

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: F2849**

**Product name(s): FERRIMAX**

**Chemical active substance(s):**

**8.07g/kg ferric phosphate anhydrous**

Low risk active substance

**Southern Zone (Field uses)**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(Authorisation renewal according to Art. 43))**

**Applicant: De Sangoisse SAS**

**Date: 07/05/2019**

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## PART A

# RISK MANAGEMENT

### 1 Details of the application

The company De Sangosse SAS has requested marketing authorisation in France for the product FERRIMAX (formulation code: F2849), containing 8.07g/kg ferric phosphate anhydrous for use as a molluscicide (non-professional use).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 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 FERRIMAX (F2849) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FERRIMAX (F2849) 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 FERRIMAX (F2849).

Appendix 1 of this document provides a copy of the product authorisation.

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

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

#### 1.1 Application background

The present registration report concerns the evaluation of De Sangosse SAS's application to market FERRIMAX (F2849) in France as a molluscicide (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 renewal of authorisation after approval of the active substance of this product in France and in other MSs of the Southern zone.

Ferric phosphate is a low risk active substance, therefore FERRIMAX (F2849) shall be authorized as a low risk plant protection product if compliant with article 47.

The present application (2016-1262) 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 for field uses, taking into account the worst-case uses ("risk envelope approach")<sup>1</sup> – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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<sup>2</sup>, 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.

<sup>1</sup> 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.

<sup>2</sup> 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.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011<sup>3</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

## 1.2 Letters of Access

Not necessary: the applicant has provided equivalent studies to those essential for renewal of active substance via data matching table (DMT).

## 1.3 Justification for submission of tests and studies

Not required for applications submitted in accordance with Article 43.

## 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of FERRIMAX (F2849), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

# 2 Details of the authorisation decision

## 2.1 Product identity

Product code	F2849
Product name in MS	FERRIMAX
Authorisation number	2150969
Low risk (article 47)	Yes
Function	Molluscicide
Applicant	De Sangosse SAS
Active substance(s) (incl. content)	8.07g/kg ferric phosphate anhydrous
Formulation type	Granular bait (GB)
Packaging	Bags in cardboard holding with dispenser 350 g, 500 g, 750 g, 900 g, 1 kg, 1.1 kg, 1.4 kg, 1.5 kg, 1.8 kg, 2 kg, 2.2 kg, 2.5 kg
Coformulants of concern for national authorisations	None
Restrictions related to identity	Maximum content of relevant impurities is established by EU Endpoints (EFSA, 2014; ferric phosphate)
Mandatory tank mixtures	None
Recommended tank mixtures	None

<sup>3</sup> 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.

## 2.2 Conclusion

The evaluation of the application for FERRIMAX (F2849) resulted in the decision **to grant** the authorization.

## 2.3 Substances of concern for national monitoring

Refer to 5.1.1.

## 2.4 Classification and labelling

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

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

Hazard class(es), categories:	-
Hazard pictograms:	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	<i>For the P phrases, refer to the extant legislation</i>
Additional labelling phrases:	-

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

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

Do not discharge into the sink, gutter or any other water hole the non-used container leftovers.

For other restrictions refer to 2.5

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

None.

## 2.5 Risk management

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<sup>4</sup> provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally stated in the product authorisation, the minimum re-entry period is 6 hours for field

<sup>4</sup> 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>.

uses and 8 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.

Finally, the French Order of 26 March 2014<sup>5</sup> 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, mainly based on the EU document on residue data extrapolation<sup>6</sup> 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.

## 2.5.1                    **Restrictions linked to the PPP**

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	refer to the Decision in Appendix 1 for the details
Worker protection:	
-	refer to the Decision in Appendix 1 for the details
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers.
Other specific restrictions	
Re-entry period	Not applicable for this application method.

## 2.5.2                    **Specific restrictions linked to the intended uses**

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

None.

<sup>5</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>.

<sup>6</sup> SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9.

## 2.6 Intended uses (only NATIONAL GAP)

**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. 1, date: 2019-05-07

PPP (product name/code):	FERRIMAX (F2849)		Formulation type:	GB <sup>(a, b)</sup>	
Active substance 1:	Ferric phosphate		Conc. of as 1:	8.1 g/kg anhydrous <sup>(c)</sup>	
Safener:	-		Conc. of safener:	- <sup>(c)</sup>	
Synergist:	-		Conc. of synergist:	- <sup>(c)</sup>	
Applicant:	De Sangoisse SAS		Professional use:	<input type="checkbox"/>	
Zone(s):	southern <sup>(d)</sup>		Non professional use:	<input checked="" type="checkbox"/>	
Verified by MS:	Yes				

Field of use: molluscicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. <sup>(e)</sup>	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	zRMS conclusion (Remarks from applicant) RMS CONCLUSION
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													
1	FR	Strawberries, Cabbages, Lettuces, Ornamental plants	F	Slugs & Snails	Spreading, Broadcast	At any time	a) 1 b) 4	14	a) 50 kg/ha (5 g/m <sup>2</sup> ) b) 200 kg/ha	a) 405 gas/ha b) 1620 gas/ha	n/a	1	Acceptable (* Edible crops)

**Remarks table heading:**

- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
- (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008.
- (c) g/kg or g/l.
- (d) Select relevant.
- (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.
- (f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

**Remarks columns:**

- 1 Numeration necessary to allow references.
- 2 Use official codes/homelacatures 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/m<sup>3</sup> 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.

