REGISTRATION REPORT

Part A

Risk Management

Product code: FRU-H250 21 E3

Product name: FERREX

Active substance: ferric phosphate, 25 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: Frunol delicia GmbH

Date: 17-09-2018

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PART A – Risk Management

The company Frunol delicia GmbH has requested marketing authorisation in France for the product FERREX (FRU-H250 21 E3), containing 25 g/L ferric phosphate [1] for use as a molluscicide (professional use). Ferric Phosphate is a low risk active substance, therefore FERREX (FRU-H250 21 E3) shall be authorized as a low risk plant protection product if compliant with article 47.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to FERREX (FRU-H250 21 E3) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FERREX (FRU-H250 21 E3) have been made using endpoints agreed in the EU peer review of ferric phosphate.

This document describes the specific conditions of use and labelling required for France for the registration of FERREX (FRU-H250 21 E3).

Appendix 1 of this document provides a copy of the French Decision.

Appendix 2 of this document is a copy of the draft product label as proposed by the applicant.

Appendix 3 of this document is a copy of the letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of Frunol delicia GmbH's application to market FERREX (FRU-H250 21 E3) in France as a molluscicide (professional use) (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Ferric phosphate

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. Commission Implementing Regulation (EU) 2015/1166 of 15 July 2015 renewing the approval of the active substance ferric phosphate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011
Specific provisions of Regulation (EU) No 540/2011 were as follows: Only uses as molluscicide may be authorised. Specific provisions of Regulation (EU) No 2015/1166 were as follows: For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ferric phosphate, and in particular Appendices I and II thereof, shall be taken into account.

[1] Iron(III) phosphate or ferric orthophosphate, $FePO_4$

The approval's expiry date was extended to 31 December 2030.
An EFSA conclusion is available (EFSA Journal 2015;13(1):3973). A Review Report is available (List of information, tests and studies relied upon Version 2 [22 July 2015] and Final review report, SANTE/10385/2015 Rev 1, 29 May 2015).

1.3 Regulatory approach

The present application (2014-1358; 2014-1359; 2014-1360; 2014-1361) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4th May 2017[3] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, drift buffer zones may be reduced under some circumstances as explained in Appendix 3 of the above-mentioned French Order.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[4], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order,

[2] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

[3] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

[4] REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

[5] COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

[6] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

mainly based on the EU document on residue data extrapolation[7] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of FERREX (FRU-H250 21 E3), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not necessary: the applicant has provided sufficient data to show that access is not required.

[7] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	FERREX (FRU-H250 21 E3)
Low risk product (article 47)	Yes
Authorisation number	2180147
Function	Molluscicide (professional use)
Applicant	Frunol delicia GmbH
Composition	25 g/kg ferric phosphate
Formulation type (code)	Granular bait (GB)
Packaging	- Polypropylene buckets (3, 10 kg) - Cardboard with inner LDPE layer-containers (3, 10 kg) - Paper/LDPE sacks (5, 25 kg) - LDPE/Aluminium sacks (5, 25 kg)

LDPE: low-density polyethylene

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	-	
Health hazards	-	
Environmental hazards	-	
Hazard pictograms	-	
Signal word	-	
Hazard statements	-	-
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

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

2.2.2 Other phrases in compliance with Regulation (EU) No 547/2011

The authorisation of the preparation is linked for professional uses only to the following conditions:

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

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment[8]: refer to the Decision in Appendix 1 for the details
Re-entry period[9]: Not applicable for this product type (granules for spreading)
Pre-harvest interval[10]: one day [11]
Other mitigation measures: -
The label must include the following recommendations: - The phrase “Do not store in a place where the temperatures can exceed 35 °C” must appear. The label must reflect the conditions of authorisation.

