

REGISTRATION REPORT

Part A

Risk Management

Product code: S15632

Product name(s): NATUREN LIMEX

Active Substance(s):

**12.4 g pure active/kg ferric phosphate hydrated
(12.5 g technical/kg)**

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(authorisation renewal (art. 43))

Applicant: Evergreen Garden Care France SAS

Date: 2019-07-10

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PART A – Risk Management

The company Evergreen Garden Care France SAS has requested renewal of the marketing authorisation in France for the product NATUREN LIMEX (product code: S15632; marketing authorisation n° 2150790), containing 12.4 g pure active/kg ferric phosphate hydrated (12.5 g/ technical/kg) for use as a molluscicide (non-professional use). Ferric Phosphate is a low risk active substance, therefore NATUREN LIMEX (S15632) 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 NATUREN LIMEX (S15632) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of NATUREN LIMEX (S15632) 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 NATUREN LIMEX (S15632).

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 Evergreen Garden Care France SAS's application to market NATUREN LIMEX (S15632) in France as a molluscicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request (Field uses) 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 (2016-1216) embodies two different evaluations:

- (1) Use of NATUREN LIMEX (S15632) as a molluscicide treatment in open fields was evaluated by France 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.
- (2) A request for mutual recognition based on the evaluation of the product NATUREN LIMEX (S15632) in United Kingdom (interzonal evaluation), for use as a molluscicide treatment for crops grown under protection.

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,

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 adjoints visés à l'article L. 253-1 du code rural et de la pêche maritime <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte>

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>

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 NATUREN LIMEX (S15632), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

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

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	NATUREN LIMEX (S15632)
Low risk product (article 47)	Yes
Authorisation number	2150790
Function	Molluscicide (non-professional use)
Applicant	Evergreen Garden Care France SAS
Composition	12.4 g pure active/kg ferric phosphate hydrated (12.5 g technical/kg)
Formulation type (code)	Granular baits (GB)
Packaging	Bottles in HDPE holding 600g, 650g, 685g, 700g Bottles in PET holding 200g, 300g, 350g, 400g, 450g, 500g, 550g, 600g, 650g, 700g, 750g, 800g, 850g, 900g, 950g, 1kg Folding box with spout in cardboard or cardboard with PE lamination or cardboard with a PET/PE sachet (PE in contact with the product), holding 200g, 300g, 350g, 375g, 400g, 450g, 500g, 550g, 600g, 650g, 700g, 750g, 785g, 800g, 850g, 900g, 950g, 1kg, 1,1kg, 1,2kg, 1,3kg, 1,4kg, 1,5kg, 1,6kg, 1,7kg, 1,8kg, 1,9kg, 2kg, 2,2kg 'Composite box' with a PET liner inside holding 200g, 250g, 300g, 350g, 375g, 400g. The packaging: Doypack bag PET / PE (PE in contact with the product) were not accepted for amateur uses because they do not guarantee a minimum exposure of the non-professional user

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	-	
Health hazards	-	
Environmental hazards	-	
Hazard pictograms	-	
Signal word	-	
Hazard statements	-	-
	-	-
	-	-
	-	-
	-	-

Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

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

2.2.2 Other phrases in compliance with Regulation (EU) No 547/2011

The authorisation of the preparation is linked for non-professional uses only to the following conditions:

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

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁷ :
Re-entry period ⁸ : Not applicable
Pre-harvest interval ⁹ : 3 days for food and feed crops. Not applicable for no-food and no-feed crops.
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.

