

REGISTRATION REPORT

Part A

Risk Management

Product code: NEU 1166 M

Product name(s): FERRAMOL

Active Substance(s):

9.9 g/kg ferric phosphate hydrated

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(renewal of authorisation Art. 43)

Applicant: W. Neudorff GmbH KG

Date: 2018-11-22

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PART A – Risk Management

The company W. Neudorff GmbH KG has requested renewal of the marketing authorisation in France for the product FERRAMOL (product code: NEU 1166 M); marketing authorisation n° 2020003), containing 9.9 g/kg ferric phosphate hydrated for use as a molluscicide (non-professional use)¹. Ferric Phosphate is a low risk active substance, therefore FERRAMOL (NEU 1166 M) 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 FERRAMOL (NEU 1166 M) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FERRAMOL (NEU 1166 M) have been made using endpoints agreed in the EU peer review(s) of ferric phosphate.

This document describes the specific conditions of use and labelling required for France for the registration of FERRAMOL (NEU 1166 M).

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 W. Neudorff GmbH KG's application to market FERRAMOL (NEU 1166 M) 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.

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,

¹ A separate Registration Report is available for FERRAMOL PRO for professional use.

the conclusions of the review report on ferric phosphate, and in particular Appendices I and II thereof, shall be taken into account.

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 (2016-1250) 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 2017³ 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 1107/2009⁴, 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 546/2011⁵, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ 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

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/AGR1632554A/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/AGR1407093A/jo>

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 extrapolation⁷ 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 FERRAMOL (NEU 1166 M), 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)	FERRAMOL (NEU 1166 M)
Low risk product (article 47)	Yes
Authorisation number	2020003
Function	Molluscicide (non-professional use)
Applicant	W. Neudorff GmbH KG
Composition	9.9 g pure active/kg ferric phosphate hydrated
Formulation type (code)	Ready to use bait (RB)
Packaging	Box in cardboard/pasteboard holding 200 g, 250 g, 300 g, 350 g, 500 g, 750 g, 900 g, 1 kg, 1.2 kg, 2 kg, 2.5 kg Bottles in high-density polyethylene holding 500 g, 600 g, 700 g, 750 g, 800 g, 1 kg

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 –	<i>For the P phrases, refer to the extant legislation</i>
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 non-professional uses only to the following conditions:

	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers
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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)
Pre-harvest interval ¹⁰ : 1 day.
Other mitigation measures: -
The label may include the following recommendations: 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.

2.3 Product uses

PPP (product name/code): **FERRAMOL (NEU 1166 M)**
active substance 1: ferric phosphate hydrated
Safener: -
Synergist: -
Applicant: **W. Neudorff GmbH KG**
Zone(s): Southern zone ^(d)
Verified by MS: yes
Field of use: molluscicide

GAP rev. 1, date: 2018-10-08
Formulation type: **RB (Ready to use bait)** ^(a, b)
Conc. of a.s.: 9.9 g/kg
Conc. of safener: - ^(c)
Conc. of synergist: - ^(c)
Professional use: ☐
Non professional use: ☒

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			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					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	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	Southern zone	All edible and non edible crops, amenity vegetation (amateur use ¹¹)	F, G	Pest slugs and snails	Strew, Agriculture crops: broadcast application Horticulture crops: between plants	At beginning of infestation	4 applications per year	a) 50 kg/ha (50 g/10 m ²) b) 200 kg/ha (200 g/10 m ²)	a) 350 g as/ha b) 1400 g as/ha	Not applicable (ready-to-use formulation)	1	Acceptable

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.

¹¹ A separate product with identical formulation, FERRAMOL PRO, is proposed for professional use.

Remarks columns:	1	Numeration necessary to allow references	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

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

FERRAMOL (NEU 1166 M) is a ready to use bait (RB). 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 turquoise, short and cylindrical granules with a faint characteristic odor. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 378°C. In aqueous solution (1%), it has a pH value of 3.3 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. Nevertheless, a new accelerated storage stability including active substance content (with a validated method), pH, flowability and attrition is required in post-registration with the formulation FERRAMOL (NEU 1166 M). The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (cardboard). Its technical characteristics are acceptable for a RB formulation.

