REGISTRATION REPORT

Part A

Risk Management

Product code: S21302

Product name: LIMEX ULTRA

Chemical active substance:

Ferric phosphate (anhydrous), 30 g/kg

non-professional uses

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Evergreen Garden Care France SAS

MS Finalisation date: 03/02/2023

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PART A

RISK MANAGEMENT

1 Details of the application

The company Evergreen Garden Care France SAS has requested a marketing authorisation in France for the product LIMEX ULTRA (formulation code: S21302), containing 30 g/kg ferric phosphate anhydrous[1] as a molluscicide for **non-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 Evergreen Garden Care France SAS's application submitted on 19/10/2021 to market LIMEX ULTRA (S21302) 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, therefore LIMEX ULTRA (S21302)shall be authorised as a low risk plant protection product where compliant with Article 47 of Regulation (EC) no 1107/2009.

The present application (2021-3098) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, 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 LIMEX ULTRA (S21302) has been made using endpoints agreed in the EU peer review of ferric phosphate. It also includes assessment of data and information related to LIMEX ULTRA (S21302) 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.

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[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.

[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

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[4], 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 LIMEX ULTRA (S21302).

1.2 Letters of Access

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

1.3 Justification for submission of tests and studies

According to the applicant: "*The present submission concerns the authorization of S21302 as a molluscicide against slugs and snails. Data relative to physical and chemical properties, analytical methods, efficacy, residues, toxicological and ecotoxicological are summarized in this section. These data are compliant with the European Regulation (EC) No. 284/2013 regarding data requirements for plant protection products*."

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of LIMEX ULTRA (S21302)*, 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	S21302
Product name in MS	LIMEX ULTRA (S21302)
Authorisation number	2230036
Kind of use	Non-professional use
Low risk product (article 47)	Yes (compliant with art 47 of Regulation (EU) N°1107/2009)
Function	Molluscicide
Applicant	Evergreen Garden Care France SAS
Active substance(s) (incl. content)	Ferric phosphate; 30 g/kg
Formulation type	Granular Bait [GB]

[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

Packaging	Bottles made of HDPE[5] with child resistant closure (CRC) and flow restrictor (150 g, 200 g, 300 g, 350 g, 400 g, 450 g, 500 g, 550 g, 600 g, 650 g, 685 g, 700 g, 750 g, 800 g, 850 g, 900 g, 950 g, 1 kg) Bottles made of PET[6] with closure dual flap and flow restrictor (150 g, 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) Carton folding box with reclosable spout device (150 g, 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, 2,3 kg) Folding box with laminated LDPE[7] inside with reclosable spout device (150 g, 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, 2,3 kg) Carton box with PET inside with reclosable spout device (150 g, 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, 2,3 kg) Folding box+plastic bag made of PET/LDPE with reclosable spout device (150 g, 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, 2,3 kg) Composite box with PET film inside with child resistant closure (CRC) and flow restrictor (150 g, 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)
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 LIMEX ULTRA (S21302) 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

[5] HDPE : high density polyethylene
[6] PET : terephtalate polyethylene
[7] LDPE : low density polyethylene

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:	-
Hazard pictograms:	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	-

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

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

	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the washing water of the spreader.
	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 2017[8] 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.

Finally, the French Order of 12 April 2021[9] provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision

[8] 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/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

[9] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

- 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 extrapolation[10] 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.

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.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
Protection phrase	
Other specific restrictions	
Re-entry period	Not applicable.
Storage	-
SPa 1	-
Risk mitigation measures	-
Risk mitigation measures	-
Agricultural recommendations	Contains a molluscicidal substance which may cause adverse effects on earthworms and other soil macro-organisms.

2.5.2 Specific restrictions linked to the intended uses

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

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

None.

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 12 April 2021 (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.

