

REGISTRATION REPORT
Part A
Risk Management

Product code: NEU 1180 M

Product name(s): SLUXX HP

Active Substance(s):

**29.7 g pure active/kg ferric phosphate
(30 g technical/kg)**

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

**NATIONAL ASSESSMENT FRANCE
(authorisation renewal according to Art. 43)**

Applicant: W. Neudorff GmbH KG

Date: 2018-12-20

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PART A – Risk Management

The company W. Neudorff GmbH KG has requested renewal of the marketing authorisation in France, according to Art.43, for the product SLUXX HP (product code: NEU 1180 M; marketing authorisation n° 2100030), containing 29.7 g pure active/kg ferric phosphate (30 g technical/kg) for use as molluscicide (professional use). Ferric Phosphate is a low risk active substance, therefore SLUXX HP (NEU 1180 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 SLUXX HP (NEU 1180 M) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of SLUXX HP (NEU 1180 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 SLUXX HP (NEU 1180 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 SLUXX HP (NEU 1180 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, 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 (2016-1230) 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

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 adjutants visés à l'article L. 253-1 du code rural et de la pêche maritime <https://www.legifrance.gouv.fr/eli/arrete/2017/54/AGR1632554A/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/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 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.

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 SLUXX HP (NEU 1180 M), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in joined excel file. Studies highlighted in grey cannot be protected (not GLP, nor GEP, calculations, etc.).

1.5 Letter(s) of Access

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	SLUXX HP (NEU 1180 M)
Low risk product (article 47)	Yes
Authorisation number	2100030
Function	Molluscicide (professional use)
Applicant	W. Neudorff GmbH KG
Composition	29.7 g pure active/kg ferric phosphate (30 g technical/kg)
Formulation type (code)	Ready to use bait (RB)
Packaging	Bags in polyethylene holding 5 kg, 10 kg, 20 kg or 25 kg product Bags in polyethylene (inner bag) and polypropylene (outer tissue) holding 200 kg, 250 kg, 300 kg, 350 kg, 400 kg, 450 kg, 500 kg, 600 kg, 700 kg , 800 kg, 900 kg or 1000 kg product

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	-

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

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
Pre-harvest interval ⁹ : 1 day
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: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

PPP (product name/code):	SLUXX HP (NEU 1180 M)	Formulation type:	GAP rev., date: 2018-12-20
Active substance 1:	Ferric phosphate	Conc. of as 1:	RB (Ready to use bait) ^(a, b)
Safener:	-	Conc. of safener:	- ^(c)
Synergist:	-	Conc. of synergist:	- ^(c)
Applicant:	W. Neudorff GmbH KG	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Southern zone ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes		
Field of use:	molluscicide		

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:
					Method / Kind			Max. number (min. interval between applications)				
								kg product / ha				
								a) max. rate per appl.				
								b) max. total rate per crop/season				
								a) max. rate per appl.				
								b) max. total rate per crop/season				
								g as/ha				
								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)	-	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)	-	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 2 Use official codes/nomenclatures of EU Member States 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure) 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application 8 The maximum number of application possible under practical conditions of use must be provided. 9 Minimum interval (in days) between applications of the same product 10 For specific uses other specifications might be possible, e.g.: g/m ³ 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 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

SLUXX HP (NEU 1180 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 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 376°C. In aqueous solution (1%), it has a pH value of 3.5 at ambient temperature. There is no effect of high temperature on the stability of the formulation 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 packagings. 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, a specific analytical method for the determination of Fe³⁺ 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	
ARfD	Not required	EU (January 2016)
AOEL	0.4 mg/kg bw/d	
Dermal absorption	A dermal absorption value of 10% is proposed as worst-case scenario (EFSA, 2015 ¹⁰).	

¹⁰ EFSA Journal 2015;13(1):3973

3.1.3.1 Acute Toxicity

SLUXX HP (NEU 1180 M) containing 29.7 g/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 sensitisier.