PPP (product name/code):	NATUREN LIMEX (S15632)	Formulation type:	GAP rev. , date: 2019-07-10
Active substance 1:	ferric phosphate hydrated	Conc. of as 1:	GB ^(a, b)
	-	Conc. of safener:	12.4 g/kg ^(c)
Synergist:	-	Conc. of synergist:	- ^(c)
Applicant:	Evergreen Garden Care France SAS	Professional use:	<input type="checkbox"/>
Zone(s):	southern ^(d)	Non professional use:	<input checked="" type="checkbox"/>
Verified by MS:	yes		
Field of use:	molluscicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	zRMS conclusion (Remarks from applicant)
					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 or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	zRMS conclusion (Remarks from applicant)
					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 or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR	All Vegetables examples: [NNNVV] [NNNVW] [NNNHP] [NNNVL]	F	Slugs Examples: <i>Arion</i> sp. [ARIOSP] <i>Arion hortensis</i> [ARIOHO] <i>Deroceras reticulatum</i> [DERORE] <i>Deroceras</i> sp. [DEROSP] <i>Arion lusitanicus</i> [ARIOLU] <i>Arion ater rufus</i> [ARIORU] <i>Helix</i> sp. HELXSP, <i>Cepaea</i> sp. CEPASP	Ready-to use pellets Broadcast spreading between plants by hand or automatic dispenser	During vegetation period (March to September)	4	10 days	a) 30 kg/ha b) 120 kg/ha	a) 300 g/ha b) 1200 g/ha	n.a. (ready to use)	3 days (food and feed crops) Not applic able (no- food and no- feed crops)	Acceptable (on food crops ensure that pellets do not rest on, or become trapped in leaves)
2	FR	All Fruit crops examples: [NNNOO] [NNNVF]	F	Slugs Examples: <i>Arion</i> sp. [ARIOSP] <i>Arion hortensis</i> [ARIOHO] <i>Deroceras reticulatum</i> [DERORE] <i>Deroceras</i> sp. [DEROSP] <i>Arion lusitanicus</i> [ARIOLU] <i>Arion ater rufus</i> [ARIORU] <i>Helix</i> sp. HELXSP, <i>Cepaea</i> sp. CEPASP	Ready-to use pellets Broadcast spreading between plants by hand or automatic dispenser	During vegetation period (March to September)	4	10 days	a) 30 kg/ha b) 120 kg/ha	a) 300 g/ha b) 1200 g/ha	n.a. (ready to use)	3 days (food and feed crops) Not applic able (no- food and no- feed crops)	Acceptable (on food crops ensure that pellets do not rest on, or become trapped in leaves)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	zRMS conclusion (Remarks from applicant)
					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 or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
3	FR	All Ornamentals examples: [NNNZZ] [NNNZA] [NNNZG] [NNNZD] [NNNZL]	F	Slugs Examples: <i>Arion</i> sp. [ARIOSP] <i>Arion hortensis</i> [ARIOHO] <i>Deroceras reticulatum</i> [DERORE] <i>Deroceras</i> sp. [DEROSP] <i>Arion lusitanicus</i> [ARIOLU] <i>Arion ater rufus</i> [ARIORU] <i>Helix</i> sp. HELXSP, <i>Cepaea</i> sp. CEPASP	Ready-to use pellets Broadcast spreading between plants by hand or automatic dispenser	During vegetation period (March to September)	4	10 days	a) 30 kg/ha b) 120 kg/ha	a) 300 g/ha b) 1200 g/ha	n.a. (ready to use)	n.a.	Acceptable
4	FR	Natural surfaces not intended to bear vegetation i.e. [NNNXX]	F	Slugs Examples: <i>Arion</i> sp. [ARIOSP] <i>Arion hortensis</i> [ARIOHO] <i>Deroceras reticulatum</i> [DERORE] <i>Deroceras</i> sp. [DEROSP] <i>Arion lusitanicus</i> [ARIOLU] <i>Arion ater rufus</i> [ARIORU] <i>Helix</i> sp. HELXSP,	Ready-to use pellets Broadcast spreading between plants by hand or automatic dispenser	During vegetation period (March to September)	4	10 days	a) 30 kg/ha b) 120 kg/ha	a) 300 g/ha b) 1200 g/ha	n.a. (ready to use)	n.a.	Acceptable

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	zRMS conclusion (Remarks from applicant)
					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 or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
				Cepaea sp. CEPAP									

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

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.

(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.

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/m³ 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

NATUREN LIMEX (S15632) is a GB formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is cream free flowing granules, with no detectable odor. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 346°C. In aqueous solution (1%), it has a pH value of 4.3 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 (HDPE, cardboard, cardboard with inner aluminium layer and PET). Its technical characteristics are acceptable for a GB formulation.