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

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical method for the determination of active substance in the formulation are available and validated. Nevertheless, a specific analytical method for the determination of Fe^{3+} in the formulation is required in post-registration. Moreover, the validation of analytical methods used in the stability studies for the determination of ferric and phosphate contents in formulation is required in post-registration.

No analytical method for the determination of the relevant impurities of the active substance ferric phosphate in the formulation is submitted and is required in post-registration.

3.1.2.2 Analytical methods for residues

No residues have been 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.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active Substance: Ferric phosphate hydrated		
ADI	0.8 mg kg bw/d	EU (January 2016)
ARfD	Not applicable	
AOEL	0.4 mg/kg bw/d	
Dermal absorption	No relevant dermal absorption of FePO4 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. (EFSA 2015)	
		Concentrate (used in formulation)

		9.9 g/kg
	Dermal absorption endpoints %	10

3.1.3.1 Acute Toxicity

FERRAMOL (NEU 1166 M) containing 9.9 g/kg ferric phosphate hydrated has a low toxicity in respect to acute oral and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitizer. Toxicity by inhalation is not expected as the product does not contain any formulant classified with acute toxicity by inhalation and the formulation type is granules. Moreover, the product is considered not dusty.

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 ¹²	Equipment	Application rate kg product/ha (g as/ha)	Spray dilution (L/ha)	Model
All edible and non-edible crops, amenity vegetation	F/G	Manual	12-50 kg pdt/ha (0.2-0.5 kg sa/ha)	NA	UPJ

Considering proposed uses, operator systemic exposure was estimated using the French study 2005 dedicated to amateur use:

Crop	Equipment	PPE and/or working coverall	% AOEL ferric phosphate
All edible and non-edible crops, amenity vegetation	Manual (F/G)	No PPE	3

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

The proposed packaging have been described in sufficient detail, and their compliance with the provisions of French regulation relating to the use of plant protection products by non-professional users can therefore be finalised except for bags in LDPE.

3.1.3.3 Bystander Exposure

In the context of use by non-professionals, it is considered that the assessment for bystanders is covered by that for the operator.

3.1.3.4 Worker Exposure

FERRAMOL (NEU 1166 M) is intended to be used by amateurs during home garden application.

¹² Open field or glasshouse

As the worker is also the user of the product, it is considered that the assessment for workers is covered by the operator exposure assessment.

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

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

In the framework of EU evaluation no residue definition has been proposed for ferric phosphate (EFSA, 2015). Furthermore ferric phosphate is included in Annex IV of Regulation (CE) No 396/2005 that regroups active substances for which no MRL are necessary.

3.1.4.2 Consumer exposure

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, considering 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 FERRAMOL (NEU 1166 M) and no risk mitigation measure is deemed necessary to insure consumer safety.

All intended uses are then considered acceptable. As ferric phosphate is included in annex IV of regulation 396/2005 and as FERRAMOL (NEU 1166 M) is intended to be used as granular bait between the plants it is considered that it is not necessary to set a PHI

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 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. The risk assessment for greenhouses uses is covered by the one provided for the outdoor uses.

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_{SOIL} 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_{SW} were required.

For home and garden uses, no PEC_{GW} were required according to EU conclusions (EFSA, 2015). According to the guidance document SANCO221/2000¹³, 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.

¹³ 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.

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 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.

Other phrases in compliance with Regulation (EC) No 547/2011:

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

Considering the first registration of FERRAMOL (NEU 1166 M) data and the new data submitted:

- the level of efficacy of FERRAMOL (NEU 1166 M) when applied at the claimed dose of 50 kg/ha on several species of slugs on different crops is considered as satisfactory.
- the level of phytotoxicity of FERRAMOL (NEU 1166 M) is considered as negligible. To prevent eventual risk due to retention of the pellets on the crop, apply product on soil, between plants. The risk of negative impact on yield, quality, propagation, succeeding crops, adjacent crops is considered as negligible.
- the risk of resistance development or appearance to phosphate ferric is considered as very low.

