non-target organisms when Hierro is applied at the proposed use pattern.

The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. The changes are introduced directly as text in blue.

9.1.1.1 Technical information on HIERRO (Iron phosphate 1.0% GB) pellets

HIERRO is a granular bait containing nominally 1.0% w/w iron phosphate. The product is applied directly to the soil for consumption by the target pests, slugs and snails. Details regarding the application rate, pellet size and approximate amount of iron phosphate in each pellet are presented below and will be referred to during the risk assessments.

Table 9.1-4 Application information and granule size for HIERRO (Iron phosphate 1.0% GB)

Application rate (product)	50 kg product/ha (0.005 kg product/m ²)
Application rate (active substance)	0.5 kg a.s./ha (0.00005 kg a.s./m ²)
Granule size	2 – 3.35 mm (99.7% of the particles)

Table 9.1-5 Granule size and density information

Granule length (mm)	kg a.s./ha	mg a.s./m ²	N° granules/m ²	Mg Iron phosphate/granule
2 - 3.35	0.5	0.05	60-70	0.000833*

* Using 60 granules/m² as worst case.

9.1.1.2 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

A quantitative risk assessment for birds was provided, and long-term risk for small birds due to ingestion as grit was observed. However, based on a weight-of-evidence approach, nature of the active substance, absence of mortality at the highest tested dose in the acute study and information from literature, a low risk for birds from the use of HIERRO can be concluded.

A quantitative risk assessment for mammals was provided and no risk was observed. In addition, based on a weight-of-evidence approach, nature of the active substance, absence of mortality at the highest tested dose in the acute study and information from literature, a low risk for mammals from the use of HIERRO can be concluded.

9.1.1.3 Effects on aquatic organisms (KCP 10.2)

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

9.1.1.4 Effects on bees (KCP 10.3.1)

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

However, hazard quotients were calculated for oral exposure (Q_{ho}) and contact exposure (Q_{hc}) to ferric phosphate and all hazard quotients (HQ) were considerably less than 50, therefore a low risk to bees is expected from the application of HIERRO at all proposed label rates.

9.1.1.5 Effects on arthropods other than bees (KCP 10.3.2)

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

9.1.1.6 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

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

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

9.1.1.7 Effects on non-target terrestrial plants (KCP 10.6)

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

9.1.1.8 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

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

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

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

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

9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

Table 9.1-2: Critical use pattern of HIERRO (Iron phosphate 1% GB) grouped according to criterion

Grouping according to criterion			
Group	Intended uses	Relevant use parameters for grouping	Relevant parameter or value for sorting
All crops	Fruit crops Vegetable crops Field crops Grapevine Ornamentals Hop	Same application parameters (application type, application rate)	Spread to soil surface at 500 g a.s/ha

zRMS comments:

zRMS agrees with the critical use pattern presented. The uses of the representative formulations assessed during the active substance renewal review are summarised below:

Product	Crop	Concentration	Number of applications	Maximum individual application rate
NEU 1165M	All edible and non-edible crops	10 g a.s./kg	1-4	0.5 kg a.s./ha 5 g product/m ²
RB 1.62 W	Various fruits, various vegetables, ornamentals, potato,	16.2 g a.s./kg	1-6	0.81 kg a.s./ha 5 g product/m ²

Where relevant, the zRMS will refer to the assessment for the EU renewal review of ferric phosphate. The maximum application rate proposed (4 x 500 g a.s./ha) for Hierro is within that assessed for the representative formulations (4-x 500-810 g a.s./ha).

Where new risk assessment is required, this will be conducted according to the Uniform Principles using agreed endpoints from the renewal review.

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of HIERRO is indicated in the table.

Table 9.1-3 Metabolites of Ferric phosphate

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
None				

9.1.4 Technical information on HIERRO (Iron phosphate 1.0% GB) pellets

HIERRO is a granular bait containing nominally 1.0% w/w iron phosphate. The product is applied directly to the soil for consumption by the target pests, slugs and snails. Details regarding the application rate, pellet size and approximate amount of iron phosphate in each pellet are presented below and will be referred to during the risk assessments.

Table 9.1-4 Application information and granule size for HIERRO (Iron phosphate 1.0% GB)

Application rate (product)	50 kg product/ha (0.005 kg product/m ²)
Application rate (active substance)	0.5 kg a.s./ha (0.00005 kg a.s./m ²)
Granule size	2 – 3.35 mm (99.7% of the particles)

Table 9.1-5 Granule size and density information

Granule length (mm)	kg a.s./ha	mg a.s./m ²	N° granules/m ²	Mg Iron phosphate/granule
2 - 3.35	0.5	0.05	60-70	0.000833*

* Using 60 granules/m² as worst case.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with ferric phosphate. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of HIERRO were not evaluated as part of the EU assessment of Ferric phosphate. However, the provision of further data on the formulation HIERRO is not considered essential, because endpoints obtained with the active substance are sufficient to evaluate the risk and new studies should not be conducted in regards of animal welfare (EFSA Journal 2009; 7(12):1438).

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Bobwhite quail	Preparation ,NEU	Oral	LD ₅₀ > 2000	EFSA Journal

Species	Substance	Exposure System	Results	Reference
	1165 M ^c	1 d Acute	mg/kg bw	2015;13(1):3973
Bobwhite quail	Preparation 'Ferric Orthophosphate RB 1.62 W ^c	Oral 1 d Acute	LD ₅₀ > 2000 mg/kg bw	EFSA Journal 2015;13(1):3973
Mallard duck	Ferric phosphate	Dietary Long-term	NOEC = 24 mg Fe/Kg bw*	EFSA Journal 2015;13(1):3973

* Data from Firman et al. (1993) for iron were used. 80 mg Fe/Kg diet for a large bird of 1 kg and a food intake of 30% of its body weight a day.

9.2.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones.

9.2.2 Risk assessment for spray applications

Not relevant.

9.2.2.1 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario

Since HIERRO is not a product for spray applications, the leaf scenario does not have to be considered.

Puddle scenario

Due to the fact that the Ferric phosphate is practically insoluble in water and that both iron and phosphate ions are ubiquitous components of soils occurring in amounts much greater than those applied a risk of water contamination resulting from application of HIERRO according to the GAP is not expected. The Puddle scenario does not have to be considered.

9.2.2.2 Effects of secondary poisoning

HIERRO is used as a molluscicide and Ferric phosphate is almost insoluble in organic solvents, hence, bioaccumulation is not expected. Furthermore, iron and phosphate are naturally occurring substances and common in the metabolism of birds. Hence, it can be expected that birds have mechanisms to regulate the amount of iron and phosphate that is absorbed from the diet. Therefore, effects of secondary poisoning do not have to be addressed.

Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

9.2.2.3 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, pills or treated seed

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

According to the EFSA 2009 guidance document birds may be exposed to granular formulations in different ways:

- a) Birds may ingest granules as a source of food
- b) Birds may ingest granules as grit
- c) Birds may mistake granules for small seed
- d) Birds may ingest granules when they eat food contaminated with soil
- e) Birds may consume food contaminated with residues resulting from granular applications

Due to the fact that the Ferric phosphate is practically insoluble in water, its contamination is not expected. Although these baits have calorific value, they emit a weak odour and are pale blue colored. In that sense, Gemmeke (1999) showed in a field study with seven different bird species and five different seeds that the colouring of seeds results in a strong avoidance by avian species.

Thus, it can be assumed that the attractiveness of the blue coloured pellets is also very small and, hence, it is unlikely that birds will mistake granules for food. However, as a worst case, scenario a) will be assessed too.

a) Birds ingesting granules as a source of food

The scenario of birds intentionally ingesting the baits as a food source will also cover the scenario of birds ingesting the baits as grit. The ingestion of baits as grit scenario is considered less critical considering that the size of the baits (> 2 mm) will make them unattractive to small birds as grit.

Tier 1 risk assessment

As the baits contain an energy source (White sugar 2.50% and Wheat flour 90.52%), birds may ingest the bait granules as a source of food. Although, in reality this is unlikely to be a regular occurrence due to various factors that will be presented later in the risk assessment. The tier 1 risk assessment must assume the worst-case condition of a vulnerable species of bird (usually a small bird with high energy demand) feeding exclusively on the baits. In this way exposure to the active substance is maximised.

The tier 1 assessment, according to the EFSA guidance document, considers the house sparrow as a suitable species of concern. The bird is small (body weight of 27.7g) and has a high daily energy expenditure (DEE) (101.65). A worst-case daily food intake (FIR) for the house sparrow was calculated using the default values for cereal seeds. This food type was selected as a surrogate for the product as it is formulated with wheat flour so can be considered to have similar calorific value.

The daily food intake rate for the house sparrow is calculated using the calorific content of the seeds (18.4

kJ/g), the moisture content of cereal seeds (14.7%) and the assimilation efficiency (80%). This results in a daily food intake of 8.10 g per day and a food intake rate (FIR/bw) of 0.29. For the first tier exposure, the indicator species is assumed to feed exclusively on the pellet baits.

The daily dietary dose (DDD) is calculated by multiplying the nominal amount of active substance per granule with the food intake rate per body weight (FIR/bw). The toxicity exposure ratio (TER) is calculated by dividing the LD₅₀ by the daily dietary dose. The calculation is only presented for the 2 – 3.35 mm granules as it is considered that all granules will have the same DDD.

Table 9.2-2: Daily dietary dose calculation for the indicator species for the 2 – 3.35 mm granules

Granule length (mm)	FIR (g/d)	BW (g)	Weight of granules (g)	Number of granules to satisfy energy demand	Ferric phosphate (mg a.s./granule)	DDD (mg a.s./kg bw/d)
2-3.35	8.10	27.7	0.0033*	2421	0.000833	0.590

FIR = food intake rate, bw = body weight, DDD = daily dietary dose

* Calculated using the physic-chemical analysis results (grain volume and bulk density)

Table 9.2-3: Acute TER value for granivorous birds ingesting granules as a source of food

Species	DDD (mg a.s./kg bw)	Toxicity (mg a.s./kg bw)	TER	Annex V Trigger
House Sparrow	0.590	2000	3390	10

Figures in **bold** represent an unacceptable risk.

For the long-term assessment, the DDD includes the default time weighted average value of 0.53. However, in reality, exposure of granivorous birds over long time periods to the pellet baits is unlikely considering the number of applications (4), the degradation of pellets by weathering and consumption of baits by the target pest. The long-term TER values are shown in Table 9.2-4.

Table 9.2-4: Long-term TER value for granivorous birds ingesting granules as a source of food

Species	DDD (mg a.s./kg bw)	Toxicity (mg a.s./kg bw)	TER	Annex V Trigger
House Sparrow	0.313	24	76.7	5

Figures in **bold** represent an unacceptable risk

The TER values are above the triggers of 10 and 5 for acute and long-term risk respectively, indicating low risk to birds.

b) Birds ingesting granules with/as grit

The ingestion of baits as grit scenario is considered less critical considering that the size of the baits (> 2 mm) will make them unattractive to small birds as grit (EFSA, 2009). Nevertheless, birds may ingest granules accidentally with soil or large birds may ingest them intentionally to aid mastication of their food. The tier 1 and 2 risk assessments are only presented here to demonstrate the potential risk posed and that the risk is sufficiently covered by the more critical scenario of birds ingesting the baits as a food source.

Tier 1 risk assessment

The acute daily grit dose (DGritD_{acute}) is calculated separately for small and large granules as it is considered that small birds only consume small granules and large birds only consume large granules, small granules are considered < 2 mm in long.

The equations use to calculate the acute daily grit dose according to EFSA (2009), are presented below:

$$DGritD_{acute}(\text{small granules}) = 651 \times \frac{G_{density}}{(15200 + G_{density})} \times G_{loading}$$

$$DGritD_{acute}(\text{large granules}) = 2453 \times \frac{G_{density}}{(71 + G_{density})} \times G_{loading}$$

Where G_{density} is the number of granules on the soil surface (number of granules/m² assuming no incorporation) and G_{loading} is the amount of active substance in one granule (mg a.s./granule).

Using the size distribution data available for HIERRO, the $DG_{\text{GritD}}_{\text{acute}}$ for large granules will be calculated just for one group size, as 99.7% of the particles have size between 2 – 3.35 mm.

For HIERRO the grouping and the corresponding G_{density} and G_{loading} and the resulting $DG_{\text{GritD}}_{\text{acute}}$ are shown below.

Table 9.2-5: $DG_{\text{GritD}}_{\text{acute}}$ for HIERRO (Iron phosphate 1.0% GB)

Granule length (mm)	G_{density} (granules/m ²)	G_{loading} (mg a.s./granule)	$DG_{\text{GritD}}_{\text{acute}}$
2 – 3.35	60	0.000833	0.936

The $DG_{\text{GritD}}_{\text{acute}}$ needs to be converted to mg a.s./kg bw before a TER can be calculated. For the small bird the body weight is assumed to be 25g (based on the value provided in the EPPO scheme) and for the large bird a conservative weight of 400g is assumed (based on the partridge and wood pigeon on which the EFSA assessment is based).

The toxicity values and TERs for large granules are shown in Table 9.2-6.

