

REGISTRATION REPORT

Part A

Risk Management

Product code : NEU 1187 M

Product name : NEU 1187 M

Chemical active substance(s):

**Ferric phosphate hydrated, 41.6 g pure active/kg
(42.0 g technical/kg)**

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: W. Neudorff GmbH KG

Date: 06/06 2022

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PART A

RISK MANAGEMENT

1 Details of the application

The company W. Neudorff GmbH KG has requested a marketing authorisation in France for the product NEU 1187 M, containing 41.6 g pure active /kg ferric phosphate¹ hydrated (42.0 g technical/kg) as a molluscicide for professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of W. Neudorff GmbH KG's application submitted on 04/02/2020 to market NEU 1187 M in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

Ferric phosphate is a low risk active substance, nevertheless, **NEU 1187 M is not authorised as a low risk plant protection product as one of the co formulants is not considered as "low risk" substance.**

The present application (2020-0496) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone for field uses, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of NEU 1187 M has been made using endpoints agreed in the EU peer review of ferric phosphate. It also includes assessment of data and information related to NEU 1187 M where those data have not been considered in the EU peer review process.

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 risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

¹ 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 (Text with EEA relevance)

² 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

³ 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](#)

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The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of NEU 1187 M.

1.2 Letters of Access

Not necessary: the applicant is the owner of data which support the renewal of approval of the active substance.

1.3 Justification for submission of tests and studies

According to the applicant: « Not relevant. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of NEU 1187 M, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	NEU 1187
Product name in MS	NEU 1187
Authorisation number	2220269
Kind of use	Professional use
Low risk product (article 47)	No The product NEU 1187 M is not compliant with Article 47 of Regulation (EC) no 1107/2009 due to the presence of a co-formulant identified as a substance of concern and currently evaluated under the REACH program.
Function	Molluscicide
Applicant	W. Neudorff GmbH KG
Active substance(s) (incl. content)	Ferric phosphate, 41.6 g ferric phosphate hydrated /kg
Formulation type	Ready to use bait (RB) Formulation
Packaging	Big bags in polypropylene tissue (960 and 1000 Kg) Big bags in polypropylene tissue with inner polyethylene low density liner (500 Kg) Bags in polyethylene low density (5 kg, 10 kg, 15 kg, 20 kg and 25 kg) Bags made of Coex polyethylene low density / polyethylene terephthalate (5 Kg)

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

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Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for NEU 1187 M resulted in the **decision to grant** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

:

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

Hazard class(es), categories:	Not classified
Hazard pictograms:	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	None

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

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

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).
	For other restrictions refer to 2.5

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁵ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

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

Moreover, the French Order of 12 April 2021⁶ provides that :

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” 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 “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” 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.

Finally, the French Order of 20 November 2021⁸ on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive culture⁹ when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific Spe 8 may include reference to this order.

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

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.

⁵ 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, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

⁶ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

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

⁸ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

⁹ List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

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Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
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).
Other specific restrictions	
Re-entry period	6 hours (field uses)
Risk mitigation measures	None

2.5.2 Specific restrictions linked to the intended uses

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

None.

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2.6 Intended uses (only NATIONAL GAP)

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” or “not finalised”, 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.

GAP rev. 1, date: 06/06/2022

PPP (product name/code): NEU 1187 M / NEU 1187 M

Formulation type: RB; Bait (ready for use) ^(a, b)

Active substance 1: ferric phosphate

Conc. of a.s. 1: 41.6 g pure active /kg ferric phosphate hydrated (42.0 g technical/kg) ^(c)

Safener: none

Conc. of safener: none ^(c)

Synergist: none

Conc. of synergist: none ^(c)

Applicant: W. Neudorff GmbH KG

Professional use: ☒

Zone(s): Southern Zone ^(d)

Non-professional use: ☐

Verified by MS: Yes

Field of use: molluscicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha (f) RMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1a	FR	Agriculture crops except	F	Slugs and snails	Strew — vehicle mounted application	Dry seed until 7 true leaves unfolded BBCH 00-17	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 0.208 b) 0.832	Not applicable (Ready to use formulation)	0	Refers to 1c