### **3 Background of authorisation decision and risk management**

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

FERRIMAX (F2849) is a ready to use bait formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a pale blue solid granule, without odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 140°C. In aqueous solution (1%), it has a pH value of 5.2 at ambient temperature. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in cardboard commercial packaging (extrapolable to HDPE packaging). Its technical characteristics are acceptable for a GB formulation.

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

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

Considering the first registration of FERRIMAX (F2849) data and the new data submitted:

- The level of efficacy of FERRIMAX (F2849) is considered as satisfactory for all the claimed uses.
- The level of phytotoxicity of FERRIMAX (F2849) is considered as negligible for all the claimed uses.
- The risks of negative impact on yield, quality, propagation, succeeding crops and adjacent crops are considered as negligible.
- The risk of resistance development or appearance to phosphate ferric is considered as very low.

#### **3.3 Methods of analysis (Part B, Section 5)**

##### **3.3.1 Analytical method for the formulation**

Analytical methods for the determination of the active substance and the relevant impurities (lead, cadmium, mercury) in the formulation are available and validated. Nevertheless, a specific analytical method for the determination of Fe<sup>3+</sup> in the formulation is required in post-registration.

##### **3.3.2 Analytical methods for residues**

No residues have to be monitored in crops and foodstuff of animal origin, as well as in soil, water and air. As a consequence, no analytical methods are proposed.

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.

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

#### Endpoints used in risk assessment

Active Substance: <b>ferric phosphate</b>			
ADI	0.8 mg/kg body weight/day	EU/ (January 2016)	
ARfD	Not required		
AOEL	0.4 mg/kg body weight/day		
Dermal absorption	A dermal absorption value of 10% is proposed as worst-case scenario (EFSA, 2015 <sup>7</sup> ).		
Oral absorption	50% oral bioavailability		

#### 3.4.1 Acute toxicity

FERRIMAX (F2849) containing 8.07g/kg ferric phosphate has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitizer.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.4.

#### 3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G <sup>8</sup>	Equipment <i>Application method</i>	Maximum application rate kg as /ha	Minimum volume wa- ter (L/ha)
Bare soil, and around all edible and non-edible crops Strawberries, Cabbages, Let- tuces, Ornamental plants	F	Spreading, Broadcast	50 kg/ha (5 g/m <sup>2</sup> )	n.a.

Considering proposed uses, operator systemic exposure was estimated using the CRD amateur use model:

Crop	Equipment	PPE and/or working coverall	% AOEL Ferric phosphate
Bare soil, and around all edible and non-edible crops	Spreading, Broadcast	No PPE	0.5 %

According to the model calculations, it can be concluded that the risk for the operator using FERRIMAX (F2849) is acceptable without PPE.

For some proposed packaging (Bags in cardboard holding), it has been described in sufficient details, and its compliance can therefore be finalised. In summary, compliance with the provisions of French Decree

<sup>7</sup> EFSA Journal 2015;13(1):3973.

<sup>8</sup> Open field or glasshouse.

No. 2010-1755 of 30 December 2010 and Orders of 30 December 2010 relating to the use of certain plant protection products by non-professional users is considered to be finalised.

**The following packaging were not compliance with the french regulation related to non professional uses, and were not accepted for non professional uses : Containers in HDPE holding 350g, 500g, 700g, 750g, 1kg, 1.5kg, 2kg**

### **3.4.3            Worker exposure**

FERRIMAX (F2849) is intended to be used by amateurs during home garden application.

In the case of non-professional user, the worker is also the user of the product. It will be necessary to ensure complete drying of the treated area or of treated plants before handling them.

### **3.4.4            Bystander and resident exposure**

FERRIMAX (F2849) is a granular bait formulation; no drift is expected. Therefore, bystander exposure estimation is considered not relevant.

A single pellet has a weight of 10mg, corresponding to a dose of 0.04mg of iron. Infants are assumed to be 1 to 3 years old and have a body weight of 10kg.

The reverse reference approach shows that 100 pellets (intake of iron) are required to reach the AOEL.

Therefore, it is concluded that there is no unacceptable risk to the resident (children) exposed to FERRIMAX (F2849).

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

### **Overall conclusion**

The data available are considered sufficient for risk assessment. Ferric phosphate is included in Annex IV of Regulation (CE) No 396/2005 that groups active substances for which no MRL are necessary.

Indeed ferric phosphate is naturally present in soils where its availability to plants is slow, 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 insure their growth.

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

Last, according the formulation as « granular baits », product is not applied directly to consumable parts of plants and if eventually present on the crop surface, it will be easily removed by normal food processing e.g. washing.

For all these reasons, consumer is not exposed to a specific risk considering intended uses of FERRIMAX (F2849) and no risk mitigation measure is deemed necessary to insure consumer safety.