GAP rev. 01, **2023-February-03**

PPP (product name/code):	LIMEX ULTRA (S21302) / S21302	Formulation type:	Granular Bait (GB) [a, b]
Active substance 1:	Ferric phosphate	Conc. of as 1:	3 % w/w
Applicant:	Evergreen Garden Care France SAS	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 and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. 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 ap-plications (days)	kg product/10 m² a) max. rate per appl. b) max. total rate per crop/season	g a.s./10 m² 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)													
1	FR	All edible crops (e.g. Lettuce, Cabbage, Strawberries, *etc.*)	Fn	Slugs: *Arion* spp., *Deroceras* spp. Snails: *Helix* spp., *Cepaea* spp	Broadcast spreading between plants by hand or au-tomatic dispenser	BBCH 12-95	4	10	a) 0.01 b) 0.04	a) 0.3 b) 1.2	n.a.	1	**Acceptable**
2	FR	Ornamental plants	Fn	Slugs: *Arion* spp., *Deroceras* spp.	Broadcast spreading between	BBCH 12-95	4	10	a) 0.01 b) 0.04	a) 0.3 b) 1.2	n.a.	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 and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. 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 ap-plications (days)	kg product/10 m² a) max. rate per appl. b) max. total rate per crop/season	g a.s./10 m² a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
				Snails: *Helix* spp., *Cepaea* spp	plants by hand or au-tomatic dispenser								
3	FR	Natural surfaces not intended to bear veg-etation	Fn	Slugs: *Arion* spp., *Deroceras* spp. Snails: *Helix* spp., *Cepaea* spp	Broadcast spreading between plants by hand or au-tomatic dispenser	BBCH 12-95	4	10	a) 0.01 b) 0.04	a) 0.3 b) 1.2	n.a.	n.a.	**Not relevant (efficacy)**

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/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 Background of authorisation decision and risk management

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

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 uniformed and free flowing light brown pellets with dark brown spots. It is not explosive, has no oxidising properties. The product is not flammable. There is no self-ignition observed. In aqueous solution, it has a pH value around 4.34°C. 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.

Its technical characteristics are acceptable for a GB formulation.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted data:

- The efficacy of the product is considered satisfying for all intended uses.

- **In absence of more information about the use of a molluscicide product on "natural surfaces not intended to bear vegetation", the use is considered as not relevant. As uncultivated areas are not supposed to be treated with a molluscicide.**

- The phytotoxicity level of is considered negligible for all the intended uses.

- The risk of negative impact on yield and succeeding crops are considered negligible for all the intended crops.

- The risk of resistance toward ferric phosphate in a non-professional use should not be amplified with regards to its professional use.

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 is available and validated.

Analytical methods for the determination of the relevant impurities (lead, cadmium and mercury) in the formulation are missing and should be provided in post authorization.

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)

Endpoints used in risk assessment

Agreed EU endpoints	
Active substance	**Ferric phosphate**
AOEL systemic	0.4 mg/kg bw/d
AAOEL	-
Oral absorption	50%
Vapour pressure	Non volatile
Reference	EFSA Conclusion (EFSA Journal 2015;13(1):3973) SANTE/10385/2015 Rev 1
Dermal absorption	Concentrate: 10% Dilution: n.a.

3.4.1 Acute toxicity

LIMEX ULTRA (S21302) containing 30 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 sensitiser.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the French study from UPJ 2009-2010[11] dedicated to non-agricultural areas and EFSA model[12]:

Model data		**Ferric phosphate**
	Level of PPE	**% AOEL**
Application : manual application of granules **Outdoor**		
Application rate: 10 kg LIMEX ULTRA (S21302)/ha		0.3 kg Ferric phosphate/ha (4 applications : 1.2 kg Ferric phosphate/ha per season)
Granule application (AOEM; 75th percentile) Body weight: 60 kg Area treated : 1 ha	No PPE	1217.83
Granule application (AOEM; 75th percentile) Body weight: 60 kg Area treated : 0.05 ha	No PPE	60.89
Granule application (UPJ Model) Body weight: 60 kg	No PPE	9.06

According to the model calculations, it can be concluded that the risk for the operator using LIMEX ULTRA (S21302) is acceptable.

[11] Studies and models that can be used to estimate operator exposure during the use of plant protection products in non- agricultural areas. Report from expert group « produits phytosanitaires : substances et préparations chimiques » Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011

[12] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

The zRMS considers that compliance with the provisions of French regulation relating to the conditions of authorisation of plant protection products by non-professional users[13] is considered to be finalised only for the packaging indicated in table 2.1 product identity.
The other claimed packaging [Doypack bags made of PET/LDPE (150 g-1 kg)] are considered not able to guarantee a minimum exposure of the non-professional user and therefore not compliant with the compliance with the provisions of French regulation.

