

REGISTRATION REPORT

Part A

Risk Management

Product code: NEU 1181 M

Product name : NEUDORF 1181 M

Active Substance :

29.7 g kg ferric phosphate hydrated

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(authorisation renewal (art. 43))

Applicant: W. Neudorff GmbH KG

Date: 2019/04/04

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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 NEUDORFF 1181 M (code: NEU 1181M) (commercial name in France: NEUDORFF 1181 M marketing authorisation n° 2110031), containing 29.7 g kg ferric phosphate hydrated for use as a molluscicide (professional use). Ferric Phosphate is a low risk active substance, therefore NEU 1181 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 NEUDORFF 1181 M (code: NEU 1181M) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of NEUDORFF 1181 M (code: NEU 1181M) 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 NEUDORFF 1181 M (code: NEU 1181M).

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 NEUDORFF 1181 M (code NEU 1181 M) 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) 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 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.

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 (2016-1220) 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”)¹ – 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 2017² 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 1107/2009³, 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 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁵ 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 extrapolation⁶ 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.

¹ 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

² 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/AGRGI632554A/jo/texte>

³ 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

⁴ 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

⁵ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

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

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 NEUDORFF 1181 M (code NEU 1181 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 is the owner of the active substance.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	NEUDORFF 1181 M (product code NEU 1181 M)
Low risk product (article 47)	Yes
Authorisation number	20110031
Function	Molluscicide (professional use)
Applicant	W. Neudorff GmbH KG
Composition	29.7 g kg ferric phosphate hydrated
Formulation type (code)	Ready to use bait (RB)
Packaging	Polyethylene bags holding 5 kg, 10 kg, 20 kg, 25 kg Professional users

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 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).
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2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁷ : refer to the Decision in Appendix 1 for the details
Re-entry period ⁸ : Not applicable for this product type (granules for spreading)
Pre-harvest interval ⁹ : As ferric phosphate is included in annex IV of regulation 396/2005 it is not necessary to set a PHI.
Other mitigation measures: -
The label may include the following recommendations: -
The label must reflect the conditions of authorisation.

⁷ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

⁸ 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]

⁹ 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

Please note:

PPP (product name/code): **NEUDORFF 1181 M (code : NEU 1181M)** Formulation type: **RB (Ready to use bait)** ^(a, b)
Active substance 1: Ferric phosphate hydrated Conc. of as 1: **29.7 g /kg hydrated** ^(c)
Safener: - Conc. of safener: - ^(c)
Synergist: - Conc. of synergist: - ^(c)
Applicant: **W. Neudorff GmbH KG** Professional use: ☒
Zone(s): Southern zone ^(d) Non professional use: ☐
Verified by MS: yes
Field of use: molluscicide

GAP rev. , date: 2019/04/04

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 zRMS conclusion
					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	F, G	Slugs and snails	Strew Agriculture crops: Broadcast application Horticulture crops: Between plants	At beginning of infestation	Up to 4 applications per year	a) 7 kg product/ha b) 28 kg product/ha	a) 207.9 g as/ha b) 831.6 g as/ha	Not applicable (ready-to-use formulation)	1	Acceptable
2	Southern zone	Fodder plants	F,	Slugs and snails	Strew: Broadcast application	At beginning of infestation	Up to 4 applications per year	a) 7 kg product/ha b) 28 kg product/ha	a) 207.9 g as/ha b) 831.6 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.

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

NEUDORFF 1181 M (code NEU 1181 M) is a ready to use bait formulation (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 a green granular bait of rods, with a slightly odor of grain. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 379°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. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging. 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 the active substance in the formulation is available and validated. Nevertheless, an analytical method for the specific determination of Fe^{3+} in the formulation is required in post-registration. Moreover, the validation of analytical methods used in 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 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.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active Substance: ferric phosphate		
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) 29.7 g/kg

	Dermal absorption endpoints %	10
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3.1.3.1 Acute Toxicity

NEUDORFF 1181 M (code NEU 1181 M) containing 29.7 g/kg ferric phosphate 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 ¹⁰	Equipment	Application rate kg product /ha (g as/ha)	Spray dilution (L/ha)	Model
All edible and non-edible crops, amenity vegetation	F	Vehicle mounted	7 kg pdt/ha (0.2079 kg sa/ha)	NA	Operator granule EFSA 2014
	G	Manual (Hand-Held equipment)			
Fodder plants	F	Vehicle mounted			

Considering proposed uses, operator systemic exposure was estimated using the AOEM model (EFSA 2014):

Crop	Equipment	PPE and/or working coverall	% AOEL ferric phosphate
All edible and non-edible crops, amenity vegetation	Vehicle mounted*	Working coverall and gloves during mixing/loading and application	1.1
	Manual (Hand-Held equipment) (F)		8.9
	Manual (Hand-Held equipment) (G)		8.9

*covers Fodder plants

According to the model calculations, it can be concluded that the risk for the operator using NEUDORFF 1181 M (code NEU 1181 M) is acceptable with a working coverall and gloves during mixing/loading and application.