All intended uses are then considered acceptable, and a PHI is not necessary for the intended uses on all edible crops under evaluation.

### **Data gaps**

- None

The preparation FERRIMAX (F2849) is composed of ferric phosphate.

### Summary for ferric phosphate

Use-No.	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
2	Strawberries, Cabbages, Lettuces, Ornamental plants	Not required	Not required	Not applicable	Not required	Not applicable	No	No

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

Ferric phosphate is included in Annex IV of Regulation (CE) No 396/2005 that regroups active substances for which no MRL are necessary no specific studies are required. Therefore, no additional data are required to support the intended use of FERRIMAX (F2849).

### Summary for FERRIMAX (F2849)

#### Information on FERRIMAX (F2849) (KCA 6.8)

Crop	PHI for FERRIMAX (F2849) proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for FERRIMAX (F2849) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Ferric phosphate			
Strawberries, Cabbages, Lettuces, Ornamental plants		NR		not necessary	-

NR: not relevant

\* Purpose of withholding period to be specified

\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

#### Waiting periods before planting succeeding crops

Not relevant.

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

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 as a low-risk active substance. Appropriate endpoints from the EU review were used to calculate PECs for the active substance for the intended use patterns.

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

The PEC of ferric phosphate in soil has been assessed according to FOCUS guidance documents, with standard FOCUS recommendations. The results for PEC<sub>SOIL</sub> for ferric phosphate are used for the eco-

toxicological risk assessment.

Given the very low water solubility, the low soil mobility of ferric phosphate and the intended uses (home and garden uses; granular application), no PEC<sub>SW</sub> were required.

For home and garden uses, no PEC<sub>GW</sub> were required according to EU conclusions (EFSA, 2015<sup>9</sup>). According to the guidance document SANCO 221/2000<sup>10</sup>, iron ions 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.

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

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

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 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.

For home and garden uses of granular products, an ecotoxicological risk assessment is only considered relevant for terrestrial vertebrates. For aquatic organisms, the exposure is considered to be negligible, therefore, a risk assessment is not deemed necessary. For terrestrial vertebrates, the risk is considered acceptable for the intended uses.

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

The active substance ferric phosphate is not approved as a candidate of substitution, therefore a comparative assessment is not foreseen.

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

### **5.1.1 Post-authorisation monitoring**

None.

### **5.1.2 Post-authorisation data requirements**

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

- An analytical method for the specific determination of Fe<sup>3+</sup> in the formulation.

<sup>9</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance ferric phosphate. EFSA Journal 2015;13(1):3973, 50 pp. doi:10.2903/j.efsa.2015.3973

<sup>10</sup> Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev.10-final, 25 February 2003.

## Appendix 1 Copy of the product authorisation



### Décision relative à une demande de renouvellement de l'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 réglementaire,*

*Vu la demande de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active phosphate ferrique, du produit phytopharmaceutique **FERRIMAX***

*de la société* **DE SANGOSSE**

*enregistrée sous les* n°2016-1262 et 2017-1519

*Vu les conclusions de l'évaluation de l'Anses du 6 mars 2019,*

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **est renouvelée** 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.



#### Informations générales sur le produit

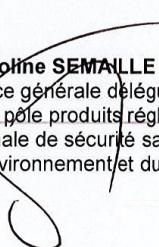
Noms du produit	FERRIMAX LIMABIOL
Type de produit	Produit de référence
Titulaire	DE SANGOSSE Bonnel CS.10005 47480 Pont du Casse France
Formulation	Appât granulé (GB)
Contenant	8,07 g/kg - phosphate ferrique anhydre
Numéro d'intrant	976-2013.01
Numéro d'AMM	2150969
Fonction	Molluscicide
Gamme d'usage	Amateur / emploi autorisé dans les jardins
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, 07 MAI 2019

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



## 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
Boites en carton, avec bec verseur	350 g ; 500 g ; 750 g ; 900 g ; 1 kg ; 1,1 kg ; 1,4 kg ; 1,5 kg ; 1,8 kg ; 2 kg ; 2,2 kg ; 2,5 kg

Les bidons de 350 g, 500 g, 700 g, 750 g, 1 kg, 1,5 kg, 2 kg en polyéthylène haute densité sont refusés car ils ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel.

### Classification du produit

La classification retenue est la suivante :

Sans classement.

Pour les phrases P se référer à la réglementation en vigueur.

**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.**



### Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.

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* Ttr Sol* Limaces et escargots	50 g/10 m <sup>2</sup>	4/an	-	1	-	-	-	-

Également autorisé sous abri.  
Uniquement sur "fraisier", "choux", "laitues" et "cultures ornementales".  
Intervalle minimum entre les applications : 14 jours.



### Conditions d'emploi du produit

#### *Délai de rentrée*

- Non applicable pour ce type d'application.

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

#### *Protection de l'eau*

- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidons non utilisés.

### 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 <sup>3+</sup> dans le produit.	24	-

## **Appendix 2 Copy of the product label**

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

The draft product label was not available in the application submitted.

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

Not applicable.