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

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical method for the determination of active substance in the formulation is available and validated. Moreover, a specific analytical method to determine Fe³⁺ in the formulation is required in post-registration.

No analytical method for the determination of 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
AOEL	0.4 mg/kg bw/d
Dermal absorption	A dermal absorption value of 10% is proposed as worst-case scenario (EFSA, 2015 ¹⁰).

3.1.3.1 Acute Toxicity

¹⁰ EFSA Journal 2015;13(1):3973

NATUREN LIMEX (S15632) containing 12.4 g/kg ferric phosphate hydrated has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitizer.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

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
All vegetables, ornamentals, fruit crops	F	Broadcast spreading between plants by hand or automatic dispenser (using the packaging as dispenser)	0.03 g ferric phosphate/m ²	Not applicable (ready-to-use)	UPJ home garden model

Considering proposed uses, operator systemic exposure was estimated using the French study 2005 dedicated to amateur use (UPJ home garden model):

Crop	Equipment	PPE and/or working coverall	% AOEL Ferric phosphate
All vegetables, ornamentals, fruit crops	Manual spreading (granules)	No PPE	3 %

According to the model calculations, it can be concluded that the risk for the operator using NATUREN LIMEX (S15632) is acceptable without PPE.

The proposed packaging has been described in sufficient detail, and their compliance with the provisions of French regulation relating to the use of plant protection products by non-professional users can therefore be finalized except for Doypack bag PET / PE (PE in contact with the product).

3.1.3.3 Bystander Exposure

NATUREN LIMEX (S15632) is a granular bait formulation; no drift is expected. Therefore, bystander exposure estimation is considered not relevant.

3.1.3.4 Worker Exposure

NATUREN LIMEX (S15632) is intended to be used by amateurs during home garden application. In the case of non professional users, the worker is also the user of the product, it is considered that the assessment for workers is covered by the operator exposure assessment.

3.1.3.5 Resident Exposure

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 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 NATUREN LIMEX (S15632) and no risk mitigation measure is deemed necessary to insure consumer safety.

All intended uses are then considered acceptable.

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.

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

The PEC of ferric phosphate in soil has been assessed according to FOCUS guidance documents, with standard FOCUS recommendations. The results for PEC_{SOIL} for ferric phosphate are used for the eco-toxicological risk assessment.

Given the very low water solubility, the low soil mobility of ferric phosphate and the intended uses (home and garden uses; granular application), no PEC_{SW} were required.

For home and garden uses, no PEC_{GW} were required according to EU conclusions (EFSA, 2015). According to the guidance document SANCO221/2000¹², 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.

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

Implications for labelling resulting from environmental fate assessment: none.

3.1.6 Ecotoxicology

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

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.

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

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

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

3.1.7 Efficacy

Considering the first registration of NATUREN LIMEX (S15632) data and the new data submitted:

- the level of efficacy of NATUREN LIMEX (S15632) when applied at the claimed dose of 30 kg/ha on several species of slugs on different crops is considered as satisfactory.
- the risk of negative impact on yield, quality, propagation, succeeding crops, adjacent crops is considered as negligible.
- the risk of resistance development or appearance to phosphate ferric is considered as very low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation **can be granted** as proposed in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

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

- An analytical method for the specific determination of Fe³⁺ in the formulation.
- The confirmation of the applicability for the product, of the determination of relevant impurities on the active substance ferric phosphate.

3.4.3 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 **NATUREN LIMEX***

*de la société EVERGREEN GARDEN CARE FRANCE SAS
enregistrée sous le n°2016-1216*

Vu les conclusions de l'évaluation de l'Anses du 29 novembre 2018,

Vu la décision du Directeur général de l'Anses du 6 février 2019,

Vu le recours gracieux formé le 22 mars 2019 par la société EVERGREEN GARDEN CARE FRANCE SAS,

Vu les éléments complémentaires transmis par la direction en charge de l'évaluation des produits réglementés de l'Anses le 17 juin 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 précisées dans la présente décision et ses annexes.