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 new accelerated storage stability (14 days at 54°C) including active substance content (with a validated method), pH, flowability and attrition is required with the formulation FERRAMOL (NEU 1166 M).
- The validation of analytical methods used in stability studies for the determination of ferric and phosphate contents in the formulation.
- An analytical method for the specific determination of Fe³⁺ in the formulation.
- An analytical method for the determination of the relevant impurities of the active substance ferric phosphate (Pb, Cd, Hg) in the formulation.

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



Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit phytopharmaceutique et de la demande associée

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 à la ré approbation de la substance active phosphate ferrique et la demande de changement de composition du produit phytopharmaceutique **FERRAMOL***

de la société NEUDORFF GMBH KG

enregistrées sous les n°2016-1250 et n°2016-1769

Vu les conclusions de l'évaluation de l'Anses du 27 avril 2018,

Vu la décision du Directeur général de l'Anses du 8 octobre 2018,

Vu le recours gracieux formé le 22 octobre 2018 par la société NEUDORFF GMBH KG,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **est renouvelée** en France, en intégrant la nouvelle composition pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision abroge et remplace la décision du 8 octobre 2018 et 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	FERRAMOL NEU 1165 M
Type de produit	Produit de référence
Titulaire	NEUDORFF GMBH KG An der Mühle 3 D-31860 EMMERTHAL Allemagne
Formulation	Appât (prêt à l'emploi) (RB)
Contenant	9,9 g/kg - phosphate ferrique hydraté
Numéro d'intrant	2020003
Numéro d'AMM	2020003
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 la réapprobation 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,

22 NOV. 2019

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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AMM n°2020003

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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
Boîtes en carton munies d'un bec verseur refermable	200 g ; 250 g ; 300 g ; 350 g ; 500 g ; 750 g ; 900 g ; 1 kg ; 1,2 kg ; 2 kg ; 2,5 kg
Bouteilles en polyéthylène haute densité	500 g ; 600 g ; 700 g ; 750 g ; 800 g ; 1 kg

Les emballages sacs soudés en polyéthylène basse densité sont refusés car ils ne sont pas en mesure 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.
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 Traînée aquatique (mètres)	Zone Non Traînée arthropodes non cibles (mètres)	Zone Non Traînée plantes non cibles (mètres)	Mention abeilles
11012903 Traitements généraux*Trt Sol* Limaces et escargots	50 g/10 m ²	4/an	-	1	-	-	-	-
Également autorisé sous abri. Application dès le début de l'infestation.								

FERRAMOL
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Conditions d'emploi du produit

Délai de rentrée :

- Non applicable.

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	Date limite	Réurrence (mois)
Fournir une nouvelle étude de stockage du produit pendant 14 jours à 54°C incluant la teneur en substance active, le pH, la faculté d'écoulement et la teneur en poussière.	08/10/2020	-
Fournir la validation de la méthode utilisée dans l'étude de stabilité au stockage 2 ans, pour la détermination du fer et du phosphate dans le produit.	08/10/2020	-
Fournir une méthode de détermination spécifique du Fe ³⁺ dans le produit.	08/10/2020	-
Fournir une méthode de détermination des impuretés pertinentes (plomb, mercure, cadmium) dans le produit.	08/10/2020	-

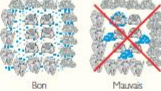
Appendix 2 – Copy of the draft product label as proposed by the applicant

Anti-Limaces Ferramol®

A base de phosphate ferrique : substance active innovante, existant dans la nature.