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 ¹¹	Equipment	Application rate kg product/ha (g as/ha)	Spray dilution (L/ha)	Model
Fodder plants	F	Vehicle-mounted Manual	7 kg/ha (495 g ferric phosphate/ha)	Not applicable (ready-to-use formulation)	EFSA
All edible and non- edible crops, amenity vegetation	F, G				

Considering proposed use, operator systemic exposure was estimated using the EFSA model:

Crop	Equipment	PPE and/or working coverall	% AOEL ferric phosphate
Fodder plant, crops	Vehicle-mounted	Working coverall and gloves during mixing/loading and application	1 %
	Manual (hand-held equipment)		9 %

According to the model calculations, it can be concluded that the risk for the operator using SLUXX HP (NEU 1180 M) is acceptable with a working coverall and gloves during mixing/loading and application.

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

3.1.3.3 Bystander Exposure

SLUXX HP (NEU 1180 M) is a granular bait formulation; no drift is expected. Therefore, bystander exposure estimation is considered not relevant.

3.1.3.4 Worker Exposure

SLUXX HP (NEU 1180 M) is a granular bait formulation; no work is expected to be practiced after application. Therefore, worker exposure estimation is considered not relevant.

3.1.3.5 Resident Exposure

SLUXX HP (NEU 1180 M) is a granular bait formulation; no drift is expected. Therefore, residential exposure estimation is considered not relevant.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

¹¹ Open field or glasshouse

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 SLUXX HP (NEU 1180 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 SLUXX HP (NEU 1180 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.

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 221/2000¹², 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.

Implications for labelling resulting from environmental fate assessment: none.

¹² 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.

3.1.6 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 conclusions for the active substance 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.

There are no labelling requirements apart from SP 1.

3.1.7 Efficacy

Considering the first registration of SLUXX HP (NEU 1180 M) data and the new data submitted:

- the efficacy of SLUXX HP (NEU 1180 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 SLUXX HP (NEU 1180 M) is considered as negligible.
- 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.

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 the formulation.
- An analytical method for the specific determination of Fe^{3+} in the formulation.
- An analytical method for the determination of the relevant impurities of the active substance ferric phosphate 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

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 **SLUXX HP***

de la société NEUDORFF GMBH KG
enregistrée sous le n°2016-1230

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

Vu la décision du Directeur Général de l'Anses du 24 septembre 2018,

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

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 abroge et remplace la décision du 24 septembre 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	SLUXX HP BABOXX
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	29,7 g/kg - phosphate ferrique hydraté
Numéro d'intrant	2080295
Numéro d'AMM	2100030
Fonction	Molluscicide
Gamme d'usages	Professionnel
Mention particulière	Produit à faible risque au sens de l'article 47 du règlement (CE) 1107/2009

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de 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 20 DEC. 2018

Françoise WEBER

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



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 basse densité	5 kg ; 10 kg ; 20 kg ; 25 kg
Sacs en polypropylène / polyéthylène basse densité	200 kg ; 250 kg ; 300 kg ; 350 kg ; 400 kg ; 450 kg ; 500 kg ; 600 kg ; 700 kg ; 800 kg ; 900 kg ; 1000 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* Trit Sol* imaces et escargots	7 kg/ha	4/an	-	1	-	-	-	

Également autorisé sous abri.
Application dès le début de l'infestation.



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 le matériel d'épandage ;
- 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 :

- Non applicable.

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.