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha (i) RMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1b	FR	Agriculture crops except potato	F	Slugs and snails	Strew manual application	Dry seed until 7 true leaves unfolded BBCH 00-17	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 0.208 b) 0.832	Not applicable (Ready to use formulation)	0	Refers to 1d
1c	FR	Agriculture main crops except potato and hop	F	Slugs and snails	Strew – vehicle mounted application	8 days before drilling until 7 true leaves unfolded until BBCH 17	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	F (BBCH 17)	Acceptable
1d	FR	Agriculture main crops except potato and hop	F	Slugs and snails	Strew – manual application	8 days before drilling until 7 true leaves unfolded until BBCH 17	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	F (BBCH 17)	Acceptable
2a	FR	Potato	F	Slugs and snails	Strew – vehicle mounted application	8 days before planting – leaves and stem dead, stems bleached and dry until BBCH 97	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	3	Acceptable
2b	FR	Potato	F	Slugs and snails	Strew – manual application	8 days before planting – leaves and stem dead, stems bleached and dry until BBCH 97	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	3	Acceptable

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, Gn, Gpn 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 (i) RMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
2e	FR	Potato	F	Slugs and snails	Strew vehicle mounted application	Emergence leaves and stem dead, stems bleached and dry BBCH 09-97	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 0.208 b) 0.832	Not applicable (Ready to use formulation)	0	Refers to 1a
2d	FR	Potato	F	Slugs and snails	Strew manual application	Emergence leaves and stem dead, stems bleached and dry BBCH 09-97	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 0.208 b) 0.832	Not applicable (Ready to use formulation)	0	Refers to 1b
3a	FR	Vegetables and herbs All vegetable crops Fragrant, aromatic, medicinal and condimental plants (edible and non edible), Spices, Herbs, Infusion plants, Poppy (PAPRH) and other oilseeds	F	Slugs and snails	Strew – vehicle mounted application	Dry seed – full ripe BBCH 00-89	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	1 day for vegetables and edible crops Not applicable for non edible crops	Acceptable

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, Gn, Gpn 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 (i) RMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
3b	FR	Vegetables and herbs All vegetable crops Fragrant, aromatic, medicinal and condimental plants (edible and non edible), Spices, Herbs, Infusion plants, Poppy (PAPRH) and other oilseeds	F	Slugs and snails	Strew – manual application	Dormancy – full ripe BBCH 00-89	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	1 day for vegetables and edible crops Not applicable for non edible crops	Acceptable
4a	FR	Fruit crops All fruit and berry crops	F	Slugs and snails	Strew – vehicle mounted application	Dormancy – harvest BBCH 00-89	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	1	Acceptable
4b	FR	Fruit crops All fruit and berry crops	F	Slugs and snails	Strew – manual application	Dormancy – harvest BBCH 00-89	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	1	Acceptable

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha (i) RMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
5a	FR	Ornamentals Trees and Shrubs, Roses, Floral crops and green plants, Ornamental bulbs	F	Slugs and snails	Strew – vehicle mounted application	Dry seed – full ripe BBCH 00-89	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	Not applicable	Acceptable
5b	FR	Ornamentals Trees and Shrubs, Roses, Floral crops and green plants, Ornamental bulbs	F	Slugs and snails	Strew – manual application	Dry seed – full ripe BBCH 00-89	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	Not applicable	Acceptable
6a	FR	Hops	F	Slugs and snails	Strew – vehicle mounted application	First pair of leaves – un- folded Cones ripe for picking BBCH 11 - 89	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	3	Acceptable
6b	FR	Hops	F	Slugs and snails	Strew – manual application	First pair of leaves – un- folded Cones ripe for picking BBCH 11 - 89	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	3	Acceptable
7a	FR	Vineyards	F	Slugs and snails	Strew – vehicle mounted application	Beginning of bud swelling – Berries ripe for harvest BBCH 01-89	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	3	Acceptable

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha (i) RMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
7b	FR	Vineyards	F	Slugs and snails	Strew – manual application	Beginning of bud swelling – Berries ripe for harvest BBCH 01-89	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	3	Acceptable
8a	FR	Grassland and meadows	F	Slugs and snails	Strew – vehicle mounted application	Dry seed until harvest BBCH 00-99	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 0.208 b) 0.832	Not applicable (Ready to use formulation)	0	Refers to 8c
8b	FR	Grassland and meadows	F	Slugs and snails	Strew – manual application	Dry seed until harvest BBCH 00-99	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 0.208 b) 0.832	Not applicable (Ready to use formulation)	0	Refers to 8d
8c	FR	Grassland and meadows	F	Slugs and snails	Strew – vehicle mounted application	8 days before drilling until harvest Until BBCH 99	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	Not applicable	Acceptable
8d	FR	Grassland and meadows	F	Slugs and snails	Strew – manual application	8 days before drilling until harvest Until BBCH 99	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	Not applicable	Acceptable

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop or situation (crop destination/purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha (f) RMS conclusion
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
9a	FR	Amenity vegetation (Gardens, Green Spaces, Infrastructures)	F	Slugs and snails	Strew – vehicle mounted application	Beginning of bud swelling – Fruit ripe for harvest BBCH 01-89	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	Not applicable	Acceptable
9b	FR	Amenity vegetation (Gardens, Green Spaces, Infrastructures)	F	Slugs and snails	Strew – manual application	Beginning of bud swelling – Fruit ripe for harvest BBCH 01-89	a) 4 b) 4	Min. 5	a) max. 5 b) 20	a) 208 b) 832	Not applicable (Ready to use formulation)	Not applicable	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.