[8] If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

[9] The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[10] According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

[11] This is on the basis of EU guidelines: EC (European Commission), 1997: *Appendix I. Calculation of maximum residue level and safety intervals* 7039/VI/95, as amended by *Classes to be used for the setting of EU pesticide maximum residue levels (MRLs)*, SANCO 10634/2010. Available online: http://ec.europa.eu/food/plant/pesticides/guidance_documents/docs/app-i.pdf

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

GAP rev. , date: 17/09/2018

PPP (product name/code)	**FERREX/(FRU-H250 21 E3)**	**Formulation type:**	**granular bait (GB)**
active substance 1	**ferric phosphate**	**Conc. of a.s. 1:**	**25 g/kg**
Applicant:	**Frunol delicia GmbH**	**professional use**	☒
Zone(s):	**southern EU**	**non-professional use**	☐
Verified by MS:	**yes**		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**				
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg product / ha a) max. rate per appl. b) max. total rate per crop/season**	**kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**	**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
1	France	All crops (general treatment, professional use[12])	F,G	Slugs and snails	Spread evenly over resp. around the crop plants	At beginning of infestation	a) 5 (7 days) b) 5 (7 days)	a) 6 kg/ha b) 30 kg/ha	a) 0.15 kg/ha b) 0.75 kg/ha	--	1 day	Acceptable (Before, while or after sowing/planting, on treated area. For maize and sunflower, apply in-furrow)

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
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

[12] A separate product with identical formulation, FERREX JARDIN, is proposed for non-professional use.

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

FERREX (FRU-H250 21 E3) is a granular bait formulation (GB). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of green granules, with an organic odour. It is not explosive or flammable and has no oxidising properties. It has a self-ignition temperature of 387 °C. In aqueous solution (1 % w/v), it has a pH value of 6.99 at 20 °C. There is no effect of low and high temperatures on the stability of the formulation, since after 12 weeks at 35 °C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in packaging made of paper/PE, PE/Alu, PP or cardboard with inner PE layer. The technical characteristics are acceptable for a GB formulation.

The formulation is not classified for the physico-chemical aspect.

The formulation must be stored at a temperature below 35 °C.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methodology for the determination of active substance in the formulation is available and validated. Moreover, a specific analytical method to determine Fe^{3+} in the formulation is required post-authorisation. Relevant impurities (lead, mercury, cadmium) cannot be formed during the manufacturing process or from degradation during storage, so an analytical method for the determination of relevant impurities in the formulation is not necessary.

3.1.2.2 Analytical methods for residues

Analytical methods for the determination of residues of ferric phosphate in plants, foodstuffs of animal origin, soil, water (surface and drinking) and air are not necessary.

To update the dossier, a confirmatory method is required for the determination of ferric phosphate in the formulation (as above).

The active substance is neither toxic nor very toxic, hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active substance: **ferric phosphate**		
ADI	0.8 mg kg bw/d	EU (2016)
ARfD	not required	
AOEL	0.4 mg/kg bw/d	
Dermal absorption	No relevant dermal absorption of $FePO_4$ is expected (extremely low solubility in water and lipids). The oral absorption is an active energy-dependent process which will not take place in the skin. A dermal absorption value of 10 % is proposed as worst-case scenario.	

3.1.3.1 Acute Toxicity

FERREX (FRU-H250 21 E3), containing 25 g/kg ferric phosphate or 9.2 g/kg of iron, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[13]	Equipment	Application rate kg product/ha (g a.s./ha)	Model
All crops	F/G	Tractor-mounted	6 kg/ha (150 g ferric phosphate/ha or 55.2 g iron/ha)	PHED Model
	F/G	Hand-held		PHED Model

Considering the proposed uses, operator systemic exposure was estimated using the PHED model:

Crop	Equipment	PPE and/or working coverall	% AOEL iron
All crops	Tractor-mounted	Normal work clothing and gloves during loading and application	0.28
	Hand-held	Normal work clothing and gloves during loading and application	2.27

According to the model calculations, it may be concluded that the risk for the operator using FERREX (FRU-H250 21 E3) is acceptable with normal work clothing and gloves during loading and application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.1.3.3 Bystander Exposure

FERREX (FRU-H250 21 E3) is applied in the sowing row and as a granular bait formulation, no drift is expected. Therefore bystander exposure estimation is considered to be unnecessary.

3.1.3.4 Resident Exposure

FERREX (FRU-H250 21 E3) is applied in the sowing row and as a granular bait formulation, no drift is expected. Therefore resident exposure estimation is considered to be unnecessary.

3.1.3.5 Worker Exposure

FERREX (FRU-H250 21 E3) is applied in the sowing row and is a granular bait formulation. No work is expected to be practised after application. Therefore worker exposure estimation is considered to be unnecessary.

For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

[13] Open field or glasshouse

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Ferric phosphate, active substance of the product FERREX (FRU-H250 21 E3), is approved at EU level.