3.4.3 Worker exposure

LIMEX ULTRA is intended to be used by amateurs during home garden application. In this case of the non-professional user, the worker is also the user. Therefore, the assessment of worker exposure is covered by the operator exposure.

There is no unacceptable risk anticipated for the worker reentering into treated crops.

3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[14].
Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

3.4.5 Resident exposure

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

There is no suitable model to assess residential exposure for non-professional uses. As a worst case the EFSA model for resident (recreational exposure) has been used by zRMS. The estimated recreational exposure for resident is presented in the table below:

EFSA model – Recreational exposure Application rate: 4 x 0.3 kg Ferric phosphate/ha		
	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Child	0.011	2.65
Adult	0.002	0.53

Furthermore, to address the potential for ingestion by infants of the pellets a reverse reference approach has been used to calculate the number of LIMEX ULTRA pellets that, if consumed by an infant would result in an exceedance of the ADI of 0.8 mg/kg bw/day for iron and 70 mg/kg bw/day for phosphate. In addition, the

[13] Arrêté du 6 avril 2020 relatif aux conditions d'autorisation d'un produit phytopharmaceutique pour la gamme d'usages « amateur » JORF n°0088 du 10 avril 2020

[14] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

number of LIMEX ULTRA pellets resulting in an exceedance of the AOEL of 0.4 mg/kg bw/day are also calculated for iron.

Infants are assumed to be 1 to 3 years old and have a body weight of 10 kg. LIMEX ULTRA is a non-dusty granular / pellet plant protection product containing 30 g/kg (3% w/w) Ferric Phosphate ($FePO_4$), corresponding to 11.11 g/kg (1.11% w/w) iron (Fe) and 18.89 g/kg (1.89% w/w) phosphate (PO_4). The individual pellet weight is confirmed as 20 mg. Using these parameters the number of pellets which would need to be consumed to reach an intake equivalent to the reference dose is calculated as follows:

- **Iron**

$$Number\ of\ pellet = \frac{ADI \times body\ weight}{concentration\ of\ a.s.\ in\ product\ \times weight\ of\ a\ single\ granule} = 36.036$$

$$Number\ of\ pellet = \frac{AOEL \times body\ weight}{concentration\ of\ a.s.\ in\ product\ \times weight\ of\ a\ single\ granule} = 18.018$$

With :
ADI (mg/kg bw/day) : 0.8
AOEL (mg/kg bw/day) : 0.4
Body weight (kg) : 10
Concentration of a.s. in product (%) : 1.11 = 0.0111
Weight of a single granule (mg) : 20

- **Phosphate**

$$Number\ of\ pellet = \frac{ADI \times body\ weight}{concentration\ of\ a.s.\ in\ product\ \times weight\ of\ a\ single\ granule} = 1851.85$$

With :
ADI (mg/kg bw/day) : 70
Body weight (kg) : 10
Concentration of a.s. in product (%) : 1.89 = 0.0189
Weight of a single granule (mg) : 20

Number of pellets that if consumed would exceed the ADI and the AOEL:

	Iron	
	ADI (0.8 mg/kg bw/day)	AOEL (0.4 mg/kg bw/day)
Number of pellets	**36 pellets**	**18 pellets**
	Phosphate ADI (70 mg/kg bw/day)	
Number of pellets	**1851 pellets**	

The reverse reference approach shows that respectively 36 and 18 individual pellets are required to achieve an intake of iron which would be equivalent to the reference doses ADI and AOEL. And **1851 pellets** to achieve an intake of phosphate which would be equivalent to the reference dose ADI.

From this assessment, it can be concluded that the risk of poisoning to children through accidental ingestion of granules after spreading is negligible.

3.4.6 Combined exposure

Not relevant. The product contains only one active substance.

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

3.5.1 Residues

Ferric phosphate is defined as an active substance for which no Maximum Residue Levels (MRLs) are required and listed in Annex IV to Regulation (EC) No 396/2005. As stated in the EFSA conclusion, for an essential element as ferric phosphate exposure is evaluated against background levels and ferric phosphate is considered to be low risk.

As far as consumer health protection is concerned, France agrees with the authorization of the intended use : all edible crops, ornementals plants and non edible crops. According to available data, no specific mitigation measures should apply.