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Remarks:	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
colu	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
mns:	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 Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

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

NEU 1187 M is a Bait formulation (ready for use). 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 that of a blue granulate with a diameter of 1-2 mm and a length of 3-4 mm. It is not explosive, has no oxidising properties, is not flammable and not self-heating. In aqueous solution, it has a pH value of 3.0 (1% suspension) and a free acidity of 2.21%. 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 changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging. The technical characteristics as determined for NEU 1187 M are acceptable for a RB formulation. The formulation is used as such.

The formulation does not contain hydrocarbons or H304 formulants ≥ 10 %.

3.2 Efficacy (Part B, Section 3)

The level of efficacy of the product NEU 1187 M is considered satisfactory for the requested uses.

The level of phytotoxicity of the product NEU 1187 M is considered negligible for the requested uses.

The risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops and adjacent crops are considered negligible for the requested uses.

The risk of resistance development or appearance to ferric phosphate does not require a monitoring for the requested uses.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substance ferric phosphate in the formulation are available and validated. Nevertheless, the determination of the counter ion phosphate using ion chromatography should be provided in post authorization. Analytical methods for the determination of relevant impurities (lead, cadmium and mercury) of ferric phosphate in the formulation are available and validated.

3.3.2 Analytical methods for residues

Ferric phosphate as active substance on Annex IV of EC Regulation no 396/2005 is exempt from MRL setting.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

The product NEU 1187 M has a low acute oral, inhalational and dermal toxicity. It is not irritating to the rabbit skin or eye and is not a skin sensitiser

Active substance (incl. content)	Ferric phosphate (41.58 g/kg) (equivalent to 15.4 g iron/kg)
AOEL systemic	0.4 mg/kg bw/d (iron)
AAOEL	NONE
Inhalation absorption	100%
Vapour pressure	Non-volatile
Oral absorption	50%
Dermal absorption	10%

3.4.2 Operator exposure

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model⁸

		Ferric phosphate	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Broadcast application of granules outdoors (vehicle mounted)			
Application rate		0.077 kg iron/ha	
Granule application (EFSA model; 75 th percentile) Body weight: 60 kg	Potential exposure	0.0160	4.01
	Certified protective coverall (arms, body and legs covered) M/L and A	0.0027	0.7
	Certified protective coverall (arms, body and legs covered) A+ gloves	0.0015	0.39
Manual application of granules outdoors (Manual)			
Application rate		0.077 kg iron/ha	
Granule application (EFSA model; 75 th percentile) Body weight: 60 kg	Potential exposure	1.2506	312.65
	Certified protective coverall (arms, body and legs covered) A	0.3751	94
	Certified protective coverall (arms, body and legs covered) A+ gloves	0.0131	3.28

According to the EFSA model calculations, it can be concluded that the risk for the operator using NEU 1187 M is **acceptable** taking into account the above mentioned personal protective equipment

3.4.3 Worker exposure

Considering that the product is a granular bait formulation the worker exposure evaluation is not relevant.

3.4.4 Bystander exposure

NEU 1187 M is a granular bait formulation; no drift is expected. Therefore, bystander exposure estimation is considered not relevant.

3.4.5 Resident exposure

According to the intended uses (ready-to-use bait pellet applied on bare soil, in furrow), no spray drift, no fall out are expected. Therefore, the resident exposure assessment is not relevant

3.4.6 Combined exposure

No relevant, the product contains only one active substance.

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

As ornamental plants and amenity vegetation are non edible commodities, the respective intended uses were not assessed.

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.

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

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

Last, considering the formulation as «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 NEU 1187 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 NEU 1187 M is intended to be used as bait between the plants it is considered that it is not necessary to set a PHI.