No residue definition was proposed by the RMS Germany and ferric phosphate is included in Annex IV of Regulation (EC) No n°396/2005, which includes active substances for which it has not been deemed necessary to propose Maximum Residue Levels (MRLs).

3.1.4.2 Consumer exposure

Ferric phosphate is naturally present in soils, where its availability to plants is low, linked to the fact that it is strongly adsorbed to soil constituents and is poorly soluble in water. It disappears slowly, and degradation products (iron and phosphates) are natural nutritive compounds, necessary for plants, to ensure their growth.

Moreover, in the United States of America ferric phosphate is used as food additive, and, for this reason, has been considered as a "generally considered as safe" substance.

Lastly, considering the formulation as "granular baits, the product is not applied directly to edible parts of plants.

For all these reasons, the consumer is not exposed to a specific risk, given the intended uses of FERREX (FRU-H250 21 E3). No risk mitigation measure is deemed necessary to ensure consumer safety.

All intended uses are thus considered acceptable, but, according to EU guidelines on the calculation of maximum residue level and safety intervals (as amended) a one-day PHI is proposed for the intended uses on all edible crops requested.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Ferric phosphate is considered to be a low-risk active substance. Appropriate endpoints from the EU review were used to calculate predicted environmental concentrations (PECs) for the active substance for the intended use patterns.

The risk assessment for greenhouse uses is covered by that provided for the outdoor uses.

Due to the natural occurrence in the environment of ferric phosphate and its dissociation products (iron and phosphate ions), no specific study to address the fate and behaviour of active substance in the environment is needed.

The PEC of ferric phosphate in soil has been assessed according to FOCUS guidance documents, with standard FOCUS recommendations. The results were used for the ecotoxicological risk assessment.

The formulated product being applied as granules, only the drainage and runoff exposure routes are considered in the PECsw calculations. The maximum concentration of the active substance in water will correspond to the water solubility of ferric phosphate (1.86×10^{-12} g/L). In addition, no risk of eutrophication due to the application of ferric phosphate is expected.

According to the guidance document SANCO221/2000 on the assessment of the relevance of metabolites in groundwater, iron and phosphate ions are considered as compounds of no concern. Given the very low water solubility and the low soil mobility of ferric phosphate, no unacceptable risk of groundwater contamination is expected for the intended uses. No PEC_{GW} calculations were required according to the EU conclusions (EFSA, 2015).

As ferric phosphate is a non-volatile salt, no significant contamination of the air compartment is expected for the intended uses.

Implications for labelling resulting from environmental fate assessment: none.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for the active substance and preparation were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro- or micro-organisms and terrestrial plants are acceptable for the intended uses.

As a direct entry of granules into water systems cannot be ruled out, a toxicity assay of FERREX (FRU-H250 21 E3) on aquatic gastropods must be provided post-authorisation.

There are no labelling requirements apart from SP 1.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy of the product FERREX (FRU-H250 21 E3) is considered satisfactory in the requested conditions of use.
- the selectivity of FERREX (FRU-H250 21 E3) is considered satisfactory.
- the risk of negative impact (on yield, quality, transformation processes, propagation, succeeding and adjacent crops) is considered to be negligible.
- the risk of resistance developing or appearing is also considered to be negligible.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation can be granted** as proposed in Appendix 1 – Copy of the product Decision.

3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

3.3.1 Post-authorisation monitoring

No further information is required.

3.3.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- A specific method for the determination of Fe^{3+} in the product.
- A toxicity study conducted on aquatic gastropods.

3.3.3 Label amendments

The draft label proposed by the applicant in Appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

*Vu la demande d'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique **FERREX***

de la société	*FRUNOL DELICIA GMBH*
enregistrées sous les	*n°2014-1358, 2014-1359, 2014-1360, 2014-1361, 2014-3481*

Vu les conclusions de l'évaluation de l'Anses du 8 mars 2018,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

FERREX
AMM n°2180147

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Informations générales sur le produit	
Noms du produit	FERREX LIMAFER TURBOPADS TURBODISQUE
Type de produit	Produit de référence
Titulaire	FRUNOL DELICIA GMBH Hansastrasse 74 b, 59425 Unna, Allemagne
Formulation	Appât granulé (GB)
Contenant	25 g/kg - phosphate ferrique
Numéro d'intrant	9658-2014.01
Numéro d'AMM	2180147
Fonction	Molluscicide
Gamme d'usages	Professionnel
Mention particulière	Produit à faible risque au sens de l'article 47 du règlement (CE) 1107/2009