Summary for LIMEX ULTRA (S21302)

Table : Information on LIMEX ULTRA (S21302) (KCA 6.8)

Crop	PHI for LIMEX ULTRA (S21302) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for LIMEX ULTRA (S21302) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Ferric phosphate		
All edible crops (e.g. Lettuce, Cabbage, Strawberries, *etc.*)	Non necessary	Yes	Non necessary	
Ornamental plants			Not applicable	Not assessed (non edible commodity)
Natural surfaces not intended to bear vegetation			Not applicable	Not assessed (non edible commodity)

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).

Waiting periods before planting succeeding crops

Not relevant.

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.

Since the product LIMEX ULTRA (S21302) is for non-professional uses, soil exposure is not considered requiring evaluation at FR national level.

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 substances and their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed end-points were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Since the product LIMEX ULTRA (S21302) is applied as bait (ready-to-use product) for amateur uses, exposure of soil and surface water compartments to active substance is considered negligible. Consequently, no risk assessment for non-target organisms is deemed necessary, except for birds, mammals and bees where an exposure cannot be excluded. However, given that the ferric phosphate is a non-systemic compound, no risk assessment for bees is needed. Based on the guidance document, the risk for birds and mammals from the proposed uses of S21302 applied as pellets for non-professional uses is concluded to be acceptable.

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 24 months regarding:

- Shelf life study in commercial containers;
- Methods for the determination of lead, cadmium and mercury in the Product with LOQ in accordance with the maximum concentration limit of these impurities in the Product.

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 règlementaire,

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***LIMEX ULTRA***

de la société *EVERGREEN GARDEN CARE France SAS*

enregistrée sous le *n°2021-3098*

Vu les conclusions de l'évaluation de l'Anses du 7 décembre 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.

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	LIMEX ULTRA
Type de produit	Produit de référence
Titulaire	EVERGREEN GARDEN CARE France SAS 4 allée des Séquoias 69760 LIMONEST France
Formulation	Appât granulé (GB)
Contenant	30 g/kg - phosphate ferrique
Numéro d'intrant	716-2021.01
Numéro d'AMM	2230036
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) n°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 03/02/2023

DocuSigned by:
Charlotte Grastilleur
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)

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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**
Bouteilles en polyéthylène haute densité avec bouchon et réducteur de débit	500 mL, 1 L et 1,1 L contenant de 150 g à 1 kg
Bouteilles en polyéthylène téréphtalate avec bouchon à clapet et réducteur de débit	1 L contenant de 150 g à 1 kg
Boîtes en carton avec bec verseur refermable	De 150 g à 2,3 kg
Boîtes en carton / polyéthylène laminé avec bec verseur refermable	De 150 g à 2,3 kg
Boîtes en carton / polyéthylène téréphtalate avec bec verseur refermable	De 150 g à 1 kg
Boîtes « composite » avec film en polyéthylène téréphtalate à l'intérieur avec bouchon et réducteur de débit	De 150 g à 2,3 kg
Boîtes en carton / polyéthylène téréphtalate / polyéthylène avec bec verseur refermable	De 150 g à 2,3 kg

Les emballages en sachets en polyéthylène téréphtalate / polyéthylène de 150 g à 1 kg avec zip refermables 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 règlementation 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.
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)	Culture attractive en floraison (arrêté du 20/11/2021)
11012903 Traitements généraux*Trt Sol* Limaces et escargots	**10g/10 m²**	**4/an**	entre les stades BBCH 12 et BBCH 95	1	-	-	-	Non concerné
	4 applications maximum par an et par culture. Intervalle minimum entre les applications : 10 jours.							

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Conditions d'emploi du produit

Délai de rentrée en application de l'arrêté du 4 mai 2017 :
- Non applicable.

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

Protection de l'eau
- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon non utilisés et les eaux de lavage de l'épandeur.

Protection de la faune
- Contient une substance molluscicide pouvant entraîner des effets néfastes pour les vers de terre et les autres macro-organismes du sol.

Exigences complémentaires post-autorisation

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

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir les résultats de l'étude en cours de réalisation concernant la stabilité au stockage pendant deux ans, à température ambiante.	24	-

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.