- A long terme, l'Anti-Limaces Ferramol® original se décompose en éléments nutritifs : phosphore et fer.
- Granulés très résistants à la pluie grâce à une technologie spécifique de fabrication.
- Préserve les animaux domestiques, les hérissons, les vers de terre, les oiseaux, les abeilles et les autres animaux utiles.
- Pas de traces de toxicité.
- Utilisable en Agriculture Biologique.*

Utilisation
5 g/m² (environ 1 cuillère à café bien remplie).
Épandre les granulés de l'Anti-Limaces Ferramol® original uniformément entre les cultures en début de soirée, quand les limaces quittent leur abri. Les granulés de l'Anti-Limaces Ferramol® original doivent être éparpillés d'un geste large sur l'ensemble de la surface à protéger dès l'apparition des premiers dégâts. Ne pas faire de petites tas ni entourer une seule plante avec les granulés.



Si le lendemain la totalité ou une partie des granulés a été mangée, il faut en éparpiller à nouveau de cette façon en éliminant également les nouvelles limaces. En cas de sol très sec, il est recommandé d'arroser légèrement le sol, ce qui rend les granulés plus adhésifs pour les limaces. Si la structure du sol est trop grossière, nous vous recommandons de le tasser pour éviter que les granulés ne tombent dans les fissures et soient inaccessibles pour les limaces.

Efficacité et contrôle
L'Anti-Limaces Ferramol® original attire toutes les limaces. Après ingestion de l'Anti-Limaces Ferramol® original, les limaces cessent de se nourrir : le produit a un effet coupe-faim. Ensuite, les limaces se résignent dans leur abri et y meurent. Contrairement à d'autres produits, les limaces ne bavent pas. L'efficacité est mise en évidence par la diminution des dégâts. Efficace également contre les escargots des jardins. Délai avant récolte : 5 jours.

ECOCERT
*Utilisable en Agriculture Biologique : conformément au règlement CE n°834/2007
Contrôlé par ECOCERT SA F-32600.

Nom homologué : Ferramol®
N°AMM : 2020003
Emploi autorisé dans les jardins.
Dépositaire de l'AMM :
W. Neudorff GmbH KG - An der Möhle 3
31860 Emmertal - Allemagne
Composition : phosphate ferrique : 9,9 g/kg (0,99%) CAS n°10045-86-0
Type d'action : molluscicide
Mode d'action : par ingestion
Type de préparation : appât granulé
Usages : traitement général - traitement du sol - limaces et escargots
Dose : 5 g/m²

Masse nette : 2 kg
Au moment de la mise en sachet.
Neudorff France Sarl
11 C rue de Courbain
77700 Magny-le-Hongre
www.neudorff.fr
Tél. 01 60 04 19 36

Sans classement toxicologique
P102 Tenir hors de portée des enfants.
EUH401 Respecter les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.
SP1 Ne pas polluer l'eau avec le produit ou son emballage.
SPe3 Pour protéger les organismes aquatiques, respecter une zone tampon non traitée de 5 mètres par rapport aux masses d'eau de surface.
En cas d'urgence : se munir de l'étiquette et appeler le 15 ou le centre régional antipoison (www.centres-antipoison.net).
Lot N° voir sur le haut du paquet.

Éliminer les produits non utilisés et les emballages vides dans une déchèterie, conformément à la réglementation locale.
Réutilisation de l'emballage autorisé.

4 603240 2 7013 5

Anti-Limaces Ferramol®

NEUDORFF

Anti-Limaces Ferramol®
Contre les limaces et les escargots sur les légumes, fraises et plantes d'ornement

Extrême résistance à la pluie

Monnaie d'Agriculture Biologique
ECOCERT

Le Original

Protéger les animaux domestiques et les hérissons

2 kg

Anti-Limaces Ferramol® original est particulièrement efficace contre :

- Les grandes limaces noires (dans les fraises)
- Les escargots du jardin
- Les petites limaces grises des champs
- Les limaces rouges d'Espagne

Nom homologué : Ferramol® AMM N° 2020003
*Utilisable en Agriculture Biologique conformément au règlement CE n°834/2007

Appendix 3 – Letter(s) of Access

Not applicable.