Table 9.2-6: Acute TERs for birds ingesting HIERRO (Iron phosphate 1.0% GB) as grit

Granule length (mm)	$DG_{\text{GritD}}_{\text{acute}}$	Body weight	Toxicity	TER	Trigger
<i>Small birds</i>					
2 – 3.35	0.936	25	2000	53.4	10
<i>Large birds</i>					
2 – 3.35	0.936	400	2000	854.7	10

The acute TERs for birds are higher than the trigger value for the used granule size indicating a potential low risk and therefore further refinement is not required.

The long-term daily grit dose ($DG_{\text{GritD}}_{\text{repro}}$) is also calculated using the equations given in EFSA (2009).

$$DG_{\text{GritD}}_{\text{repro}} \text{ (for small granules)} = 386 \times \frac{G_{\text{density}}}{(15200 + G_{\text{density}})} \times G_{\text{loading}}$$

$$DG_{\text{GritD}}_{\text{repro}} \text{ (for large granules)} = 1306 \times \frac{G_{\text{density}}}{(71 + G_{\text{density}})} \times G_{\text{loading}}$$

For HIERRO the granule size grouping and the corresponding G_{density} and G_{loading} and the resulting $DG_{\text{GritD}}_{\text{repro}}$ are shown below.

Table 9.2-7: $DG_{\text{GritD}}_{\text{repro}}$ for HIERRO (Iron phosphate 1.0% GB)

Granule length (mm)	G_{density} (granules/m ²)	G_{loading} (mg a.s./granule)	$DG_{\text{GritD}}_{\text{repro}}$
2 – 3.35	60	0.000833	0.498

As for the acute risk assessment, the $D_{GritD_{repro}}$ needs to be converted to mg a.s./kg bw before a TER can be calculated. Again, a body weight of 25 g is assumed for small birds, and 400 g for large birds.

The toxicity values and TERs for both small and large granules are shown in Table 9.2-8.

Table 9.2-8: Long-term TERs for birds ingesting HIERRO (Iron phosphate 1.0% GB) as grit

Granule length (mm)	$D_{GritD_{repro}}$	Body weight	Toxicity	TER	Trigger
<i>Small birds</i>					
2 – 3.35	0.498	25	24	1.2	5
<i>Large birds</i>					
2 – 3.35	0.498	400	24	19.3	5

Figures in **bold** demonstrate an unacceptable risk

The long-term TERs for small birds are lower than the trigger value for the used granule sizes indicating a potential risk posed. However, prolonged exposure of avian species to pellets is considered negligible.

c) Birds may mistake granules for small seed

It is considered that the risk to birds from mistaking granules as small seeds is unlikely and also this risk would be covered by the risk for birds consuming granules as a source of grit.

Moreover, the size of the granules is in the range considered as “large”, being therefore larger than most seeds from which the birds feed.

No further consideration is required.

d) Birds may ingest granules when they eat food contaminated with soil

It is considered that the risk to birds from ingesting granules when eating food contaminated with soil is unlikely and also this risk would be covered by the risk for birds consuming granules as a source of grit.

However, as a worst case scenario, acute risk assessment is presented below. The equation use to calculate the acute daily dry soil dose ($DDSD_{acute}$) for a small omnivorous bird according to EFSA (2009), is presented below:

$$DDSD_{acute} \text{ for bird} = 0.283 \times \text{dosage [kg a.s./ha]}.$$

$$DDSD_{acute} = 0.283 \times 0.5 \text{ kg a.s./ha} = 0.1415$$

The TERs are calculated using the acute LD_{50} value:

$$TER = 2000/0.1415 = 14134$$

The acute TER for birds are higher than the trigger value of 10 indicating a potential low risk and therefore further refinement is not required.

The equation use to calculate the acute daily dry soil dose ($DDSD_{acute}$) for the reproductive risk assessment for a small omnivorous bird according to EFSA (2009), is presented below:

$DDSD_{\text{repro}} \text{ for birds} = 0.025 \times \text{dosage in kg a.s./ha.}$

$$DDSD_{\text{acute}} = 0.025 \times 0.5 \text{ kg a.s./ha} = 0.0125$$

The TERs are calculated using the chronic NOEL value:

$$TER = 24/0.0125 = 1920$$

The long-term TER for birds are higher than the trigger value of 5 indicating a potential low risk and therefore further refinement is not required.

e) Birds may consume food contaminated with residues resulting from granular applications

Birds may also be exposed to ferric phosphate residues by consuming food contaminated with the substance e.g. poisoned slugs, snails and contaminated earthworms. As slugs and snails are the intended target organism and actively eat the pellets it can be considered that exposure of slug eating birds is the worst case scenario to consider. The risk to earthworm and slugs eating birds can be considered less critical as ferric phosphate is insoluble in organic solvents and, hence, is not expected to bioaccumulate.

No further consideration is required.

Weight of evidence

The risk assessment for ferric phosphate and HIERRO preparation takes into account the following weight-of-evidence approach for birds:

- Ferric phosphate occurs naturally in soils. Consequently, the activity of ferric phosphate in the environment is well known. Actually, the naturally present amounts of iron and phosphorus in soil (0.5 to 5% iron and 0.01 to 0.2% phosphorus) is higher than the provided by HIERRO application.
- Both iron and phosphorus are normally added to the soil as a fertilizers.
- Ferric phosphate as well as the representative formulations are of no, if at all, very low toxicity against birds.
- The active substance is non-volatile and practically insoluble in water and organic solvents and will only be absorbed to a limited degree and thus is only partly bioavailable.
- Bioaccumulation can be excluded.
- Ferric phosphate is being used as a nutrient and dietary supplement in foods (FAO, amendment of March 2002)
- Ferric phosphate may already be present in the food sources of the living organisms in the environment.
- Iron and phosphate ions are an inherent part of plant and animal metabolism.

The acute oral toxicity study in Japanese quails did not reveal mortality or any signs of toxicity after a single oral administration of 2000 mg/kg b.w. In the acute toxicity study no mortality and only slight effects (transiently diarrhoea and bleeding at the intestines at gross necropsy in 1 of 10 birds) occurred at the highest test dose 2000 mg prod/kg b.w.

Ramsey et al. (1954) and Planas et al. (1961) observed that female bird elevated their serum iron level during egg laying. This was regarded as a response to compensate for the loss caused by the transfer of iron to the eggs. This shows that birds are able to partly regulate their iron concentration in the serum and that they can handle increased iron levels.

The log P_{ow} of ferric phosphate cannot be estimated since ferric phosphate is practically insoluble in wa-

ter. However, a risk of bioaccumulation is not expected based on the natural occurrence of ferric phosphate in the environment and the function as dietary supplement in food sources.

Therefore, exposure to birds from the use of the preparation HIERRO is considered negligible.

zRMS comment:

The risk assessment was accepted. According to the EFSA 2009 guidance document birds may be exposed from granular formulations in different ways:

- f) Birds may ingest granules as a source of food
- g) Birds may ingest granules as grit
- h) Birds may mistake granules for small seed
- i) Birds may ingest granules when they eat food contaminated with soil
- j) Birds may consume food contaminated with residues resulting from granular applications

~~Therefore, the risk assessment should be presented by the applicant according to this way for completeness of the risk at Tier 1.~~

In addition taking into account that risk assessment finally based on WoE approach and proposed uses are covered by the risk assessment for representative formulation (the same application rate 4 x 500 g a.s./ha) the risk may be considered acceptable.

9.2.4 Overall conclusions

A quantitative risk assessment for birds was provided, and long-term risk for small birds due to ingestion as grit was observed. However, based on a weight-of-evidence approach, nature of the active substance, absence of mortality at the highest tested dose in the acute study and information from literature, a low risk for birds from the use of HIERRO can be concluded.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with ferric phosphate. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of HIERRO were not evaluated as part of the EU assessment of ferric phosphate. However, the provision of further data on the formulation HIERRO is not considered essential, because endpoints obtained with the active substance are sufficient to evaluate the risk and new studies should not be conducted in regards of animal welfare (EFSA Journal 2009; 7(12):1438).

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Ferric phosphate	Oral 1 d Acute	LD ₅₀ > 5000 mg/kg bw	EFSA Journal 2015;13(1):3973

Species	Substance	Exposure System	Results	Reference
Rat	Ferric phosphate	Reproductive toxicity	No data submitted	EFSA Journal 2015;13(1):3973
Rat	Preparation ,NEU 1165 M‘	Acute	LD ₅₀ >5000	EFSA Journal 2015;13(1):3973
Mice	Preparation ‘Ferric Orthophosphate RB 1.62 W‘	Acute	LD ₅₀ >5000	EFSA Journal 2015;13(1):3973

9.3.1.1 Justification for new endpoints

The used endpoints were the EU agreed ones.

9.3.2 Risk assessment for spray applications

Not relevant.

9.3.2.1 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the fact that the Ferric phosphate is practically insoluble in water and that both iron and phosphate ions are ubiquitous components of soils occurring in amounts much greater than those applied a risk of water contamination resulting from application of HIERRO according to the GAP is not expected. The Puddle scenario does not have to be considered.

9.3.2.2 Effects of secondary poisoning

HIERRO is used as a molluscicide and Ferric phosphate is almost insoluble in organic solvents, hence, bioaccumulation is not expected. Furthermore, iron and phosphate are naturally occurring substances and common in the metabolism of mammals. Hence, it can be expected that mammals have mechanisms to regulate the amount of iron and phosphate that is absorbed from the diet. Therefore, effects of secondary poisoning do not have to be addressed.

Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

9.3.2.3 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, pills or treated seed

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

According to the EFSA 2009 guidance document mammals may be exposed to granular formulations in different ways:

- a) Mammals may ingest granules as a source of food
- b) Mammals may ingest granules when they eat food contaminated with soil
- c) Mammals may consume food contaminated with residues resulting from granular applications

Due to the fact that the Ferric phosphate is practically insoluble in water, its contamination is not expected. Further, the risk from mammals ingesting granules when they eat food contaminated with soil is considered as less critical than mammals ingesting the granules as a food source. In fact, as the baits contain an energy source (White sugar 2.50% and Wheat flour 90.52%), it is considered that these have calorific value. However, they emit a weak odour and are blue colored. In that sense, it is unlikely that mammals will mistake granules for food.

The assessment is conducted below

a) Mammals ingesting granules as a source of food

Tier 1 risk assessment

As the baits contain an energy source (White sugar 2.50% and Wheat flour 90.52%), mammals may ingest the bait granules as a source of food. Although, in reality this is unlikely to be a regular occurrence due to various factors that will be presented later in the risk assessment. The tier 1 risk assessment must assume the worst-case condition of a vulnerable species of mammal (usually a small mammal with high energy demand) feeding exclusively on the baits. In this way exposure to the active substance is maximised.

The tier 1 assessment, according to the EFSA guidance document, considers the house wood mouse as a suitable species of concern. The mouse is small (body weight of 21.7g) and has a high daily energy expenditure (DEE) (58.83). A worst-case daily food intake (FIR) for the wood mouse was calculated using the default values for cereal seeds. This food type was selected as a surrogate for the product as it is formulated with wheat flour so can be considered to have similar calorific value.

The daily food intake rate for the wood mouse is calculated using the calorific content of the seeds (18.4 kJ/g), the moisture content of cereal seeds (14.7%) and the assimilation efficiency (84%). This results in a daily food intake of 4.46 g per day and a food intake rate (FIR/bw) of 0.21. For the first tier exposure, the indicator species is assumed to feed exclusively on the pellet baits.

The daily dietary dose (DDD) is calculated by multiplying the nominal amount of active substance per granule with the food intake rate per body weight (FIR/bw). The toxicity exposure ratio (TER) is calculated by dividing the LD₅₀ by the daily dietary dose. The calculation is only presented for the 2 – 3.35 mm granules as it is considered that all granules will have the same DDD.

Table 9.3-2: Daily dietary dose calculation for the indicator species for the 2 – 3.35 mm granules

Granule length (mm)	FIR (g/d)	BW (g)	Weight of granules (g)	Number of granules to satisfy energy demand	Ferric phosphate (mg a.s./granule)	DDD (mg a.s./kg bw/d)
2-3.35	4.46	21.7	0.0033*	1333	0.00083	0.228

FIR = food intake rate, bw = body weight, DDD = daily dietary dose

* Calculated using the physic-chemical analysis results (grain volume and bulk density)

Table 9.3-3: Acute TER value for mammals ingesting granules as a source of food

Species	DDD (mg a.s./kg bw)	Toxicity (mg a.s./kg bw)	TER	Annex V Trigger
Wood mouse	0.228	5000	21930	10

Figures in **bold** represent an unacceptable risk.

For the long-term assessment, the DDD includes the default time weighted average value of 0.53. However, in reality, exposure of granivorous mammals over long time periods to the pellet baits is unlikely considering the number of applications (4), the degradation of pellets by weathering and consumption of baits by the target pest. The long-term TER values are shown in Table 9.3-4.

Table 9.3-4: Long-ter TER value for mammals ingesting granules as a source of food

Species	DDD (mg a.s./kg bw)	Toxicity (mg a.s./kg bw)	TER	Annex V Trigger
Wood mouse	0.121	1.2	9.92	5

Figures in **bold** represent an unacceptable risk.