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2031.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le 17 SEP. 2018

Françoise WEBER
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Bidons en carton / polyéthylène basse densité	3 kg ; 10 kg
Seaux en polypropylène	3 kg ; 10 kg
Sacs en papier / polyéthylène basse densité	5 kg ; 25 kg
Sacs en polyéthylène basse densité / aluminium	5 kg ; 25 kg

Classification du produit
La classification retenue est la suivante : Sans classement.
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
11012903 Traitements généraux*Trt Sol*Limaces et escargots	**6 kg/ha**	**5/an**	Dès le début de l'infestation	1	-	-	-	-
	- Egalement autorisé sous abri. - Intervalle minimum entre les applications : 7 jours. - Application avant, pendant ou après le semis, en plein sur la parcelle traitée. Sur maïs et tournesol, application dans la raie de semis.							

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Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
16012901 Cultures légumières*Trt Sol*Limaces et escargots	6 kg/ha	5/an	-
	Motivation du refus : L'usage est refusé puisqu'il est inclus dans l'usage n°11012903		
17402901 Cultures ornementales*Trt Sol*Limaces et escargots	6 kg/ha	5/an	-
	Motivation du refus : L'usage est refusé puisqu'il est inclus dans l'usage n°11012903		
15102901 Grandes cultures*Trt Sol*Limaces et escargots	6 kg/ha	5/an	-
	Motivation du refus : L'usage est refusé puisqu'il est inclus dans l'usage n°11012903		
00701001 Plantes d'intérieur et balcons*Trt Substrats*Limaces et escargots	6 kg/ha	5/an	-
	Motivation du refus : L'usage est refusé puisqu'il est inclus dans l'usage n°11012903		
15901901 Tournesol*Trt Sem.*Limaces et escargots	6 kg/ha	5/an	-
	Motivation du refus : L'usage est refusé puisqu'il est inclus dans l'usage n°11012903		

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anses

Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas stocker le produit dans un local où la température peut dépasser 35°C.

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un tracteur :

• pendant le chargement du matériel d'épandage

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester 65 %/coton 35 % (combinaison ou ensemble veste + pantalon) ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

• pendant l'épandage

- Gants certifiés EN 374-2 à usage unique en cas d'intervention sur semoir, épandeur à engrais ou microgranulateur ;
- Combinaison de travail polyester 65 %/coton 35 % (combinaison ou ensemble veste + pantalon) ;

• pendant le nettoyage du matériel d'épandage

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester 65 %/coton 35 % (combinaison ou ensemble veste + pantalon) ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

Dans le cadre d'une application manuelle :

• pendant le chargement du matériel d'épandage (ex : microgranulateur)

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester 65 %/coton 35 % (combinaison ou ensemble veste + pantalon) ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

• pendant l'épandage

- Gants certifiés EN 374-2 à usage unique en cas d'intervention sur microgranulateur ;
- Combinaison de travail polyester 65 %/coton 35 % (combinaison ou ensemble veste + pantalon) ;

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• **pendant le nettoyage du matériel d'épandage**

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester 65 %/coton 35 % (combinaison ou ensemble veste + pantalon) ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

Délai de rentrée en application de l'arrêté du 4 mai 2017

- Non pertinent pour ce type d'application

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir une méthode de détermination spécifique du Fe^{3+} dans le produit.	24	-
Fournir un essai de toxicité du produit sur les gastéropodes aquatiques.	24	-

FERREX
AMM n°2180147

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Appendix 2 – Copy of the draft product label as proposed by the applicant

Ferrex®

Numéro d'AMM : xxxxx

Teneur: xx kg/ xx g

Informations réglementaires :
Nom homologué: Ferrex ®- n° d'AMM xxxx détenue par frunol delicia GmbH
Composition : 25 g/kg de Phosphate ferrique (2.5 %) – Appât granulé prêt à l'emploi – Molluscicide
Code d'usage : XXX

Dose: 6 kg/ha
Nombre max. d'applications par an: 5
Délai avant récolte: aucun

Numéro de lot.: (XXXX-XX)
Date de production: xxxxxx

Fabricant/ détenteur de l'autorisation :
frunol delicia GmbH
Hansastraße 74 bDübener Straße 145
D-59425 Unna D- 04509 Delitzsch
info@frunol-delicia.de www.frunol-delicia.de
Tél. : +49 34 202 65 300

Molluscicide

Le produit innovant pour lutter efficacement contre les limaces et les escargots dans toutes les cultures en plein air et en serre ainsi que dans les prairies et les terrains non cultivés.