La présente décision **abroge et remplace** la décision du 6 février 2019 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	NATUREN LIMEX LIMEX NAPPA
Type de produit	Produit de référence
Titulaire	EVERGREEN GARDEN CARE FRANCE SAS 21, chemin de la Sauvegarde 69130 ECULLY France
Formulation	Appât granulé (GB)
Contenant	12,4 g/kg - phosphate ferrique hydraté
Numéro d'intrant	980-2013.01
Numéro d'AMM	2150790
Fonction	Molluscicide
Gamme d'usage	Amateur / emploi autorisé dans les jardins
Mention particulière	Produit à faible risque au sens de l'article 47 du règlement (CE) 1107/2009

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2031.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort le, 10 JUIL. 2019

Caroline SEMAILLE

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

NATUREN LIMEX
AMM n°2150790

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Boîtes en carton avec boc verseur, avec sachet polyéthylène téréphthalate / polyéthylène à l'intérieur	200 g ; 300 g ; 350 g ; 375 g ; 400 g ; 450 g ; 500 g ; 550 g ; 600 g ; 650 g ; 700 g ; 750 g ; 785 g ; 800 g ; 850 g ; 900 g ; 950 g ; 1 kg ; 1,1 kg ; 1,2 kg ; 1,3 kg ; 1,4 kg ; 1,5 kg ; 1,6 kg ; 1,7 kg ; 1,8 kg ; 1,9 kg ; 2 kg ; 2,2 kg
Boîtes en carton avec boc verseur	200 g ; 300 g ; 350 g ; 375 g ; 400 g ; 450 g ; 500 g ; 550 g ; 600 g ; 650 g ; 700 g ; 750 g ; 785 g ; 800 g ; 850 g ; 900 g ; 950 g ; 1 kg ; 1,1 kg ; 1,2 kg ; 1,3 kg ; 1,4 kg ; 1,5 kg ; 1,6 kg ; 1,7 kg ; 1,8 kg ; 1,9 kg ; 2 kg ; 2,2 kg
Boîtes en carton avec boc verseur, avec polyéthylène laminé à l'intérieur	200 g ; 300 g ; 350 g ; 375 g ; 400 g ; 450 g ; 500 g ; 550 g ; 600 g ; 650 g ; 700 g ; 750 g ; 785 g ; 800 g ; 850 g ; 900 g ; 950 g ; 1 kg ; 1,1 kg ; 1,2 kg ; 1,3 kg ; 1,4 kg ; 1,5 kg ; 1,6 kg ; 1,7 kg ; 1,8 kg ; 1,9 kg ; 2 kg ; 2,2 kg
Boîtes « composite » type « boîte à sel » avec film PET à l'intérieur	200 g ; 250 g ; 300 g ; 350 g ; 375 g ; 400 g
Bouteilles en polyéthylène haute densité avec bouchon sécurité enfant et restricteur de débit	600 g ; 650 g ; 685 g ; 700 g
Bouteilles en polyéthylène téréphthalate avec bouchon à clapet et restricteur de débit	200 g ; 300 g ; 350 g ; 400 g ; 450 g ; 500 g ; 550 g ; 600 g ; 650 g ; 700 g ; 750 g ; 800 g ; 850 g ; 900 g ; 950 g ; 1 kg

Les emballages de type sachets avec zip en polyéthylène téréphthalate / polyéthylène sont refusés car ils ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel.

Classification du produit
La classification retenue est la suivante :
Sans classement.
Pour les phrases P se référer à la réglementation en vigueur.
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.



Liste des usages autorisés

En l'absence de 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 anthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
11012903 Traitements généraux* Trt Sol* Limaces et escargots	30 g/10 m ²	4/an	-	3	-	-	-	-
			Également autorisé sous abri. Uniquement sur cultures alimentaires. Application entre les rangs des cultures. Application durant la période de végétation. Intervalle minimum entre les applications : 10 jours.		Non applicable	-	-	-



Conditions d'emploi du produit

Délai de rentrée :

- Non pertinent pour ce type d'application.