The TER values are above the triggers of 10 and 5 for acute and long-term risk respectively, indicating low risk to mammals. In addition, prolonged exposure of mammal species to pellets is considered negligible.

b) Mammals ingesting granules when they eat food contaminated with soil

It is considered that the risk to mammals from ingesting granules when eating food contaminated with soil is unlikely but also this risk will be covered by the risk for mammals consuming granules as a source of food.

However, as a worst case scenario, acute risk assessment is presented below. The equation use to calculate the acute daily dry soil dose (DDSD_{acute}) for a small omnivorous mammal according to EFSA (2009), is presented below:

$$\text{DDSD}_{\text{acute}} \text{ for mammal} = 0.097 \times \text{dosage [kg a.s./ha]}$$

$$\text{DDSD}_{\text{acute}} = 0.097 \times 0.5 \text{ kg a.s./ha} = 0.049$$

The TERs are calculated using the acute LD₅₀ value:

$$\text{TER} = 5000/0.020 = 102040$$

The acute TER for mammals are higher than the trigger value of 10 indicating a potential low risk and therefore further refinement is not required.

The equation use to calculate the acute daily dry soil dose (DDSD_{acute}) for the reproductive risk assessment for a small omnivorous mammal according to EFSA (2009), is presented below:

$$\text{DDSD}_{\text{repro}} \text{ for mammal} = 0.005 \times \text{dosage [kg a.s./ha]}$$

$$\text{DDSD}_{\text{repro}} = 0.005 \times 0.5 \text{ kg a.s./ha} = 0.0025$$

The TERs are calculated using the chronic value (LD50/10):

$$\text{TER} = 1.2/0.001 = 480$$

The long-term TER for mammals are higher than the trigger value of 5 indicating a potential low risk and therefore further refinement is not required.

c) Mammals may consume food contaminated with residues resulting from granular applications

Mammals may also be exposed to ferric phosphate residues by consuming food contaminated with the substance e.g. poisoned slugs, snails and contaminated earthworms). As slugs and snails are the intended target organism and actively eat the pellets it can be considered that exposure of slug eating mammals is the worst case scenario to consider. The risk to earthworm and slugs eating mammals can be considered less critical as ferric phosphate is insoluble in organic solvents and, hence, is not expected to bioaccumulate. Then, no further consideration is required.

Weight of evidence

The risk assessment for ferric phosphate and HIERRO preparation takes into account the following weight-of-evidence approach for mammals:

- Ferric phosphate occurs naturally in soils. Consequently, the activity of ferric phosphate in the environment is well known. Actually, the naturally present amounts of iron and phosphorus in soil (0.5 to 5% iron and 0.01 to 0.2% phosphorus) is higher than the provided by HIERRO application.
- Both iron and phosphorus are normally added to the soil as a fertilizers.
- Ferric phosphate as well as the representative formulations are of no, if at all, very low toxicity against birds.
- The active substance is non-volatile and practically insoluble in water and organic solvents and will only be absorbed to a limited degree and thus is only partly bioavailable.
- Bioaccumulation can be excluded.
- Ferric phosphate is being used as a nutrient and dietary supplement in foods (FAO, amendment of March 2002)
- Ferric phosphate may already be present in the food sources of the living organisms in the environment.
- Iron and phosphate ions are an inherent part of plant and animal metabolism.

In toxicity studies with rats, no effects were observed after oral administration up to the top dose of 5000 mg/kg b.w. In view of the natural occurrence of ferric phosphate and lacking toxicity of the compound for terrestrial vertebrates, no quantitative risk assessment was deemed necessary. It can be concluded that the endpoints obtained from mammalian toxicity studies and the publicly available information on iron salts indicate no risk to mammals from exposure to iron phosphate.

The log P_{ow} of ferric phosphate cannot be estimated since ferric phosphate is practically insoluble in water. However, a risk of bioaccumulation is not expected based on the natural occurrence of ferric phosphate in the environment and the function as dietary supplement in food sources.

Therefore, exposure to mammals from the use of the preparation HIERRO is considered negligible.

zRMS comment:

The risk assessment was accepted According to the EFSA 2009 guidance document birds may be exposed to granular formulations in different ways:

- a) Mammals may ingest granules as a source of food
- b) Mammals may ingest granules when they eat food contaminated with soil
- c) Mammals may consume food contaminated with residues resulting from granular applications

~~Therefore, the risk assessment should be presented by the applicant according to this way for completeness of the risk at Tier 1.~~

In addition, taking into account that risk assessment finally based on WoE approach and proposed uses are covered by the risk assessment for representative formulation (the same application rate 4 x 500 g a.s./ha) the risk may be considered acceptable.

9.3.4 Overall conclusions

A quantitative risk assessment for mammals was provided and no risk was observed. In addition, based on a weight-of-evidence approach, nature of the active substance, absence of mortality at the highest tested dose in the acute study and information from literature, a low risk for mammals from the use of HIERRO can be concluded.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

No guidance is available for risk assessment on reptiles and amphibians. These effects are supposed to be covered by the risk assessment on birds and mammals. No studies with the formulation were conducted on wild mammals or other wild terrestrial vertebrates.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with ferric phosphate. Full details of these studies are provided in the respective EU DAR and related documents, as well as in Appendix 2 of this document (new studies).

Effects on aquatic organisms of HIERRO were not evaluated as part of the EU assessment of ferric phosphate. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2. These studies were performed using a formulation with 2.97% iron phosphate, however the recipe was the same than the present one, hence the results are considered valid for the evaluation.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – ferric phosphate

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	Preparation 'Ferric Orthophosphate RB 1.62 W'	96 hr (semi-static)	Mortality, EC ₅₀ > 17 prod. (mm)	EFSA Journal 2015;13(1):3973
<i>Daphnia magna</i>	Preparation 'Ferric Orthophosphate RB 1.62 W'	48 h (static)	Mortality, EC ₅₀ > 19 prod. (mm) (supportive information)	EFSA Journal 2015;13(1):3973
<i>Scenedesmus subspicatus</i>	Preparation 'Ferric Orthophosphate RB 1.62 W'	72 h (static)	Biomass: EbC ₅₀ > 49 prod. (mm) Growth rate: ErC ₅₀ > 49 prod. (mm)	EFSA Journal 2015;13(1):3973
Higher-tier studies (micro- or mesocosm studies)				
Not required.				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – HIERRO

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	Ferric phosphate 2.9% GB	96 h, ss	LC ₅₀ >18.29 mg f.p./L _{mm} LC ₅₀ >0.50 mg a.s./L _{mm}	KCP 10.2.1-01 Halappa, R., 2019 G14344
<i>Daphnia magna</i>	Ferric phosphate 2.9% GB	48 h, s	EC ₅₀ >15.19 mg f.p./L _{mm} EC ₅₀ >0.42 mg a.s./L _{mm}	KCP 10.2.1-02 Halappa, R., 2019 G14346
<i>Pseudokirchneriella subcapitata</i>	Ferric phosphate 2.9% GB	72 h, s	ErC ₅₀ and EyC ₅₀ >11.46 mg f.p./L _{mm} (>0.32 mg a.s./L _{mm})	KCP 10.2.1-03 Halappa, R., 2019 G14345
Higher-tier studies (micro- or mesocosm studies)				
-				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

zRMS comments:

The studies for aquatic organism for formulation Hierro was not submitted by the applicant. The applicant refers to the study for similar formulation with higher amount of the a.s.- : Ferric phosphate 2.9%GB in comparison to Ferric phosphate 1.)% GB. In zRMS opinion it can be considered as acceptable and additional studies are not required.

9.5.1.1 Justification for new endpoints

Not relevant.

9.5.2 Risk assessment

According to EFSA conclusions (EFSA Journal 2015;13(1):3973) and Renewal Assessment Report (Annex B.9 – 2013), the calculation of Predicted Environmental concentrations in surface water (PEC_{sw}) of ferric phosphate was not performed and was not considered to be required. The active substance ferric phosphate is a stable, non-volatile inorganic salt which is practically insoluble in water (1.86×10^{-12} g/L). In soil the representative formulation HIERRO will be spread across cultivated area as a ready to use bait and a contamination of surface water via spray drift can therefore be excluded. The possible entry route into adjacent water bodies is considered to be via runoff of soil particles containing the active substance after heavy rain events. The maximum environmental concentration which will be expected in the water phase will correspond to the water solubility of ferric phosphate. The insoluble portion remaining in the sediment will add to the natural content of iron and phosphate in the sediment.

Both, ferric and phosphate ions are naturally occurring in soil. Iron phosphates occurring in soils are e.g. strengite ($\text{FePO}_4 \cdot 2 \text{H}_2\text{O}$, stable in acidic soils) and vivianite ($\text{Fe}_3(\text{PO}_4)_2 \cdot 8 \text{H}_2\text{O}$, stable under anaerobic conditions). Iron occurs in a wide variety of minerals and is the fourth most abundant element in the lithosphere. In soils under aerobic conditions iron is present mostly in form of insoluble Fe(III)oxides (e.g. goethite, haematite, ferrihydrite).

Furthermore, the type of formulation (GB) in connection with the method of application and the application rates of 500 g a.s./ha leads to a low risk of contamination of surface water.

Hence, a low risk to aquatic organisms from the exposure to HIERRO is expected.

zRMS comment:

According to the EFSA Conclusion on the peer-review of the pesticide risk assessment of the active substance ferric phosphate (EFSA Journal 2015;13(1):3973); “*Acute toxicity studies with the formulation ‘Ferric Orthophosphate RB 1.62 W’ (that was ground up before mixing with water) on fish, invertebrates and algae were available. These studies were considered sufficient to confirm the toxicity of the active substance, taking also into account the very low solubility of ferric phosphate in water. However, pending the outcome of the data gap identified in the environmental fate and behaviour (see section 4) for further information regarding the surface water pattern of exposure, further information may be needed to characterize the risk to aquatic organisms from exposure to the formulated products and the risk characterization for aquatic organisms could not be finalized. A low risk to aquatic organisms is expected from the iron and HPO_4^{2-} and H_2PO_4^- ions since the amount of elemental ions present in surface water consequent from the representative uses will be limited compared to the background levels.*”

The endpoints presented are according to the LoEP (2015). However, no risk assessment is conducted as no PEC_{sw} have been calculated.

The zRMS concludes that there is no unacceptable acute or chronic risk for aquatic organisms.

9.5.3 Overall conclusions

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

zRMS comment:

The EU renewal review for ferric phosphate identified the risk to aquatic organisms to be an area which could not be finalised, due to the uncertainty in the potential for and nature of the exposure. However, the risk to aquatic organisms was not identified in the EU review as a particular area requiring MS consideration. It is also noted that <50% effect on aquatic organisms were observed at the highest concentration tested in the available toxicity studies.

The following is stated in the RR:

“Surface water calculations were not performed during the Annex I assessment due to the water solubility of the compound. The EFSA (2015) conclusion concludes ‘due to the very low solubility no PEC surface water calculations were performed for ferric phosphate’”

Thus, due to the practical insolubility of ferric phosphate, possible exposure to aquatic organisms is negligible, and no surface water exposure assessment has been provided by the applicant. This is accepted by the zRMS, and in line with the EU review no further assessment of the risk to aquatic organisms is conducted for the proposed uses of Hierro.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with ferric phosphate. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of HIERRO were not evaluated as part of the EU assessment of ferric phosphate. The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	Ferric phosphate	Oral	LD ₅₀ >109.9 µg/bee	EFSA Journal 2015;13(1):3973
<i>Apis mellifera</i>	Ferric phosphate	Contact	LD ₅₀ >100 µg/bee	EFSA Journal 2015;13(1):3973
Higher-tier studies (tunnel test, field studies)				
None				

9.6.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones.

9.6.2 Risk assessment

Applications of pesticides can potentially result in exposure of honeybees either through direct over-spray, or by contact with residues on plants whilst bees are foraging for food.

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

The laboratory data with technical ferric phosphate show that ferric phosphate can be classified as practically non-toxic to honeybees. According to EFSA conclusions (EFSA Journal 2015;13(1):3973, *a quantitative risk assessment is not required due to the negligible exposure and the low toxicity of ferric phosphate.*

Although the calculation of hazard quotients does not seem to be appropriate, the evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final). October 17. 2002).

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of HIERRO in all crops

Intended use	All crops		
Active substance	Ferric phosphate		
Application rate (g/ha)	4 x 500		
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}. Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	>109.9	500	<4.55
Contact toxicity	>100		<5.00

Due to the results of laboratory tests with ferric phosphate, the formulation HIERRO is considered to be practically non-toxic to bees. All hazard quotients are clearly below the trigger of 50, indicating that the intended use poses a low risk to bees in the field.

zRMS comment:

The acute risk assessment is considered acceptable for the active substance (though the applicability of these HQ calculations for a granule application is limited). No acute test for formulation is required as the low risk for the a.s is concluded.