Ne pas polluer l'eau avec le produit ou son emballage.
Pour protéger les oiseaux, récupérer tout produit accidentellement répandu.
Conserver uniquement dans le récipient d'origine.
Ne pas réutiliser l'emballage vide.
Eliminer les emballages, avec ou sans reliquat de produit, dans une déchetterie ou par un organisme agréé.

MODE D'EMPOI

Utilisation et mode d'emploi
Pour protéger les semis et pour diminuer les dégâts sur les feuilles et les fruits infestés par les limaces ou les escargots, épandre les appâts de façon homogène avec un épandeur approprié.
Les limaces et les escargots sont principalement actifs pendant la nuit, l'application de Ferrex® doit donc avoir lieu le soir par temps sec. Le produit doit être épandu uniformément sur les plants ou entre les plantes cultivées pour atteindre toutes les limaces/escargots. La substance active contenu dans Ferrex®, le phosphate de fer, entraîne une désintégration cellulaire des organes digestifs et des glandes. Peu de temps après l'ingestion des granulés, les limaces/escargots arrêtent de manger et se retirent dans le sol où ils meurent quelques jours plus tard.

Conditions d'utilisation

Culture/ situation	Nuisible ciblé	Dose	Utilisation	Nbre d'applications max. par an	Min. intervalle (jours)
Toutes cultures *En plein air et en serre*	Limaces et escargots	6 kg/ha	Dès l'infestation	5	7

Applications autorisées : Avant le semis, au moment du semis ou après le semis – En plein sur la parcelle à traiter

Dans la raie de semis au moment du semis (Maïs, Tournesol)

En cas de forte infestation, Ferrex[le] peut être appliqué en préventif durant la pré-levée ou en mélange à la semence.

Délai avant récolte: -

Consignes de protection de l'utilisateur
Seulement pour lutter contre les limaces et escargots conformément aux instructions. Conserver hors de portée des enfants. Conserver à l'écart des aliments et boissons, y compris ceux pour animaux. Porter des gants de protection lors de l'épandage. Ne pas former de tas. Se laver les mains et toutes les autres parties de la peau exposées soigneusement à l'eau et au savon après le travail. Ne pas laisser les enfants s'approcher des surfaces traitées.
À conserver au frais et au sec.

Consignes de protection de l'environnement
Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

Respectez les instructions d'utilisation pour éviter les risques pour l'homme et pour l'environnement

Gestion des déchets / Elimination
Les déchets et les récipients doivent être éliminés en toute sécurité. Ne pas réutiliser les emballages vides. Ne jetez pas les restes de produits dans les ordures ménagères mais dans leurs emballages d'origine dans les conteneurs d'ordures spéciales de votre lieu de résidence. Vous obtiendrez de plus amples informations auprès de votre municipalité ou de votre commune.

PREMIERS SECOURS
En cas d'ingestion :
Rincer la bouche. Faire boire un peu d'eau. Consulter le Centre Antipoisons pour savoir si la prise de charbon de bois en suspension dans l'eau est indiquée. Consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.
Appel en cas d'urgence : 15 ou centre antipoison

En cas de contact avec la peau :
Rincer abondamment à l'eau ou prendre une douche pendant 15 minutes. Enlever entre-temps les chaussures et les vêtements contaminés. En cas de symptômes, consulter un médecin et lui montrer l'emballage ou l'étiquette.

En cas de projection dans les yeux :
Rincer abondamment à l'eau pendant 10 minutes. Ne pas faire couler l'eau vers l'œil non atteint. Porteurs de lentilles de contact : enlever si possible les lentilles de contact, puis rincer. Consulter un médecin et lui montrer l'emballage ou l'étiquette.

GARANTIE
Une application selon le mode d'emploi et un stockage appropriés étant hors de notre contrôle, nous garantissons la qualité irréprochable du produit jusqu'à sa livraison,

Appendix 3 – Letter(s) of Access

Not applicable.