¹⁰ Open field or glasshouse

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

3.1.3.3 Bystander Exposure

NEUDORFF 1181 M (code NEU 1181 M) is a granular bait formulation; no drift is expected. Therefore, bystander exposure estimation is considered not relevant.

3.1.3.4 Worker Exposure

Broadcast application and manual application of granules is intended for NEUDORFF 1181 M (code NEU 1181 M); no work is expected to be practiced after application. Therefore, worker exposure estimation is considered not relevant.

3.1.3.5 Resident Exposure

NEUDORFF 1181 M (code NEU 1181 M) is a granular bait formulation; no drift is expected. Therefore, resident exposure estimation is considered not relevant. **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 puts together 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 NEUDORFF 1181 M (code NEU 1181 M) 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.

3.1.4 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.

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

According to the guidance document SANCO 221/2000¹¹, 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. No PEC_{GW} were required according to 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.

3.1.5 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.

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

3.1.6 Efficacy

Considering the first registration of NEUDORFF 1181 M (code NEU 1181 M) data and the new data submitted:

- The level of efficacy of NEUDORFF 1181 M (code NEU 1181 M) when applied at the claimed dose of 7 kg/ha on several species of slugs on different crops is considered as satisfactory.
- The level of phytotoxicity of NEU 1181 M is considered as negligible. To prevent eventual risk due to retention of the pellets on the crop, a recommendation mentioning to not apply the preparation NEUDORFF 1181 M (code NEU 1181 M) directly on harvested parts of plants must be indicated on the label.
- The risk of negative impact on yield, quality, transformation processes, propagation, succeeding crops, adjacent crops is considered as negligible.
- The risk of resistance development or appearance to phosphate ferric is considered as very low.

¹¹ 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.

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:

- The validation of analytical methods used in stability studies for the determination of ferric and phosphate contents in formulation.
- An analytical method for the specific determination of Fe^{3+} in the formulated product.
- An analytical method for the determination of the relevant impurities of the active substance ferric phosphate is available. The application of the method to the formulated product should be confirmed.

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

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 hydraté, du produit phytopharmaceutique **NEUDORFF 1181 M***

de la société NEUDORFF GMBH KG

enregistrée sous le n°2016-1220

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	
Nom du produit	NEUDORFF 1181 M
Type de produit	Produit de référence
Titulaire	W. NEUDORFF GMBH KG An der Mühle 3 D-31860 EMMERTHAL Allemagne
Formulation	Appât (prêt à l'emploi) (RB)
Contenant	29,7 g/kg - phosphate ferrique hydraté
Numéro d'intrant	2090050
Numéro d'AMM	2110031
Fonction	Molluscicide
Gamme d'usage	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,

04 AVR. 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)



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
Sacs en polyéthylène	5 kg ; 10 kg ; 20 kg ; 25 kg

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 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	7 kg/ha	4/an	-	1	-	-	-	-
Également autorisé sous abri. Application dès le début de l'infestation.								

NEUDORFF 1181 M
AMM n°2110031

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Conditions d'emploi du produit

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

• pendant le chargement du matériel d'épandage

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester/coton 65 %/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/coton 65 %/35 % (combinaison ou ensemble veste + pantalon) ;

• pendant le nettoyage du matériel d'épandage

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester/coton 65 %/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 la validation des méthodes utilisées dans les études de stabilité pour la détermination du fer et du phosphate dans le produit.	24	-
Fournir une méthode spécifique pour la détermination du Fe ³⁺ dans le produit.	24	-
Fournir une méthode de détermination des impuretés pertinentes (plomb, cadmium, mercure) dans le produit.	24	-

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

NEUDORFF 1181 M

Granulés anti-limaces (molluscicide) pour toutes cultures
Substance active : phosphate ferrique 29.7 g/kg (2.97% m/m)
Appât (prêt à l'emploi) (RB)
Usage : Professionnel, Traitements généraux*Trt Sol*Limaces et escargots
<u>Mentions d'avertissements</u> EUH210 Fiche de données de sécurité disponible sur demande. EUH401 Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement. <u>Conseils de prudence</u> P102 Tenir hors de portée des enfants. P270 Ne pas manger, boire ou fumer en manipulant ce produit. P501 Éliminer le contenu et le récipient dans un centre de collecte des déchets dangereux ou spéciaux. SP1 Ne pas polluer l'eau avec le produit ou son emballage.
Date d'expiration :

CONTENU : **XXX** kg
Date de production et Numéro de lot : voir emballage

AMM N° 2110031

Détenteur d'AMM:
W. Neudorff GmbH KG
An der Mühle 3
31860 Emmerthal
Allemagne

Lire attentivement l'étiquette

Tenir à l'abri du gel et de l'humidité.