According to Reg.284/2009 the chronic toxicity studies with adult honeybees and honeybee larvae should always be submitted, and a chronic risk assessment for adult honeybees and honeybee larvae should be performed for exposure via pollen and nectar. However, ferric phosphate is formulated as a granule and applied to the ground. Systemic movement of ferric phosphate into plant parts that may be attractive to bees is not anticipated. In the EFSA conclusion (2015) no chronic data was required, and acceptable risk to bees was concluded on the basis of negligible exposure. Therefore, the zRMS accepts the omission of a chronic risk assessment in this case.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not required

9.6.3 Effects on bumble bees

Not required

9.6.4 Effects on solitary bees

Not required

9.6.5 Overall conclusions

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

However, hazard quotients were calculated for oral exposure (Q_{ho}) and contact exposure (Q_{hc}) to ferric phosphate and all hazard quotients (HQ) were considerably less than 50, therefore a low risk to bees is expected from the application of HIERRO at all proposed label rates.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with ferric phosphate. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of HIERRO were not evaluated as part of the EU assessment of Ferric phosphate. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2. These studies were performed using a formulation with 2.97% iron phosphate, however the recipe was the same than the present one, hence the results are considered valid for the evaluation.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
<i>Aphidius rhopalosophi</i>	Preparation 'NEU 1165 M'	Laboratory test glass plates (2D) (Limit test); 48h Test rate: 10 g/m ² corresp. to 1000 g a.s./ha	Mortality: 2.5 % Mortality corr.: 0 % Reduction in beneficial capacity: 52.2 %	EFSA Journal 2015;13(1):3973

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i>	Preparation 'NEU 1165 M'	Laboratory test glass plates (2D) (Limit test); 7d Test rate: 10 g/m ² corresp. to 1000 g a.s./ha	Mortality: 15 % Mortality corr.: 6.6 % Reduction in beneficial capacity: 3.8 %	EFSA Journal 2015;13(1):3973
<i>Aleochara bilineata</i>	Preparation 'NEU 1165 M'	Extended laboratory studies 1000 g a.s./ha initial	Mortality: 0% Reduction in parasitic capacity: 5.5%	EFSA Journal 2015;13(1):3973
<i>Poecilus cupreus</i>	Preparation 'NEU 1165 M'	Extended laboratory studies 1000 g a.s./ha initial	Mortality: 3.3% Reduction in food uptake: 16.25%	EFSA Journal 2015;13(1):3973
<i>Aleochara bilineata</i>	Preparation 'Ferric Orthophosphate RB 1.62 W'	Extended laboratory studies 2 x 1000 g a.s./ha	Mortality: No effects observed. Reduction in beneficial capacity: No effects observed.	EFSA Journal 2015;13(1):3973
<i>Poecilus cupreus</i>	Ferric phosphate 2.9% GB	Laboratory test quartz sand (2D) 194.1 – 1272.3 g a.s./ha	LR ₅₀ > 1272.3 g a.s./ha	KCP 10.3.2.1-01 Angayarkanni, V., 2020 6121/2019
<i>Aleochara bilineata</i>	Ferric phosphate 2.9% GB	Laboratory test quartz sand (2D) 193.1 – 1272.3 g a.s./ha	LR ₅₀ = 1156.73 g a.s./ha	KCP 10.3.2.1-02 Angayarkanni, V., 2020. 6193/2019
Field or semi-field tests				
None				

9.7.1.1 Justification for new endpoints

There is no deviation from the EU agreed endpoints. Studies with the formulation HIERRO were done and the endpoints were used for the risk assessment.

According to the ESCORT 2 document, for special PPP formulations like granular formulations the Tier I testing proposed in the Escort scheme with laboratory studies on *T. pyri* and *A. rhopalosiphi* is not appropriate and that the recommendations of ESCORT 1 should be followed, i.e. the formulations should be tested on appropriate ground dwelling species. Therefore, Tier I study was conducted on soil inhabiting non-target arthropods, *Poecilus cupreus* and *Aleochara bilineata*.

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

9.7.2.1 Risk assessment for in-field exposure

FEROCIOUS is a granular bait intended for four applications per season with a maximum application rate of 50 g prod./ha (=500 g a.s./ha).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group “all crops” also covers the risk for non-target arthropods from all other intended uses (see 9.1.2).

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of HIERRO¹ in all crops

Intended use	All crops		
Active substance/product	Ferric phosphate		
Application rate (g/ha)	4 x 500		
MAF	2.7 (foliar)		
Test species Tier I	LR₅₀ (lab.) (g/ha)	PER_{in-field} (g/ha)	HQ_{in-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	Not applicable**		
<i>Aphidius rhopalosiphi</i>	Not applicable**		
<i>Poecilus cupreus</i>	>1272.3	1350	1.06
<i>Aleochara bilineata</i>	1156.73		1.17
Intended use	All crops		
Active substance/product	Ferric phosphate		
Application rate (g/ha)	4 x 500		
MAF	3.4 (soil)		
Test species Tier I	LR₅₀ (lab.) (g/ha)	PER_{in-field} (g/ha)	HQ_{in-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	Not applicable**		
<i>Aphidius rhopalosiphi</i>	Not applicable**		
<i>Poecilus cupreus</i>	>1272.3	1700	1.34
<i>Aleochara bilineata</i>	1156.73		1.47

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.

* If an LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

** ESCORT 2 hazard quotients calculations are not suitable for formulations which are to be applied as granular treatments. In the case of granular formulations ESCORT 2 states that risk assessment methodology provided in ESCORT 1 should be followed, i.e. the formulations should be tested on appropriate ground dwelling species. Therefore, the risk assessment is based on the relevant toxicity test on *Poecilus cupreus* and *Aleochara bilineata*.

¹ the data for formulation 2.9 %GB

zRMS comment:

Accepted, the available data for similar formulation Ferocious 2.9 %GB indicated that the risk to non-target arthropods is acceptable.

The risk in –field provided by the applicant for two soil NTA such as *Poecilus cupreus* and *Aleochara bilineata* was considered acceptable by zRMS.

Furthermore, since the product is a pellet applied to bare soil or around plants, it is considered that the potential for exposure in non-treated areas via drift will be minimal and as such an assessment of the off-field risk is not required and only the in-field risk requires consideration. SANCO (2002) guidance on terrestrial risk assessment indicates that studies with *Hypoaspis aculeifer* and *Folsomia candida* can be used to address the risk to non-target arthropods for solid formulations such as pellets/granules. Studies on the toxicity of the formulation to *Hypoaspis aculeifer* and *Folsomia candida* have been submitted and based on these results an acceptable risk to soil macro-organisms is demonstrated below. Therefore, acceptable risks to non-target arthropods is concluded based on studies provided by soil NTA as well as basis on the risk assessment for *Hypoaspis aculeifer* and *Folsomia candida* provided below.

9.7.2.2 Risk assessment for off-field exposure

HIERRO are non-dusty baits used against slugs and snails in ornamentals and different edible and non-edible crops. Since the granules are directly spread onto soil surface, off-field exposure to non-target arthropods from dust drift is expected to be minimal.

Due to this negligible exposure to the formulation in off-field areas, it is considered that the risk to off-field non-target arthropods is acceptable.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

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

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with Ferric phosphate. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of HIERRO were not evaluated as part of the EU assessment of Ferric phosphate. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2. These studies were performed using a formulation with 2.97% iron phosphate, however the recipe was the same than the present one, hence the results are considered valid for the evaluation.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	Preparation 'NEU 1165 M'	Acute	LC ₅₀ > 1000 mg Prod./kg d.w.soil LC ₅₀ > 10 mg as/kg d.w.soil	EFSA Journal 2015;13(1):3973

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	Preparation 'Ferric orthophosphate RB 1.62 W'	Acute	LC ₅₀ > 1000 mg prod./kg d.w.soil LC ₅₀ > 16.2 mg as/kg d.w.soil	EFSA Journal 2015;13(1):3973
<i>Eisenia fetida</i>	Preparation 'NEU 1165 M'	Chronic 8 weeks	NOEC = 50000 mg prod./m ² NOEC = 6.7 mg as/kg ^a (highest test concentration)	EFSA Journal 2015;13(1):3973
<i>Eisenia fetida</i>	Preparation 'Ferric orthophosphate RB 1.62 W'	Chronic 8 weeks	NOEC = 1000 mg prod./kg d.w.soil NOEC = 16.2 mg as/kg d.w.soil (highest test concentration)	EFSA Journal 2015;13(1):3973
<i>Eisenia fetida</i>	Ferric phosphate 2.9% GB	Mixed into substrate 28 d, chronic 5 % peat content	NOEC >1000 mg/kg dw (>27.6 mg a.s./kg dw)	KCP 10.4.1.1 Halappa, R., 2019. G14350
<i>Folsomia candida</i>	Preparation 'Ferric orthophosphate RB 1.62 W'	Chronic 28 d	NOEC ≥ 1000 mg prod./kg d.w.soil NOEC ≥ 16.2 mg as/kg d.w.soil (highest test concentration)	EFSA Journal 2015;13(1):3973
<i>Hypoaspis aculeifer</i>	Ferric phosphate 2.9% GB*	Mixed into substrate 14 d, chronic 5 % peat content	NOEC >1000 mg/kg dw (>28.4 mg a.s./kg dw)	KCP 10.4.2.1-01 Rajeshwari, S., 2019. 6077/2019
<i>Folsomia candida</i>	Ferric phosphate 2.9% GB*	Mixed into substrate 28 d, chronic 5 % peat content	NOEC >1000 mg/kg dw (>28.4 mg a.s./kg dw)	KCP 10.4.2.1-02 Murali, K., 2019. 6076/2019
Field studies				
Not required				
Litter bag test				
Not required				

^a assuming a density of soil of 1.5 kg/L and a soil depth of 5 cm

¹ the data for formulation 2.9 %GB

9.8.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones, except for formulation, corresponding to data proper to HIERRO formulation.

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for Ferric phosphate.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group “all crops” also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2).

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of HIERRO

Intended use	All crops		
Chronic effects on earthworms			
Product/active substance	NOEC (mg a.s./kg dw)	PEC _{soil} * (mg/kg dw)	TER _{tt} (criterion TER ≥ 5)
Ferric phosphate (NEU 1165 M)	>6.7	2.667	>2.51
Ferric phosphate (Ferric orthophosphate RB 1.62W)	>16.2	2.667	>6.07
Ferric phosphate 2.9% GB ¹	>27.6	2.667	>10.35
Chronic effects on other soil macro- and mesofauna			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{tt} (criterion TER ≥ 5)
Ferric phosphate (<i>Folsomia candida</i>)	>16.2	2.667	>6.07
Ferric phosphate 2.9% GB (<i>Folsomia candida</i>) ¹	>28.4	2.667	>10.65
Ferric phosphate 2.9% GB (<i>Hypoaspis aculeifer</i>) ¹	>28.4	2.667	>10.65

TER values shown in bold fall below the relevant trigger.

¹ Endpoint based on the active substance (mg a.s./kg dw)

*PECs agreed in e-fate expert in Section 8.

The TER value for earthworms was below the trigger of 5 when the NOEC from the study with NEU 1165 M formulation (>6.7 mg a.s./kg soil) was considered. However it has to be noted that 6.7 mg a.s./kg soil was the maximum tested dose in the study and the resulting NOEC is above such maximum dose. Another formulation in the EFSA conclusions was tested on earthworms, Ferrix orthophosphate RB 1.62 W, given a NOEC = 16.2 mg a.s./kg d.w. soil, which again is the maximum tested dose in the study; and when considering this endpoint for the risk assessment, the TER was above trigger. The endpoint obtained with the Sharda study, NOEC >27.6 mg a.s./kg d.w. soil, is also above the maximum tested dose in the study and the TER value showed no risk.

In addition to this, it has to be noted that iron is present in all soils being a constituent of several minerals and that the amount of iron added to the soil after application of the product is negligible in comparison to the quantities which naturally exist in soil. Both iron and in particular phosphate are applied in considerable amounts to agricultural soils in fertilisers. Furthermore, when used according to the intended GAP, the product will be eaten up by the slugs, so that concentrations in the soil will also be far lower than the calculated PEC values.

Therefore, considering all the above information it can be concluded that the risk to earthworms is acceptable.

zRMS comment:

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for Ferric phosphate.

All TER_{LT} values for earthworm and soil macro - organism from exposure of similar formulation 2.9%GB in comparison to ppp Hierro (expressed in a.s./kg dws) were above trigger of 5 indicating an acceptable risk.

It should be noted that from the EFSA conclusion it appears that one of the lines of evidence considered in the weight-of-evidence approach used to conclude an acceptable risk to earthworms from the representative formulation 'NEU 1165 M' during the EU review was the absence of effects in the laboratory and field studies.

- The comparison of ferric phosphate from pesticide application to background levels in the EU review is equally applicable for the use of Hierro. In fact, given the similar application rate compared to the representative formulation, soil concentrations for Hierro will be the same or lower. Concentrations of iron and phosphate in soil from application of Hierro can be expected to be low compared to background levels, as concluded in the EU review.
- In the RAR for ferric phosphate a study by Edwards et al. (2006) is reviewed by the RMS. In this study the effects of the combination of ferric phosphate and chelating agents on earthworms were investigated in laboratory and microcosm tests. The acute toxicity to earthworms was assessed in a laboratory test and the LC50 when exposed to ferric phosphate and the chelating agent in combination was 78.16 mg/kg soil, compared to 156.46 mg/kg soil for the chelating agent in isolation and >10000 mg/kg soil for ferric phosphate in isolation. However, the RMS noted that results from the microcosm test showed that survival and body weights were not significantly different from control for any of the treatment groups tested (i.e. the combination of ferric phosphate and chelating agent did not lead to a significant increase in mortality or affect bodyweight relative to the negative control or to ferric phosphate or the chelating agent in isolation). Therefore, the RMS concluded that there is no clear evidence that formulations of ferric phosphate combined with chelating agents may present significant environmental hazards to earthworms.