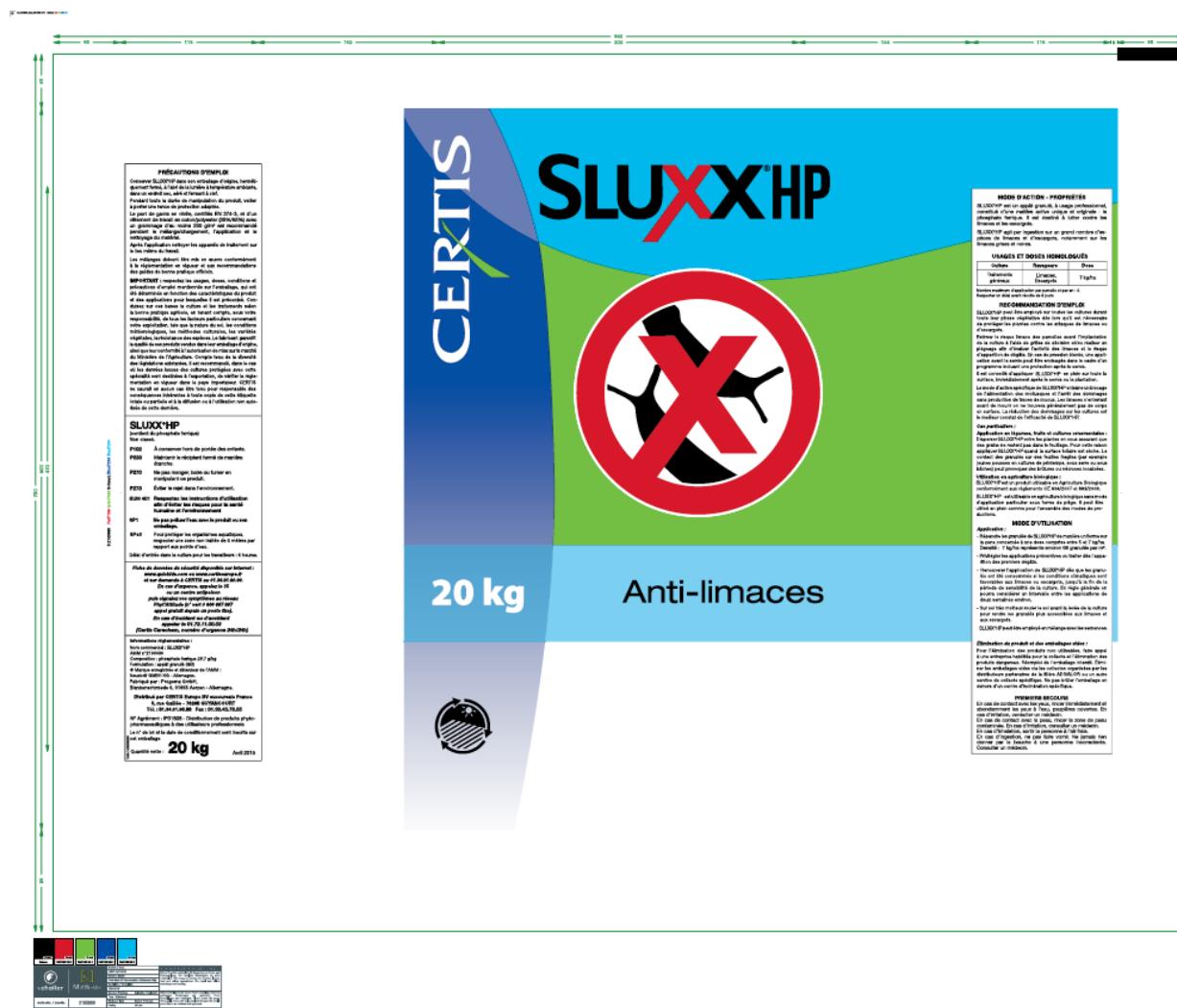


Exigences complémentaires post-autorisation

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	Date limite	Réurrence (mois)
Fournir la validation des méthodes utilisées dans les études de stabilité pour la détermination du fer et du phosphate dans le produit.	24/09/2020	-
Fournir une méthode de détermination des impuretés pertinentes (plomb, cadmium, mercure) dans le produit.	24/09/2020	-
Fournir une méthode spécifique pour la détermination du Fe ³⁺ dans le produit.	24/09/2020	-

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



Appendix 3 – Letter(s) of Access

Not applicable.