NEUDORFF 1181M

NEUDORFF 1181 M est un molluscicide en granulés utilisé contre les limaces en champ et en serre en cultures agricoles ainsi qu'en cultures horticoles. Les granulés anti-limaces attirent toutes les limaces qui endommagent les plantes. Immédiatement après avoir ingéré les granulés, les limaces arrêtent de se nourrir. Cet arrêt permet une protection immédiate de la culture.

Mode d'action

NEUDORFF 1181 M possède un nouveau mode d'action. Etant donné que le mode d'action ne repose pas sur le dessèchement des limaces, le produit ne perd pas en efficacité lorsqu'il est appliqué en période de pluie ou par temps humide, lorsque les limaces sont particulièrement actives. Aucune trace de bave ni de limace morte dans les plantes. Les limaces mortes se décomposent naturellement.

NEUDORFF 1181 M offre une très bonne résistance à la pluie grâce à une nouvelle technologie de fabrication des appâts.

La substance active phosphate ferrique est naturellement présente dans l'environnement. Le phosphate et le fer sont des éléments nutritifs pour les plantes.

Mode d'emploi

Le port de gants en nitrile certifiés EN 174-3, et d'une combinaison de travail en polyester 65% / coton 35% avec un grammage de 230 g/m² ou plus avec traitement déperlant est recommandé pendant le mélange/chargement, l'application et le nettoyage du matériel.

NEUDORFF 1181 M est appliqué dès le début de l'infestation en limaces ou dès l'observation des premiers symptômes de dégâts de limaces sur la plante. Appliquer de préférence en début de soirée, lorsque les limaces sortent de leur abri. L'effet molluscicide dure jusqu'à 2 semaines. Un traitement supplémentaire est nécessaire si les dégâts continuent et si les granulés ont disparu en respectant un maximum de 4 applications par saison.

NEUDORFF 1181 M est appliqué manuellement autour des plantes en cultures horticoles ou en jardins. En culture agricole, les granulés sont appliqués avec un épandeur d'engrais en granulés.

Culture	Pour lutter contre	Dose	Nombre d'applications par saison
Toutes cultures	Limaces	0.7 g/m ² ou 7 kg/ha	1 - 4 applications

La dose agréée est la plus petite dose qui garantit la meilleure efficacité dans la plupart des situations. Elle peut être réduite, sous la responsabilité de l'utilisateur, par exemple dans les situations où le risque de dégâts est faible. La diminution de la dose appliquée n'autorise pas l'augmentation du nombre maximal d'applications, ni la réduction du délai avant récolte.

Procédure de nettoyage du matériel d'épandage

Nettoyer le matériel d'épandage avec de l'eau. Aucun agent de nettoyage n'est requis.

Précautions de sécurité

Tenir hors de portée des enfants. Eviter tout contact inutile avec le produit. Porter des gants appropriés pendant la phase de chargement et la phase d'application lorsqu'elle est manuelle est recommandé. Une mauvaise utilisation peut se révéler nocive. Eviter tout contact du produit, des restes de produit ou de l'emballage vide avec les eaux de surface.

Stockage

Conserver à l'écart de la nourriture, y compris celle pour animaux.

Conserver le produit dans son emballage d'origine, hermétiquement fermé, à l'abri de la lumière et dans un endroit sec, aéré et fermant à clef.

Premiers secours

Premiers soins

- **Inhalation** : Air frais, repos. En cas de symptômes, consulter un médecin et lui montrer l'étiquette ou l'emballage.
- **Ingestion** : Rincer la bouche. En cas de symptômes, consulter un médecin et lui montrer l'emballage ou l'étiquette.
- **Contact avec la peau** : En cas de symptômes, consulter un médecin et lui montrer l'emballage ou l'étiquette.
- **Projection dans les yeux** : Rincer abondamment à l'eau pendant 10 minutes. 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.

Remarques pour le médecin

Prise en charge : traitement symptomatique.

Contacter le Centre Antipoison pour le traitement ultérieur en milieu hospitalier.

Pour toute information complémentaire, contacter le
Centre Antipoison

Emballages vides et surplus de traitement

Ne pas contaminer les étangs, les cours d'eau ou les fossés avec le produit ou l'emballage vide.

Éliminer les produits non utilisés et les emballages vides via un service de collecte spécifique (par exemple ADIVALOR), conformément à la réglementation locale. Réutilisation de l'emballage interdite.

Garantie

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur cette étiquette qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est autorisé. Conduire sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous les facteurs particuliers concernant votre exploitation tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché. Pour les denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.

Appendix 3 – Letter(s) of Access

Not applicable.