During the peer review of ferric phosphate, a data requirement (5:9) was set regarding the risk to soil macro-organisms. The RAR was updated to address this point and the requirement was concluded to be addressed on the following basis (taken from the evaluation table): '*A low risk was concluded to soil macro-organisms considering that the amount of ferric phosphate present at soil surface which goes into solution will be present as elemental iron ions and HPO₄²⁻ and H₂PO₄⁻ ions and that the amounts of these ions in the upper soil layers consequent from the representative uses will be limited compared to background levels.*' This indicates that soil background levels were the key factor in concluding acceptable risks rather than results from the toxicity studies.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

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

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with Ferric phosphate. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of HIERRO were not evaluated as part of the EU assessment of Ferric phosphate. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Ferric phosphate	Not required.		
C-mineralisation	Ferric phosphate	Not required.		
N-mineralisation	Preparation 'NEU 1165 M'	56 d	22.2 % effect at day 56 at 666.67 mg Prod/kg d.w.soil	EFSA Journal 2015;13(1):3973
C-mineralisation	Preparation 'NEU 1165 M'	42 d	19.73 % effect at day 42 at 666.67 mg Prod/kg d.w.soil	EFSA Journal 2015;13(1):3973
N-mineralisation	HIERRO*	28 d, sandy clay loam soil	2.33% at 1333.32 mg f.p./kg soil (12.53 mg a.s./kg soil) 4.94% at 3333.30 mg f.p./kg soil (31.33 mg a.s./kg soil)	KCP 10.5-01 Anand, H. S., 2019 G14362
C-mineralisation	HIERRO*	28 d, sandy clay loam soil	8.78% at 1333.32 mg f.p./kg soil (12.53 mg a.s./kg soil) 12.36% at 3333.30 mg f.p./kg soil (31.33 mg a.s./kg soil)	KCP 10.5-02 Anand, H. S., 2019 G14361

*Ferric phosphate 2.9% GB

9.9.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones, except for formulation, corresponding to data proper to HIERRO formulation

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group "all crops" also covers the risk for the soil microorganisms from all other intended uses in groups (see 9.1.2).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of HIERRO in all crops

Intended use		All crops	
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Ferric phosphate	666.67 mg prod/kg d.w.soil (6.6 mg a.s./kg d.w.soil*)	2.667	Yes
HIERRO ¹	31.33 mg/kg soil	2.667	Yes
C-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Ferric phosphate	666.67 mg prod/kg d.w.soil (6.6 mg a.s./kg d.w.soil*)	2.667	Yes
HIERRO ¹	31.33 mg/kg soil	2.667	Yes

* Considering nominal purity of 9.9 g a.s./kg

¹ Endpoint based on the active substance (mg a.s./kg dw)

zRMS comment:

According to the EFSA Conclusion on the peer-review of the pesticide risk assessment of the active substance ferric phosphate (EFSA Journal 2015;13(1):3973); “A low risk was also concluded on soil micro-organisms and non-target terrestrial plants”.

The data requirements for soil micro-organisms according to Commission Regulation (EU) No 284/2013 are fulfilled. The risk assessment for soil micro-organisms is carried out according to the Guidance document on terrestrial ecotoxicology (SANCO/10329, 17 October 2002).

The endpoints presented are according to the LoEP (2015). A formulation study is also available. The risk is acceptable at the maximum PECs agreed at in Section 8 and at first tier risk assessment with effects of < ± 25% on nitrogen transformation.

The zRMS concludes that there is no unacceptable risk for soil micro-organisms when the product is used in accordance with the recommended use pattern.

9.9.3 Overall conclusions

Based on the risk assessment presented above, the risk to soil microorganisms from the proposed uses of HIERRO is considered to be acceptable.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

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

Effects on non-target terrestrial plants of HIERRO were not evaluated as part of the EU assessment of ferric phosphate. However, the provision of further data on the formulation HIERRO is not considered essential. Ferric phosphate is an inorganic salt naturally occurring in the environment. It is transformed into iron and phosphate by microorganisms and is then bioavailable for plants. In general, these ions are

taken up by plants as nutrients. Moreover, HIERRO is a non-dusty granular bait intended for use as a molluscicide applied to the soil surrounding plants. Therefore, no unacceptable effects are expected on non-target flora after application of HIERRO.

9.10.1.1 Justification for new endpoints

Not relevant.

9.10.2 Risk assessment

zRMS comment:

According to the EFSA Conclusion on the peer-review of the pesticide risk assessment of the active substance ferric phosphate (EFSA Journal 2015;13(1):3973); “A low risk was also concluded on non-target terrestrial plants”.

In the EU review of ferric phosphate, no risk assessment was conducted as exposure was considered negligible. Therefore, in line with the EU review, no risk assessment is requested and the zRMS concludes that there is no unacceptable risk for non-target terrestrial plants when the product is used in accordance with the recommended use pattern.

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

Not relevant.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

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

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

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

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

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

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

HIERRO	
Common name	Iron phosphate 1.0% GB
Classification and proposed labelling	
With regard to ecotoxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes, categories: Not classified Code(s) for hazard pictogram(s): - Signal word: - Hazard statement(s): - EU specific statements: EUH401 Precautionary statement: -

zRMS comment:

Agreed. No environmental classification is needed.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.
 MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2.1-01	XXXXXXX	2019	Iron phosphate 2.9% GB: Fish, acute toxicity test with rainbow trout. Study code: XXXXXXXX GLP, Unpublished	Y	Sharda Cropchem Limited
KCP 10.2.1-02	Halappa, R.	2019	Iron phosphate 2.9% GB. <i>Daphnia magna</i> , acute immobilisation test. Study code: G14346. Eurofins. GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-03	Halappa, R.	2019	Ferric Phosphate 2.9% GB: Alga, Growth Inhibition Test. Study code: G14345. Eurofins. GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.1-01	Angayarkanni, V.	2020	A laboratory test for evaluating the effects of Ferric phosphate 2.9% GB on the carabid beetle, <i>Poecilus cupreus</i> L. (Coleoptera, Carabidae). Study code: 6121/2019. Bioscience Research Foundation. GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.1-02	Angayarkanni, V.	2020	A laboratory test for evaluating the effects of Ferric phosphate 2.9% GB on the rove beetle, <i>Aleochara bilineata</i> (Gyllenhal). Study code: 6193/2019. Bioscience Research Foundation. GLP, Unpublished	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4.1.1	Halappa, R.	2019	Iron phosphate 2.9% GB: Earthworm Reproduction Test. Study code: G14350. Eurofins. GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-01	Rajeshwari, S.	2019	Effect of Ferric phosphate 2.9% GB on the reproductive output of the predatory soil mite <i>Hypoaspis (Geolaelaps) aculeifer</i> Canestrini (Acari: Laelapidae) in artificial soil. Study code: 6077/2019. Bioscience Research Foundation. GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-02	Murali, K.	2019	Effect of Ferric phosphate 2.9% GB on reproduction of the collembolans (<i>Folsomia candida</i>) in artificial soil. Study code: 6076/2019. Bioscience Research Foundation. GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.5-01	Anand, H. S.	2019	Soil microorganisms: nitrogen transformation test of Iron phosphate 1.0% GB. Study code: G14362. Eurofins. GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.5-02	Anand, H. S.	2019	Soil microorganisms: carbon transformation test of iron phosphate 1.0% GB. Study code: G14361. Eurofins. GLP, Unpublished	N	Sharda Cropchem Limited

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the new studies

zRMS comment:

The studies for formulation Hierro for non-target organism were not provided by the applicant. Instead of the study for similar formulation 2.9 %GB were provided in the current dossier. zRMS agrees that no additional studies is required.

- A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates**
- A 2.1.1 KCP 10.1.1 Effects on birds**
- A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity**
- A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds**
- A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds**
- A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals**
- A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals**
- A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)**
- A 2.2 KCP 10.2 Effects on aquatic organisms**
- A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes**

Comments of zRMS:	<p>The study is considered valid. All validity criteria were met.</p> <p>Agreed endpoints: 96h LC₅₀ ≥18.29 mg/L (geometric mean of the measured concentrations). 96h LC₅₀ ≥0.5 mg/L (geometric mean of the measured concentrations of ferric phosphate). NOEC ≥18.29 mg/L (geometric mean of the measured concentrations); ≥0.5 mg/L</p>
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	(geometric mean of the measured concentrations).
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Reference: KCP 10.2.1-01

Report “Iron phosphate 2.9% GB: Fish, acute toxicity test with rainbow trout”.
Ramesh Halappa, 2019, G14344

Guideline(s): OECD Guideline No. 203 (1992)

Deviations: No

GLP: Yes

Acceptability: Yes

**Duplication
(if vertebrate study)** Yes

Materials and methods

Test item:

Description: Iron phosphate 2.9% GB
Production batch: SCL-58946
A.i. content: 2.76% w/w of ferric phosphate

Test system:

Species: Rainbow trout (*Oncorhynchus mykiss*)
Strain: -
Age: average body length: 4.1 cm ± 0.1 cm
Source: Fisheries department, Avalanchi Udhagamandalam - 643001
Acclimation period: 7 days
Diet: The fish were not fed during the test

Experimental conditions:

Temperature: 14.0 – 14.4°C
Dissolved O₂: 90 – 96%
Hardness: 2.38 mmol/L (as CaCO₃)
pH: 7.42 – 7.78
Light and photoperiod: 16h light and 8h dark.
Loading: 0.64 g fish/L test solution. Each aquarium comprised 7 fish and 5L test solution.

Test procedure: -

Experimental period: 96h

Test design and treatment

Semi-static system (96 hours) with renewals at every 24h interval (one replicate of each test item concentration and the control. Seven fish were introduced into each aquarium).

Based on the results of the range finding test, the definitive test was carried out using semi-static method at the test concentration of 120 mg/L (against the guideline requirement of 100 mg/L due to solubility limit of test item in test medium and analytical restrictions) along with a control. The calculated geometric mean measured concentrations was 18.29 mg/L. The fish were observed for visible abnormalities like loss of equilibrium, changes in swimming and breathing patterns and mortality after 3, 6, 24, 48, 72 and 96 h of exposure.

The concentrations of ferric phosphate were chemically determined using a validated method with ICP-MS detection. The concentrations of ferric phosphate were chemically determined in samples of all the test solutions along with control group at the start and at the end of all four 24h renewals.

The active ingredient concentration analysis showed that the percent agreement with claimed concentration of the samples analysed at the start and end of all four renewals were not within the acceptable limit (80 to 120 % of the claimed concentrations with an RSD of ≤ 20%): 10.26 to 21.09% at the start of all four 24h renewal and 17.03 to 25.26% at the end of all four 24h renewal. Hence, the test item concentration was recalculated by taking geometric mean values from the analysis results at the start and end of all four renewals. The calculated geometric mean of the measured concentrations was 18.29 mg/L against the claimed concentration of 120 mg/L.

Results

There were no mortality and toxic signs observed in control group and test item concentration of 120 mg/L up to 96 h exposure. No toxic signs in treated fish were observed at any of the tested concentrations up to 96 h exposure.

On the basis of the observations made during this test, the NOEC was 18.23 mg/L (0.5 mg a.i./L), based on the geometric mean of the measured concentrations.

The LC₅₀ value for iron phosphate 2.9% GB at 96 h was higher than 18.29 mg test item/L or 0.5 mg a.i./L, based on the geometric mean of the measured concentrations.

Validity criteria

The test was considered valid because:

- The mortality in the control was 0% at exposure termination (should not exceed 10%);
- The pH of the test solutions was ranged from 7.42 to 7.78 and the temperature of the test solutions was 14.0 to 14.4°C which is within one unit variation during the test.
- Dissolved oxygen saturation of the test solution range from 90 to 96% (obligatory above 60% of air saturation value).

Conclusion

The 96h LC₅₀ value is ≥ 18.29 mg/L (geometric mean of the measured concentrations).

The 96h LC₅₀ value is ≥ 0.5 mg/L (geometric mean of the measured concentrations of ferric phosphate).

The 96h No-Observed Effect Concentration (NOEC) is ≥ 18.29 mg/L (geometric mean of the measured concentrations); ≥ 0.5 mg/L (geometric mean of the measured concentrations).

Comments of zRMS:	The study is considered valid. All validity criteria were met. Agreed endpoints: The EC ₅₀ /48 h ≥ 15.19 mg/L The NOEC/48 h ≥ 15.19 mg/L The EC ₅₀ /48 h ≥ 0.42 mg/L The NOEC/48 h ≥ 0.42 mg/L
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Reference:	KCP 10.2.1-02
Report	“Iron phosphate 2.9% GB. <i>Daphnia magna</i> , acute immobilisation test”, Ramesh Halappa (2019), Report No. G14346
Guideline(s):	OECD Guideline No. 202 (2004)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

Immobilisation of *Daphnia magna* (< 24 hours old) exposed to the test item Iron phosphate 2.9% GB (batch No. SCL-58946) was investigated during a 48-hour static test. Based on the results of the range finding test, a limit test concentration of 100 mg/L (respective mean measure concentration was 15.19 mg/L) was selected for the definitive test along with control. Four replicates per each test item concentration and the control with five daphnids per replicate were used. The *Daphnia magna* were observed for immobilisation after 24 and 48 h of exposure.