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

Protection de l'eau

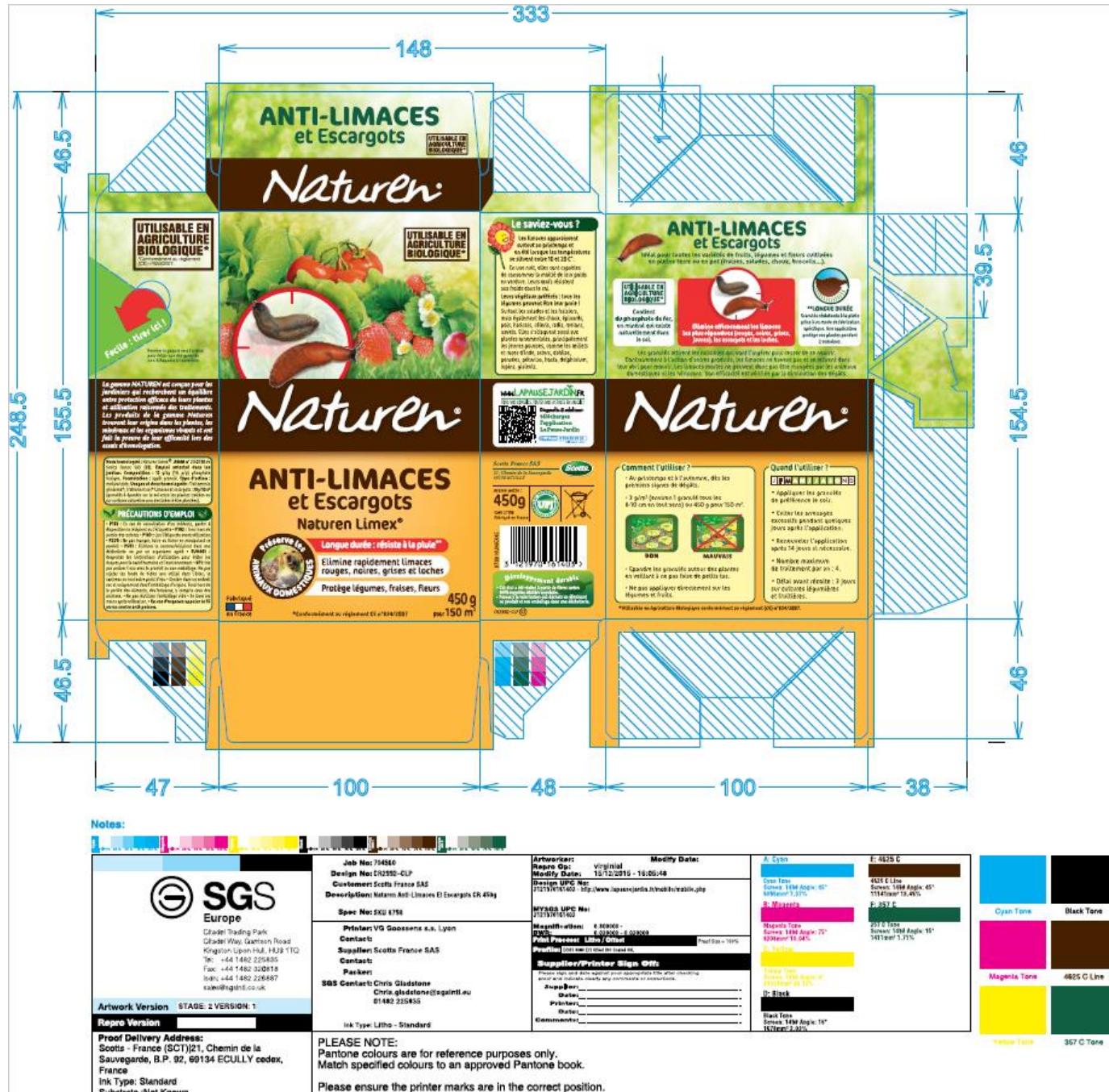
- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidons non utilisés.

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Date limite	Référence (mois)
Fournir une méthode de détermination spécifique du Fe ³⁺ dans le produit.	06/02/2021	-
Fournir la confirmation de l'applicabilité au produit de la méthode de détermination des impuretés pertinentes dans la substance active technique.	06/02/2021	-

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



Appendix 3 – Letter(s) of Access

Not applicable.