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Summary for NEU 1187 M

Information on NEU 1187 M

Crop	PHI for NEU 1187 M proposed by applicant	PHI/ Withholding period* sufficiently supported for Ferric phosphate	PHI for NEU 1187 M proposed by zRMS	zRMS Comments (if different PHI proposed)
Agriculture crops except potato	No PHI required	NR	No PHI required	
Potato				
Vegetables				
Fruit crops				
Hop				
Vineyards				
Grassland and meadows				
Ornamentals	NR		NR	Not assessed (non edible commodity)
Amenity vegetation				

NR: not relevant

* Purpose of withholding period to be specified

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

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

The fate and behaviour in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active substance for the intended use patterns.

Due to the natural occurrence in the environment of ferric phosphate and its dissociation products (iron ions and phosphate ions), no specific study to address the fate and behavior of active substance in environment is needed. The PEC of ferric phosphate in soil has been assessed according to FOCUS guidance documents, with standard FOCUS recommendations. The results for PEC_{SOIL} for ferric phosphate are used for the ecotoxicological risk assessment.

For the aquatic risk assessment the maximum solubility in water (1.86×10^{-12} g/L) is used.

Due to the nature of the active substance, no unacceptable risk of groundwater contamination by ferric phosphate is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

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

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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.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

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

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

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

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 12 months regarding:

- For the purpose of controlling the product on the market, a method for the determination of the phosphate ions in the formulation by ion chromatography to specifically quantify Fe^{3+} by calculation.

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Appendix 1 Copy of the product authorisation

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

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

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

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **NEU 1187 M***

de la société **W. NEUDORFF GMBH KG**

enregistrée sous le **n°2020-0496**

Vu les conclusions de l'évaluation de l'Anses du 15 mars 2022,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et son annexe.

Considérant que, bien que la substance active phosphate ferrique soit approuvée en tant que substance active à faible risque conformément à l'article 22 du règlement (CE) n°1107/2009, le produit NEU 1187 M contient un coformulant identifié comme substance préoccupante et ne répond pas à ce titre aux exigences de l'article 47 de ce règlement. Le produit NEU 1187 M ne peut en conséquence être qualifié de produit à faible risque.

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.

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Informations générales sur le produit	
Nom du produit	NEU 1187 M
Type de produit	Produit de référence
Titulaire	W. NEUDORFF GMBH KG An der Mühle 3 31860 EMMERTHAL Allemagne
Formulation	Appât prêt à l'emploi (RB)
Contenant	41,6 g/kg - phosphate ferrique hydraté
Numéro d'intrant	138-2020.01
Numéro d'AMM	2220269
Fonction	Molluscicide
Gamme d'usage	Professionnel

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 06/06/2022

DocuSigned by:

 AE281A955A42454
 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 : 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 téréphtalate / polyéthylène basse densité	5 kg
Sacs en polyéthylène basse densité	5 kg ; 10 kg ; 15 kg ; 20 kg ; 25 kg
Big-bags en polypropylène avec doublure intérieure en polyéthylène basse densité	500 kg
Big-bags en polypropylène	960 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.

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Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
11012903 Traitements généraux* Trt Sol* Limaces et escargots	5 kg/ha	4/an	jusqu'au stade BBCH 17	F (BBCH 17)	-	-	-	Non concerné
	Uniquement sur « grandes cultures » sauf « houblon » et « prairies ». Intervalle minimum entre les applications : 5 jours.							
	5 kg/ha	4/an	jusqu'au stade BBCH 97	3	-	-	-	Non concerné
	Uniquement sur « pomme de terre ». Intervalle minimum entre les applications : 5 jours.							
	5 kg/ha	4/an	entre les stades BBCH 11 et BBCH 89	3	-	-	-	Non concerné
	Uniquement sur « houblon ». Intervalle minimum entre les applications : 5 jours.							
	5 kg/ha	4/an	-	Non applicable	-	-	-	Non concerné
	Uniquement sur « prairies » et « gazons de graminées ». Intervalle minimum entre les applications : 5 jours.							
	5 kg/ha	4/an	jusqu'au stade BBCH 89	Non applicable	-	-	-	Non concerné
	Uniquement sur « cultures ornementales ». Intervalle minimum entre les applications : 5 jours.							

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Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
11012903 Traitements généraux*Trt Sol*Limaces et escargots	5 kg/ha	4/an	jusqu'au stade BBCH 89	3	-	-	-	Non concerné
	Uniquement sur « vigne ». Intervalle minimum entre les applications : 5 jours.							
	5 kg/ha	4/an	-	Non applicable	-	-	-	Non concerné
	Uniquement sur jardins, espaces végétalisés et infrastructures (JEVI). Intervalle minimum entre les applications : 5 jours.							
	5 kg/ha	4/an	entre les stades BBCH 00 et BBCH 89	1	-	-	-	Non concerné
Uniquement sur « PPAMC », « cultures fruitières » et « cultures légumières » sauf « pomme de terre ». Intervalle minimum entre les applications : 5 jours.								