The concentrations of ferric phosphate were chemically determined using a validated method with ICP-MS detection. All test item concentrations along with the control were analysed for the test item concentration at the beginning and end of test. The active ingredient concentration analysis showed that the percent agreement with claimed concentration of the samples of all the analysis were not within the acceptable limit (80 to 120% of the claimed concentration with an RSD of $\leq 20\%$): 15.81% at the start of the test and 14.57 at the end of the test. Hence, the test item concentration was recalculated by taking mean value from the analysis results. The calculated mean of the measured concentrations was 15.19 mg/L against the claimed concentration of 100 mg/L.

Results

Range finding test

No immobility of the daphnia was observed in the control as well as at any of the tested concentrations: 0.1, 1, 10, 50 and 100 mg/L at 24 and 48 h of exposure.

Definitive test

There was no immobilization of daphnia in the control and at the mean measured concentration of 15.19 mg/L at 24 and 48 h of exposure.

Table 1 Immobilization of *Daphnia magna*, definitive test

Nominal test item concentration [mg/L]	Number of <i>Daphnia magna</i>	Number of immobilized <i>Daphnia magna</i>								Total of immobilised <i>Daphnia magna</i> [%]	
		24 h				48 h					
		Replicates								24 h	48 h
		A	B	C	D	A	B	C	D		
Control (0.0)	20	0	0	0	0	0	0	0	0	0	0
15.19	20	0	0	0	0	0	0	0	0	0	0

Validity criteria

The test met all the validity criteria:

- The immobilization of *Daphnia magna* in the control was 0%.
- The dissolved oxygen concentrations in the test vessels were within the range of 8.2 – 9.1 mg/L (criterion: not less than 3 mg/L).

Conclusion

The endpoint values determined based on nominal test item concentrations:

The EC₅₀/48 h is ≥ 15.19 mg/L

The NOEC/48 h is ≥ 15.19 mg/L

The endpoint values based on the nominal concentrations of ferric phosphate in the test item:

The EC₅₀/48 h is ≥ 0.42 mg/L

The NOEC/48 h value is ≥ 0.42 mg/L

Comments of zRMS:	The study is considered valid. All validity criteria were met. Agreed endpoints The E _{r,y} C ₅₀ > 11.46 mg test item/L correspond to 0.32 mg Iron Phosphate/L.
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Reference: KCP 10.2.1-03

Report “Ferric Phosphate 2.9% GB: Alga, Growth Inhibition Test”, Ramesh Halappa (2019), Report No. G14345. Eurofins Advinus Limited

Guideline(s): OECD Guideline No. 201 (2006)

Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

The effect of Ferric Phosphate 2.9% GB was tested on the growth of freshwater single cell green alga *Pseudokirchneriella subcapitata*.

A range finding test resulted in the 0.7, 2.7, 0.3, 1.3, 0 and 0.3 reduction in cell biomass at the tested concentrations of 0.01, 0.1, 1, 10, 50 and 100 mg/L at 72h post treatment, respectively.

The alga was exposed to the test item at the nominal limit test concentration of 100 mg/L (respective mean measured concentration was 11.46 mg/L) along with a control. The cell growth was measured at 24, 48 and 72 hours after the initiation of the test.

The concentration/effect relationship was determined using two factors namely growth rate and yield at the end of the test (72 hours).

The test item was recoverable at claimed concentrations of 3.100 and 124.0 mg/L in the test medium. The active ingredient concentration analysis in all test concentration showed that the recovery with the nominal concentration was 12.24% at the start of the test and 10.68% at the end of the test (72 h). Since the analysis of results of samples drawn at the start and end of the test was less than the acceptable limit (80 to 120% of the claimed concentration with an RSD of $\leq 20\%$). Hence the nominal concentration of test item group was recalculated and presented as mean measured concentration.

Results

Preliminary test

The test item exhibited 0, 0.25, 0.49, 0.49, 0.82, 2.49 and 16.53% cell reduction at the tested concentrations of 0.0001, 0.001, 0.01, 0.1, 1, 10 and 100 mg/L.

Table 10.2.1-03.1 Average cell biomass, preliminary test (non-GLP)

Nominal test item concentration [mg/L]	Average cell counts ($\times 10^4$ cells/mL)				% Reduction at end of test
	0 h	24 h	48 h	72 h	
Control	1	6.0	17.8	75.3	-
0.01	1	6.3	17.0	74.8	0.7
0.1	1	6.3	17.0	73.3	2.7
1	1	6.3	17.5	75.0	0.3
10	1	6.3	16.3	74.3	1.3
50	1	6.0	16.5	75.8	-0.7*
100	1	6.5	16.0	75.0	0.3

* to be considered as zero

Definitive test

At mean measured concentration of 11.46 mg/L, the observed growth rate and yield of algal biomass was comparable with the control during the test period.

Observed cells were found morphologically normal.

The EC₅₀ value for growth rate and yield on the basis of the mean measured concentration of the test item was higher than 11.46 mg test item/L or 0.32 mg Iron Phosphate/L.

Table X.2 Growth rate and yield inhibition, definitive test

Nominal test item concentration [mg/L]	% inhibition after 72 h of exposure (growth rate)	% inhibition after 72 h of exposure (yield)
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Control	-	-
11.46	-0.56*	-2.45*

Note: Respective nominal test item concentration for G2 is 100 mg/L.

* To be considered as zero

Validity criteria

In the definitive test, the following validity criteria specified in OECD Guideline No. 201 (2006) were met:

- There was an increase in cell concentration of the negative control culture by a factor of 70.83 which is more than the required factor limit of at least 16 at the end of the test.
- The mean coefficient of variation for section by section specific growth rates in the negative control cultures during the course of the test was 21.02 % which is within the required limit of 35%.
- The coefficient of variation of average growth rate between replicate cultures of negative control was 0.40% which is within the required limit of 7 %.

Conclusion

The EC₅₀ value for growth rate and yield on the basis of the mean measured concentration of the test item was higher than 11.46 mg test item/L or 0.32 mg Iron Phosphate/L.

A 2.2.2	KCP 10.2.2	Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms
A 2.2.3	KCP 10.2.3	Further testing on aquatic organisms
A 2.3	KCP 10.3	Effects on arthropods
A 2.3.1	KCP 10.3.1	Effects on bees
A 2.3.1.1	KCP 10.3.1.1	Acute toxicity to bees
A 2.3.1.1.1	KCP 10.3.1.1.1	Acute oral toxicity to bees
A 2.3.1.1.2	KCP 10.3.1.1.2	Acute contact toxicity to bees
A 2.3.1.2	KCP 10.3.1.2.	Chronic toxicity to bees
A 2.3.1.3	KCP 10.3.1.3	Effects on honey bee development and other honey bee life stages
A 2.3.1.4	KCP 10.3.1.4	Sub-lethal effects
A 2.3.1.5	KCP 10.3.1.5	Cage and tunnel tests
A 2.3.1.6	KCP 10.3.1.6	Field tests with honeybees

A 2.3.2 KCP 10.3.2 Effects on non-target arthropods other than bees

A 2.3.2.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

Comments of zRMS:	<p>The study is considered valid. All validity criteria were met.</p> <ul style="list-style-type: none"> • Mortality in the control group: 0.0% (criterion: a maximum total mortality of 2 beetles (6.7%) is acceptable for the water control group after 2 weeks), • Mortality in the reference group: 100% (criterion: 65 ± 35% after 2 weeks). <p>Agreed endpoints: LR₅₀ >44.8 L/ha, i.e. >1272.3 g Ferric phosphate/ha. NOER >44.8 L/ha, i.e. >1272.3 g Ferric phosphate/ha. ER₅₀ >44.8 L/ha, i.e. >1272.3 g Ferric phosphate/ha. NOER >44.8 L/ha, i.e. >1272.3 g Ferric phosphate/ha.</p>
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Reference:	KCP 10.3.2.1-01
Report	“A laboratory test for evaluating the effects of Ferric phosphate 2.9% GB on the carabid beetle, <i>Poecilus cupreus</i> L. (Coleoptera, Carabidae)”, Dr. V. Angayarkanni, 2020, 6121/2019. Bioscience Research Foundation
Guideline(s):	ESCORT 1 (Barrett K. L. <i>et al.</i> , 1994) ESCORT 2 (Candolfi M.P. <i>et al.</i> , 2001) Guidelines developed by the IOBC, BART and EPPO Joint Initiative (Heimbach U. <i>et al.</i> , 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

A laboratory test for evaluating the effects of Ferric phosphate 2.9% GB on mortality of the carabid beetle, *Poecilus cupreus* L. (Coleoptera, Carabidae) and its food consumption was conducted for Sharda Cropchem Ltd, India at Bioscience Research Foundation, India according to the ESCORT 1 and the ESCORT 2 guidance documents, the guidelines developed by the IOBC, BART and EPPO Joint Initiative, and the study plan.

The study was carried out based on Sponsor recommended rates for the test item as the definitive test, i.e. 6.8, 10.9, 17.5, 28.0 and 44.8 L/ha. The quartz sand was used as test substrate, whereas the carabid beetle, *Poecilus cupreus* L. (Coleoptera, Carabidae) was used as test organism.

Each tested group consisted of 30 test organisms, divided in 5 parallel replicates, each containing 3 adult male and 3 adult female. The conditions of the test organisms were recorded during 14 days. Mortality was assessed after 2 hours and after 1, 2, 4, 7, 10 and 14 days. The toxicity effects of the test item were also observed. Food consumption was recorded on 2, 4, 7, 10 and 14 days after the exposure by evaluation of the fly pupae, which was consumed and untouched.

Mortality and mean food consumption by the beetles after 14 days of exposure were the endpoints. To verify the sensitivity of the biological test system and the precision of the test procedure, the insecticide, PARATHION (50% parathion, w/w) was used as reference item. The rate of the reference item was 9 mL/ha (4.5 g parathion/ha). The control group was treated with distilled water.

Results and discussions

Table 1: Mortality results.

Mortality							
Day after treatment	Control (0.0)	T1 (6.8)	T2 (10.9)	T3 (17.5)	T4 (28.0)	T5 (44.8)	Paration (9 mL/ha)
Mortality in 1 st week (%)	0.0	0.0	0.0	0.0	0.0	0.0	100
Corrected mortality (%)	-	-	-	-	-	-	-
Mortality in 2 nd week (%)	0.0	0.0	0.0	0.0	0.0	0.0	-
Corrected mortality (%)	-	-	-	-	-	-	-
Mortality in the experiment (%)	0.0	0.0	0.0	0.0	0.0	0.0	100
Corrected mortality (%)	-	-	-	-	-	-	-
LR50_{mortality}	> 44.8 L/ha > 1272.3 g a.i./ha*						
NOER_{mortality}	> 44.8 L/ha > 1272.3 g a.i./ha*						
Food consumption							
Day after treatment	Control (0.0)	T1 (6.8)	T2 (10.9)	T3 (17.5)	T4 (28.0)	T5 (44.8)	Paration (9 mL/ha)
Mean number of consumed flies/beetle in 1 st week	1.0	1.0	1.0	1.0	1.0	1.0	0.4
Reduction in consumption in 1 st week (%)	-	-	-	-	-	-	60.0
Mean number of consumed flies/beetle in 2 nd week	1.0	1.0	1.0	1.0	1.0	1.0	-
Reduction in consumption in 2 nd week (%)	-	-	-	-	-	-	-
Mean number of consumed flies/beetle in the experiment	1.0	1.0	1.0	1.0	1.0	1.0	0.4
Reduction in consumption in the experiment(%)	-	-	-	-	-	-	60.0
ER50_{consumption}	> 44.8 L/ha > 1272.3 g a.i./ha*						
NOER_{consumption}	> 44.8 L/ha > 1272.3 g a.i./ha*						

Findings:

- The validity criterion for mortality was met, because mortality of the control was 0.0% (criterion: ≤6.7% after 14 days), whereas mortality of the beetles after exposure to Ferric phosphate 2.9% GB at rates of 6.8, 10.9, 17.5, 28.0 and 44.8 L/ha was 0.0, 0.0, 0.0, 0.0 and 0.0% respectively. Due to no mortality at all rates of the test item statistical analysis were not performed.
- For the reference item, the mortality of the beetles at the rate of 9.0 mL/ha was 100%, hence the criterion (65 ± 35%) specified in the method description was met. The results showed that the test organisms were sensitive to parathion.
- The mean number of consumed flies per beetles in the control group during the experimental period was 1.0, whereas in the group treated with Ferric phosphate 2.9% GB at rates of 6.8, 10.9, 17.5, 28.0 and 44.8 L/ha was 1.0, 1.0, 1.0, 1.0 and 1.0 respectively. Reduction of food consumption in the group treated with Ferric phosphate 2.9% GB at rates of 6.8, 10.9, 17.5, 28.0 and 44.8 L/ha during the experimental period was 0.0, 0.0, 0.0, 0.0 and 0.0% respectively in comparison with the control group. Due to similar values obtained for the control and for all rates of the test item statistical analysis were not performed.

Conclusion

The rate of Ferric phosphate 2.9% GB causing a 50% mortality of the beetles within the exposure period (LR₅₀) is >44.8 L/ha, i.e. >1272.3 g Ferric phosphate/ha.

The highest rate at which Ferric phosphate 2.9% GB is observed to have no statistically significant effects on mortality of the beetles (NOER) is >44.8 L/ha, i.e. >1272.3 g Ferric phosphate/ha.

The rate of Ferric phosphate 2.9% GB causing a 50% in food consumption by the beetles within the exposure period (ER₅₀) is >44.8 L/ha, i.e. >1272.3 g Ferric phosphate/ha.

The highest rate at which Ferric phosphate 2.9% GB is observed to have no statistically significant effects on food consumption of the beetles (NOER) is >44.8 L/ha, i.e. >1272.3 g Ferric phosphate/ha.

zRMS comment:

The study is considered valid. All validity criteria were met.

Agreed endpoint:

LR₅₀ = 40.73 L ferric phosphate 2.9% GB/ha, i.e., 1156.73 g Ferric phosphate a.i./ha.

NOER_{mortality} = 17.5 L ferric phosphate 2.9% GB/ha, i.e., 497.0 g Ferric phosphate a.i./ha.

ER₅₀ = 40.98 L Ferric phosphate 2.9% GB/ha, i.e., 1163.83 g Ferric phosphate a.i./ha.

NOER_{fecundity} = 10.9 L Ferric phosphate 2.9% GB/ha, i.e., 309.6 g Ferric phosphate a.i./ha.

Reference:	KCP 10.3.2.1-02
Report	“A laboratory test for evaluating the effects of Ferric phosphate 2.9% GB on the rove beetle, <i>Aleochara bilineata</i> (Gyllenhal)”, Dr. V. Angayarkanni, 2020, 6193/2019. Bioscience Research Foundation
Guideline(s):	ESCORT 1 (Barrett K. L. <i>et al.</i> , 1994) ESCORT 2 (Candolfi M.P. <i>et al.</i> , 2000) Guidelines developed by the IOBC, BART and EPPO Joint Initiative (Grimm C. <i>et al.</i> , 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The laboratory test for evaluating the effects of Ferric phosphate 2.9% GB on mortality and fecundity of rove beetle, *Aleochara bilineata* (Gyllenhal) was conducted for Sharda Cropchem Ltd, India at Bioscience Research Foundation.

The study was carried out based in Sponsor recommended rates for the test item as the definitive test, i.e. 6.8, 10.9, 17.5, 28.0 and 44.8 Kg/ha. Quartz sand was used as test substrate, whereas rove beetles, *Aleochara bilineata* (Gyllenhal) were used as test organisms. Each group was divided into four replicates. There were 20 adult beetles (10 females and 10 males) in each replicate.

The duration of the study was 77 days and included the following phases: exposure phase (mortality assessment) – 4 weeks (28 days), drying substrate phase – 1 week (7 days) and hatching (production of offsprings) phase (fecundity assessment) – 6 weeks (42 days). After 7, 14 and 21 days post-application, approximately 500 unparasitised onion fly (*Delia antiqua*) pupae were added to each test vessel. After 28 days post-application, the remaining parental generation of adults were removed and counted and the soil was left to dry for a further 7 days, after which the soil was sieved to separate the host puparia. Fecundity was assessed daily by counting the number of offspring produced over 42 days.

Mortality of the beetles after 28 days of exposure and fecundity after the 6-week period were the end-points.

To verify the sensitivity of the biological test system and the precision of the test procedure, the insecticide, ROGOHIT (30% dimethoate, w/w) was used as a reference item. The rate of the reference item was 5.0 mL/ha (1.5 g dimethoate/ha). The control group was treated with distilled water.

Results and discussions

Table 10.3.2.1-02.1: Mortality and fecundity results.

Study group (application rate) [L/ha]	Mortality		Fecundity	
	Total [%]	Corrected [#] [%]	Offspring produced [No]	Fecundity reduction [%]
Control				
0.0	0.00	-	870.0	-
Ferric phosphate 2.9% GB				
6.8	0.00	0.00	861.3	1.01
10.9	1.25	1.25	819.5	5.80
17.5	12.5	12.50	752.0	13.56 ⁺
28.0	35	35.00 ⁺	550.8	36.70 ⁺
44.8	51.25	51.25 ⁺	421.5	51.55 ⁺
Reference item – ROGOHIT (DIMETHOATE 30% EC)				
5.0 (mL/ha)	93.75	93.75 ⁺	77.25	91.03 ⁺
Endpoints	LR50_{mortality}	40.73 L/ha (1156.73 g a.i./ha)	ER50_{fecundity}	40.98 L/ha (1163.83 g a.i./ha)
	NOER_{mortality}	17.5 L/ha (497.0 g a.i./ha)	NOER_{fecundity}	10.9 L/ha (309.6 g a.i./ha)

[#]: Mortality corrected according to Abbott's formula:

Corrected mortality [%] = ((Mt – Mc) / (100 – Mc)) x 100; Mt = Mortality treated, Mc = Mortality control.

⁺: Statistically significant difference between the control and the treatment group at $p < 0.05$

Validity criteria

The validity criteria were met, because the mean number of beetles emerging from the fly pupae in the control was 870.0 (criterion: >400) and the reduction in the reproduction of beetles in the reference group was 91.03 (criterion: ≥50%).

Conclusion

On the basis of the obtained mortality results, the **LR₅₀** value is **40.73 L ferric phosphate 2.9% GB/ha, i.e., 1156.73 g Ferric phosphate a.i./ha**. The **NOER_{mortality}** value is **17.5 L Ferric phosphate 2.9% GB/ha, i.e., 497.0 g Ferric phosphate a.i./ha**.

On the basis of the obtained fecundity results, the **ER₅₀** value is **40.98 L Ferric phosphate 2.9% GB/ha, i.e., 1163.83 g Ferric phosphate a.i./ha**. The **NOER_{fecundity}** value **10.9 L Ferric phosphate 2.9% GB/ha, i.e., 309.6 g Ferric phosphate a.i./ha**.

Conclusion: On the basis of the obtained results, it can be concluded that **Ferric phosphate 2.9% GB** had no adverse effects on mortality of the beetles at the rates of 6.8, 10.9 and 17.5 L/ha and had no adverse effects on fecundity of the beetles at the rates of 6.8 and 10.9 L/ha.

A 2.3.2.2 KCP 10.3.2.2 Extended laboratory testing, aged residue with non-target arthropods

A 2.3.2.3 KCP 10.3.2.3 Semi-field studies with non-target arthropod

Not required.

A 2.3.2.4 KCP 10.3.2.4 Field studies with non-target arthropods

Not required.

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS:	<p>zRMS comment:</p> <p>The study is considered valid. All validity criteria were met.</p> <p>Agreed endpoints:</p> <p>NOEC_{rep} of Ferric phosphate 2.9% GB ≥1000 mg/kg dry soil (27.6 mg Iron phosphate/kg dry soil). EC_{10rep} of Ferric phosphate 2.9% GB ≥1000 mg/kg dry soil (27.6 mg Iron phosphate/kg dry soil). EC_{50rep} of Ferric phosphate 2.9% GB ≥1000 mg/kg dry soil (27.6 mg Iron phosphate/kg dry soil).</p>
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Reference:	KCP 10.4.1.1
Report	“Iron phosphate 2.9% GB: Earthworm Reproduction Test”. Ramesh Halappa, 2019, G14350. Eurofins Advinus Limited
Guideline(s):	OECD Guideline No. 222 (2004)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Ferric phosphate 2.9% GB; Batch Number SCL-58946; active substance: 2.76% w/w
Test species:	<i>Eisenia fetida</i> bred at test facility: Ecotoxicology Laboratory, Eurofins Advinus limited, Bengaluru 560 058, India. 4.5 to 5 month adults.
Soil:	5% sphagnum peat, 20% kaolin clay, 75% industrial sand
Study design:	Number of replicates: 4 replicates / concentration + 8 replicates / control Number of earthworms: 10 earthworms/replicate Test duration: 8 weeks

Application rates:	Control, 1000 mg/kg dry soil
Test conditions:	Temperature: 19.9 – 20.2 °C; humidity: 27.1 – 28.5%; lighting: 16 h light 8 h dark; light intensity: 526 – 560 lux; pH: 6.68 – 6.99
Statistical analysis:	The statistical analysis of the earthworm bodyweight and juvenile production data was carried out using licensed copies of SYSTAT Statistical package Ver.12.0. The body weight of adult earthworms at the end of first 4 week test and juvenile production data collected at the end of second 4 week test was tested for normality (Shapiro-Wilk test) and homogeneity of variances before performing further analysis. The body weight of earthworms and juvenile production data were found to be normal. Variance for body weight was heterogeneous and performed Mann-Whitney U Test. For juvenile production data variance were found to be homogeneous and performed two sample t-test.
Endpoints:	EC ₁₀ , EC ₅₀ , NOEC

Results and Conclusions

On the range finding test, there was no mortality of earthworms at any of the tested concentration till Day 28. No pathological and behavioral symptoms were observed during the test period in the control and treated groups. The reduction in the body weight of earthworms in test item treated groups was comparable with the control.

On the definitive test, there was no mortality of earthworms in control and test item treated group on Day 28. Adult mortality of 18.8% was recorded in reference substance group. Statistically there was no difference in body weight change of treated groups (except reference substance group which exhibited statistically significant change in body weight) when compared with the control group. No pathological and behavioral symptoms were observed during the test period in the control and treated groups (including reference substance).

The production of juveniles in the test item treated group was comparable with the control group since statistically it is found not significant. The juvenile production in the reference substance showed statistically significant from the control group. No pathological and behavioral symptoms were observed in juveniles on Day 56 in the control and treated groups (test item and reference substance). No cocoons were observed in any of the treatment groups.

Reference substance (Carbendazim) group exhibited statistically significant reduction in juvenile production at 3 mg a.i./kg dry soil as compared with the control. Hence the test has met the validity acceptance criteria that significant effects should be observed between 1 and 5 mg a.i./kg dry soil in a test. This result infers that the obtained results during this test are valid and hence test is acceptable.

The reproduction NOEC of Ferric phosphate 2.9% GB is equal or higher than 1000 mg/kg dry soil (27.6 mg Iron phosphate/kg dry soil).

The reproduction EC₁₀ of Ferric phosphate 2.9% GB is higher than 1000 mg/kg dry soil (27.6 mg Iron phosphate/kg dry soil).

The reproduction EC₅₀ of Ferric phosphate 2.9% GB is higher than 1000 mg/kg dry soil (27.6 mg Iron phosphate/kg dry soil).

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

Comments of zRMS:	zRMS comment:		
	The study is considered valid. All validity criteria were met.		
	Agreed endpoints:		
	Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]
	LC ₁₀	> 1000 (n.d.)	> 28.40 (n.d.)
	LC ₂₀	> 1000 (n.d.)	> 28.40 (n.d.)
	LC ₅₀	> 1000 (n.d.)	> 28.40 (n.d.)
	NOEC	≥ 1000	≥ 28.40
	LOEC	> 1000	> 28.40
	Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]
	EC ₁₀	> 1000 (n.d.)	> 28.40 (n.d.)
	EC ₂₀	> 1000 (n.d.)	> 28.40 (n.d.)
	EC ₅₀	> 1000 (n.d.)	> 28.40 (n.d.)

	NOEC	≥ 1000	≥ 28.40
	LOEC	> 1000	> 28.40
n.d. – not determined			

Reference:	KCP 10.4.2.1-01
Report	“Effect of Ferric phosphate 2.9% GB on the reproductive output of the predatory soil mite <i>Hypoaspis (Geolaelaps) aculeifer</i> Canestrini (Acari: Laelapidae) in artificial soil”. Ms. S. Rajeshwari, 2019, 6077/2019. Bioscience Research Foundation
Guideline(s):	OECD Guideline No. 226 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Ferric phosphate 2.9% GB; Batch Number SCL-600243; active substance: Ferric phosphate 2.84% (w/w)
Test species:	<i>Hypoaspis aculeifer</i> from BFR insectary. The collembolans used in the study were adult females (i.e. 33 rd day after the parental females have started egg laying).
Soil:	5% sphagnum peat; 20% kaolin clay; 75% air-dried industrial sand
Study design:	Number of replicates: 4 replicates / concentration + 8 replicates / control Number of collembolans: 10 females / replicate Test duration: 14 days
Application rates:	Control, 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000 mg of the test item/kg of dry weight of the artificial soil
Test conditions:	Temperature: 20.8 – 21.9°C; humidity: 19.23 – 21.56 % water content; lighting: 16 h light, 8 h dark; light intensity: 520 – 660 lux; pH: 6.08– 6.41
Statistical analysis:	Probit analysis in the NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0,
Endpoints:	LCx/ECx-values for the reproductive output and adult survival LOEC/NOEC for the reproductive output and adult survival

Results and Conclusions

Mortality at the concentrations ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil ranged from 0.0 to 12.5. As for the control group, it was 1.25%.