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
16012901 Cultures légumières*Trt Sol* Limaces et escargots	5 kg/ha	4/an	-
	Motivation du refus : L'usage est refusé car transformé en l'usage n°11012903 Traitements généraux*Trt Sol*Limaces et escargots mieux adapté		
17402901 Cultures ornementales*Trt Sol* Limaces et escargots	5 kg/ha	4/an	-
	Motivation du refus : L'usage est refusé car transformé en l'usage n°11012903 Traitements généraux*Trt Sol*Limaces et escargots mieux adapté		
15102901 Grandes cultures*Trt Sol* Limaces et escargots	5 kg/ha	4/an	-
	Motivation du refus : L'usage est refusé car transformé en l'usage n°11012903 Traitements généraux*Trt Sol*Limaces et escargots mieux adapté		



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

Dans le cadre d'une application effectuée à l'aide d'un matériel d'épandage (ex : microgranulateur) :

• pendant le chargement du matériel d'épandage

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;

• pendant l'épandage

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (type A, B ou C) à usage unique, en cas d'intervention sur semoir, épandeur à engrais ou microgranulateur ;

• pendant le nettoyage du matériel d'épandage

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).

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

- 6 heures.

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.

Appendix 2 Copy of the product label

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

Projet d'étiquette pour NEU 1187 M
14/01/2020 – BMA

AUTORISATION DE MISE EN MARCHÉ

AUTORISATION DE MISE EN MARCHÉ

NEU 1187 M

AMM n° XXXXXX, détenue par W. NEUDORFF GmbH KG - An der Mühle 3 - 31860 Emmerthal – Allemagne.

Substance active : Phosphate ferrique hydraté 41,6 g/kg (4,2%).

Molluscicide, agit par ingestion.

Type de préparation : Appât (prêt à l'emploi) (RB).

Usages autorisés : Traitements généraux – Traitement du sol – Limaces et escargots.

Dose maximale d'emploi : 5 kg/ha par application, 20 kg/ha par saison.

Nombre maximum d'applications : 4/an.

Délai minimum entre applications : 5 jours.

Application dès le début de l'infestation sur toute la surface du sol.

Peut également s'appliquer dans la ligne de semis ou en mélange avec les semences.

Application en plein champ et sous abri.

Délai avant récolte : 0 jour.

Zones non traitées : non.

Gamme d'usages : professionnel.

Délai de rentrée : non applicable.

Classement de danger : sans classement.

Mention particulière : Produit à faible risque au sens de l'article 47 du règlement (CE) 1107/2009.

Conditions d'emploi

Pour l'opérateur, porter

- pendant le chargement et 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.

- 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).

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

ETIQUETTE DE SECURITE

PRECAUTIONS

Tenir hors de portée des enfants.
Ne pas manger, boire ou fumer en manipulant ce produit.
Éviter le rejet dans l'environnement.
Éliminer le contenu et le récipient conformément à la réglementation.
Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Premiers soins :

Après inhalation, assurer un apport d'air frais. En cas de malaise, conduire le malade auprès d'un médecin.
En cas de contact avec la peau, laver immédiatement et abondamment à l'eau. En cas de contact avec les yeux, laver immédiatement et abondamment avec de l'eau.

En cas d'urgence :
Composer le 15 ou le 112 ou contacter
le centre antipoison le plus proche.

CONDITIONNEMENT

Masse nette : **xx kg**

Distribué par :

tbc

Numéro de lot : voir impression sur l'emballage.

Date de fabrication : voir impression sur l'emballage.

GESTION DES DECHETS

ELIMINATION DU PRODUIT ET DE L'EMBALLAGE

Ne pas réutiliser l'emballage.

Apporter les emballages vides à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique.
Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine.
Interroger votre distributeur partenaire d'A.D.I.VALOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.
CERTIS Europe B.V. est partenaire de la filière A.D.I.VALOR.

CONSEILS D'UTILISATION

CONSEILS D'UTILISATION

Produit Utilisable en Agriculture Biologique, en application du règlement européen de l'agriculture biologique

Stockage

Conserver le produit dans son emballage d'origine hermétiquement fermé, dans un local phytopharmaceutique conforme à la réglementation en vigueur. Conserver le produit à l'abri de la lumière directe du soleil, dans un endroit frais, à l'abri du gel, sec et aéré.