The concentration of Ferric phosphate 2.9% GB causing a 50% mortality of adults within the exposure period (LC₅₀) is >1000 mg/kg dry weight of the artificial soil, i.e. >28.40 mg Ferric phosphate/kg dry weight of the artificial soil.

The endpoint values showing the impact of the test item on the survival of adult *Hypoaspis aculeifer* are presented in Table given below.

Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]
LC ₁₀	> 1000 (n.d.)	> 28.40 (n.d.)
LC ₂₀	> 1000 (n.d.)	> 28.40 (n.d.)
LC ₅₀	> 1000	> 28.40

	(n.d.)	(n.d.)
NOEC	≥ 1000	≥ 28.40
LOEC	> 1000	> 28.40

After the exposure of *Hypoaspis aculeifer* to the test item at the concentrations ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 127.50 and 129.75 per replicate. As for the control group, the number of juveniles was equal to 130.88 per replicate. The endpoint values showing the impact of the test item on reproductive output of *Hypoaspis aculeifer* are presented in Table given below.

Endpoint values

Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]
EC₁₀	> 1000 (n.d.)	> 28.40 (n.d.)
EC₂₀	> 1000 (n.d.)	> 28.40 (n.d.)
EC₅₀	> 1000 (n.d.)	> 28.40 (n.d.)
NOEC	≥ 1000	≥ 28.40
LOEC	> 1000	> 28.40

n.d. – not determined

Comments of zRMS:	zRMS comment:																		
	The study is considered valid. All validity criteria were met.																		
	Agreed endpoints:																		
	<table border="1"> <thead> <tr> <th>Endpoint</th> <th>Value [mg test item/kg dry soil]</th> <th>Value [mg of active substance/kg dry soil]</th> </tr> </thead> <tbody> <tr> <td>LC₁₀</td> <td>> 1000 (n.d.)</td> <td>> 28.40 (n.d.)</td> </tr> <tr> <td>LC₂₀</td> <td>> 1000 (n.d.)</td> <td>> 28.40 (n.d.)</td> </tr> <tr> <td>LC₅₀</td> <td>> 1000 (n.d.)</td> <td>> 28.40 (n.d.)</td> </tr> <tr> <td>NOEC</td> <td>> 1000</td> <td>> 28.40</td> </tr> <tr> <td>LOEC</td> <td>> 1000</td> <td>> 28.40</td> </tr> </tbody> </table> <p>n.d. – not determined</p>	Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]	LC₁₀	> 1000 (n.d.)	> 28.40 (n.d.)	LC₂₀	> 1000 (n.d.)	> 28.40 (n.d.)	LC₅₀	> 1000 (n.d.)	> 28.40 (n.d.)	NOEC	> 1000	> 28.40	LOEC	> 1000	> 28.40
Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]																	
LC₁₀	> 1000 (n.d.)	> 28.40 (n.d.)																	
LC₂₀	> 1000 (n.d.)	> 28.40 (n.d.)																	
LC₅₀	> 1000 (n.d.)	> 28.40 (n.d.)																	
NOEC	> 1000	> 28.40																	
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Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]																	
EC₁₀	> 1000 (n.d.)	> 28.40 (n.d.)																	
EC₂₀	> 1000 (n.d.)	> 28.40 (n.d.)																	
EC₅₀	> 1000 (n.d.)	> 28.40 (n.d.)																	
NOEC	> 1000	> 28.40																	
LOEC	> 1000	> 28.40																	

Reference: KCP 10.4.2.1-02
 Report “Effect of Ferric phosphate 2.9% GB on reproduction of the collembolans (*Folsomia candida*) in artificial soil.” Mr. K. Murali, 2019, 6076/2019. Bio-science Research Foundation
 Guideline(s): OECD 232 (2016)
 Deviations: No
 GLP: Yes

Acceptability: Yes
 Duplication (if vertebrate study) No

Materials and methods

Test item: Ferric phosphate 2.9% GB; Batch code: SCL-600243; active substance: 2.84% (w/w)
 Test species: *Folsomia candida* from a culture maintained at BFR, India, juveniles (9 - 12 days).
 Soil: 5% sphagnum peat; 20% kaolin clay; 75% industrial sand
 Study design: Number of replicates: 4 replicates / concentration + 8 replicates / control
 Number of collembolans: 10 / replicate
 Test duration: 28 days
 Application rates: Control, 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000 mg test item/kg soil dry weight
 Test conditions: Temperature: 19.6 – 21.3C; humidity: 42.6 – 43.4 % of maximum WHC; lighting: 16 h light: 8 h dark; light intensity: 555 – 675 lux; pH: 5.68 – 6.16
 Statistical analysis: The number of the surviving adults and juvenile collembolans was assessed 4 weeks after introduction.
 The endpoint values for mortality and reproduction were determined by using Probit analysis in the NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0.
 Endpoints: EC₅₀, EC₂₀, EC₁₀, NOEC, LOEC
 LC₅₀

Results and Conclusions

Mortality at the concentrations ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil ranged from 0.0 to 7.5%. As for the control group, it was 0.0%.

The concentration of the test item causing a 50% mortality of adults within the exposure period (LC₅₀) is >1000 mg/kg dry weight of the artificial soil (i.e. >28.40 mg Ferric phosphate/kg dry weight of the artificial soil).

The endpoint values showing the impact of the test item on the survival of adult collembolans are presented in Table given below:

Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]
LC ₁₀	> 1000 (n.d.)	> 28.40 (n.d.)
LC ₂₀	> 1000 (n.d.)	> 28.40 (n.d.)
LC ₅₀	> 1000 (n.d.)	> 28.40 (n.d.)
NOEC	> 1000	> 28.40
LOEC	> 1000	> 28.40

n.d. – not determined

After the exposure of collembolans to the test item at the concentrations ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 628.25 and 786.25 per replicate. As for the control group, the number of juveniles was equal to 805.75 per replicate.

The endpoint values showing the impact of the test item on reproduction of *Folsomia candida* are presented in Table given below:

Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]
EC ₁₀	> 1000 (n.d.)	> 28.40 (n.d.)
EC ₂₀	> 1000 (n.d.)	> 28.40 (n.d.)
EC ₅₀	> 1000	> 28.40

	(n.d.)	(n.d.)
NOEC	> 1000	> 28.40
LOEC	> 1000	> 28.40

n.d. – not determined

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study is considered valid. All validity criteria were met. Agreed endpoints: Based on the experiment results, it can be concluded that the test item Iron phosphate 2.9% GB at the tested doses of 186.8 mg test item/kg dw soil (5.6 mg a.s./kg dry weight of soil) and 467.0 mg test item/kg dw soil (13.9 mg a.s./kg dry weight of soil), does not have long-term influence on nitrogen transformation in the soil microorganisms
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Reference:	KCP 10.5-01
Report	“Soil microorganisms: nitrogen transformation test of Iron phosphate 1.0% GB” H. S. Anand, 2019, G14362. Eurofins.
Guideline(s):	OECD Guideline No. 216 (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Test item:	
Description:	Iron phosphate 1.0% GB
Production batch:	SCL-89425
Active ingredients content:	Ferric phosphate 0.94% w/w
Vehicle and control:	Milli-Q water
Test system:	
Species:	Microorganisms
Source:	Collected on 13 May 2019 from a site where no crop protection products have been applied for a minimum of one year before sampling and no organic fertilizer have been applied for at least six months before.
Experimental conditions:	
Temperature:	20 ± 2°C
Humidity:	43.87 ± 0.06% MWHC
Air changes:	-
Light and photoperiod:	Dark (24/24h)

Study design and methods

Experimental period: June 6, 2019 – July 15, 2019
Test design and treatment: 3 portions of soil (sieved to particle size equal to 2 mm): one control group and two groups containing the test item weighing. Every portion was divided into three replicates, each containing 25 g dry weight. Test duration: 28 days. The soil was amended with organic substrate, powdered Lucerne plant meal. The amount of nitrate formed in each treated and control replicate was determined at each sampling time by spectroscopic measurement and was extracted from soil by shaking samples with 0.1M KCl solution. Test duration: 28 days.

Concentrations of the test material:

Control; Lower PEC: 1333.32 mg test item/kg dry weight of soil (12.53 mg a.s./kg dry weight of soil) and Higher PEC: 3333.30 mg test item/kg dry weight of soil (31.33 mg a.s./kg dry weight of soil). The soil treated with test item and untreated (control) were incubated and sampled for analysis after 0, 7, 14 and 28 days of incubation. The nitrate formation rate [mg/kg dry weight of soil/day] in each treated group was compared with that in the control, and the percent deviation of the treated from the control was calculated for selected time points i.e. 0, 7, 14 and 28 days.

Results

After 28 days of incubation, the lowest treatment group deviated by 2.33% and highest treatment group deviated by 4.94% from the control with respect to the nitrate content and which was < 25%.

Mean nitrate ion concentration - deviations from the control [%]:

Time interval [d]	Lower PEC 1333.32 mg test item/kg dw soil (12.53 mg a.s./kg dw soil)	Higher PEC 3333.30 mg test item/kg dw (31.33 mg a.s./kg dw)
0	5.46	7.89
7	3.41	5.93
14	-1.75	-0.95
28	2.33	4.94

Validity

The calculated % variations among the replications of control samples were less than 15% indicating the validity of the test on all the intervals.

Conclusion

Based on the experiment results, it can be concluded that the test item Iron phosphate 1.0% GB at the tested doses of 1333.32 mg test item/kg dw soil (12.53 mg a.s./kg dw soil) and 3333.30 mg test item/kg dw (31.33 mg a.s./kg dw), does not have long-term influence on nitrogen transformation in the soil microorganisms.

Comments of zRMS:	The study is considered valid. All validity criteria were met. Agreed endpoints: Based on the experiment results, it can be concluded that the test item, Iron phosphate 2.9% GB at the tested doses of 186.8 mg test item/kg dw soil (5.6 mg a.s./kg dry weight of soil) and 467.0 mg test item/kg dw soil (13.9 mg a.s./kg dry weight of soil), does not have long-term influence on carbon transformation in soil microorganisms.
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Reference:	KCP 10.5-02
Report	“Soil microorganisms: carbon transformation test of iron phosphate 1.0% GB”, H. S. Anand, 2019, G14361. Eurofins.
Guideline(s):	OECD Guideline No. 217 (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Materials

Test item:	
Description:	Iron phosphate 1.0% GB
Production batch:	SCL-89425
Active ingredients content:	Ferric phosphate 0.94% w/w
Vehicle and control:	Milli-Q water
Test system:	
Species:	Microorganisms
Source:	Collected on 13 May 2019 from a site where no crop protection products have been applied for a minimum of one year before sampling and no organic fertilizer have been applied for at least six months before.
Experimental conditions:	
Temperature:	20 ± 2°C
Humidity:	43.87 ± 0.06 of MWHC

Air changes: -
Light and photoperiod: Dark (24/24h)

Study design and methods

Experimental period: June 6, 2019 – July 15, 2019
Test design and treatment: 3 portions of soil (sieved to particle size equal to 2 mm): one control group and two groups containing the test item weighing. Every portion was divided into three replicates, each containing 25 g dry weight. Test duration: 28 days.

Concentrations of the test material:

Control; Lower PEC: 1333.32 mg test item/kg dry weight of soil (12.53 mg a.s./kg dry weight of soil) and Higher PEC: 3333.30 mg test item/kg dry weight of soil (31.33 mg a.s./kg dry weight of soil).

The mean respiration rate in the treated soil samples was compared with that in the control, and the percent deviation of the treated from the control was calculated after 0, 7, 14 and 28 days of incubation. The glucose-induced respiration rate in each treated and control replicate was determined at each sampling time.

Statistics: The variable CO₂, mg/kg dw of soil/h was tested using ANOVA. Comparison of means between treatment groups and control groups was done using F-test.

Results

After 28 days of incubation, the lowest treatment group deviated by 8.78% and highest treatment group deviated by 12.36% from control with respect to the glucose induced respiration rates (CO₂ released rates). The variations between results of replicate control samples were within $\pm 15\%$ on every occasion tested.

The difference in respiration rates between the treated and the control was $< 25\%$ on day 28 and hence, the experiment was concluded after 28 days interval.

Percent deviation of glucose induced respiration rate of treated from control.

Day	Lower PEC	Higher PEC
	1333.32 mg test item/kg dw soil (12.53 mg a.s./kg dw soil)	3333.30 mg test item/kg dw (31.33 mg a.s./kg dw)
0	10.65	16.24
7	18.21	24.46
14	12.19	16.32
28	8.78	12.36

““ the value of the oxygen consumption higher than the one obtained for the control group.

Conclusion

Based on the experiment results, it can be concluded that the test item, **Iron phosphate 1.0% GB** at the tested doses of 1333.32 mg test item/kg dw soil (12.53 mg a.s./kg dw soil) and 3333.30 mg test item/kg dw (31.33 mg a.s./kg dw), does not have long-term influence on carbon transformation in soil microorganisms.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.8 KCP 10.8 Monitoring data