

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: ADA102/0402208**

**Product name: ULTIMUS**

**Chemical active substance:**

**Ferric phosphate 30 g/kg**

**Interzonal and**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(new application)**

**Applicant: ADAMA FRANCE SAS**

**Date: 2021-11-24**

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# **PART A**

## **RISK MANAGEMENT**

### **1 Details of the application**

The company ADAMA FRANCE SAS has requested a marketing authorisation in France for the product ULTIMUS (formulation code: ADA102/0402208), containing 30 g/kg Ferric phosphate<sup>1</sup> 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).

Appendix 3 of this document is a copy of the letter(s) of Access.

#### **1.1 Application background**

The present registration report concerns the evaluation of ADAMA FRANCE SAS's application submitted on 13/08/2020 to market ULTIMUS (ADA102/0402208) in France (product uses described under point 2.3). France acted as a interzonal and 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 European Union.

Ferric phosphate is a low risk active substance, therefore ULTIMUS (ADA102/0402208) shall be authorised as a low risk plant protection product where compliant with Article 47 of Regulation (EC) no 1107/2009.

The present application (2020-2674) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009<sup>2</sup>, the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the European Union, taking into account the worst-case uses ("risk envelope approach")<sup>3</sup>. 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 ULTIMUS (ADA102/0402208) has been made using endpoints agreed in the EU peer review of Ferric phosphate. It also includes assessment of data and information related to ULTIMUS (ADA102/0402208) 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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<sup>1</sup> 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

<sup>2</sup> 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

<sup>3</sup> 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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## **1.2 Letters of Access**

The applicant has provided a letters of access for active substance and PPP data. These letters of access are available upon request

## **1.3 Justification for submission of tests and studies**

Where protection for data is being claimed for information supporting registration of ULTIMUS (ADA102/0402208), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.Details of the authorisation decision.

## **1.4 Product identity**

Product code	ADA102/0402208
Product name in MS	ULTIMUS
Authorisation number	2210940
Kind of use	Professional use
Low risk product (article 47)	Yes
Function	Molluscicide
Applicant	ADAMA FRANCE SAS
Active substance(s) (incl. content)	ferric phosphate, 30g/kg
Formulation type	RB ready to use bait
Packaging	sack PE (15 kg, 16 kg, 20 kg)
Coformulants of concern for national authorisations	None
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	None

## **1.5 Conclusion**

The evaluation of the application for ULTIMUS (ADA102/0402208) resulted in the decision **to grant the authorisation.**

## **1.6 Substances of concern for national monitoring**

Refer to 5.1.1.

## **1.7 Classification and labelling**

### **1.7.1 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:	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	

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

### 1.7.2 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

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

None.

## 1.8 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<sup>4</sup> 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<sup>5</sup> provides that:

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

<sup>4</sup> 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>

<sup>5</sup> Arrêté du 12 avril 2021 relatif à la mise en œuvre du catalogue national des usages phytopharmaceutiques visés dans les décisions d'autorisation de mise sur le marché et de permis de commerce parallèle des produits phytopharmaceutiques et des adjuvants - Légi

- 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<sup>6</sup> 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.

### 1.8.1 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	
Other specific restrictions	
Re-entry period	6 hours (fiels uses) 8 hours (greenhouse uses)
Pre-harvest interval <sup>7</sup> :	Not applicable for non edible crops 3 days for edible crops

### 1.8.2 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 1.8.1 (mandatory labelling):

None.

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

<sup>7</sup> According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

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## 1.9 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 izRMS. 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. 1, date: 2021-11-24

PPP (product name/code): ULTIMUS / ADA102/0402208

Formulation type: RB <sup>(a, b)</sup>

Active substance 1: Ferric phosphate

Conc. of a.s. 1: 30 g/kg <sup>(c)</sup>

Applicant: ADAMA FRANCE SAS

Professional use: ☒Zone(s): Interzonal <sup>(d)</sup>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. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, F <sub>pn</sub> G, G <sub>n</sub> , G <sub>pn</sub> 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. g safener/synergis per ha <sup>(f)</sup>  <b>RMS CONCLUSION</b>
					Method/Ki nd	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)													
1	FR	Edible and non edible crops	F G	Slugs & snails All growth stages	Soil, over- all broadcast or local- ised treatment	Pre or post- emergence at beginning of slug activity	a) 4 b) 4	7days	a) 7 kg b) 28 kg	a) 210 b) 840		3 days for edible crops  Not applica ble for non edible crops	<b>Acceptable</b>

\* As some standards may have undergone changes, it is the responsibility of the applicant to update the references.



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<b>Remarks table heading:</b>	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(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.
<b>Remarks columns:</b>	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

## **2 Background of authorisation decision and risk management**

### **2.1 Physical and chemical properties (Part B, Section 2)**

All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of an uniform blue coloured granule approximately 2mm in length 2mm wide, with a musty odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of above 140°C. In aqueous solution, it has a pH value of 6.78 at 20.0 °C. There is no effect of 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 formulation type RB Pellet.

**The shelf life study in commercial containers should be provided in post-authorization.**

### **2.2 Efficacy (Part B, Section 3)**

Given the submitted data:

The efficacy of the product ULTIMUS (ADA102/0402208) is considered satisfactory for all the requested uses.

The phytotoxicity level of ULTIMUS (ADA102/0402208) is considered negligible for all the requested uses.

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

The risk of resistance appearing or developing to ferric phosphate does not require a monitoring for all the requested uses.

### **2.3 Methods of analysis (Part B, Section 5)**

#### **2.3.1 Analytical method for the formulation**

Analytical methods for the determination of the active substance ferric phosphate in the formulation are available and validated.

Analytical methods for the determination of relevant impurities (lead, cadmium and mercury) of ferric phosphate in the formulation are available and validated. However the limits of quantification are higher than the maximum content in the plant protection product.

**Thus, new methods for the determination of relevant impurities (lead, mercury and cadmium) with LOQ covering the maximum content in PPP should be provided in post-authorization.**

### 2.3.2 Analytical methods for residues

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

## 2.4 Mammalian toxicology (Part B, Section 6)

The product ULTIMUS (ADA102/0402208) is considered similar to the product DOFF ANTI-LIMACES ET ESCARGOTS PRO (AMM 2190537) based on the original UK application for IRONCLAD MAPP 18970, COP 2018/01560 & 2019/00987.

A letter of access for the full data package of DOFF ANTI-LIMACES ET ESCARGOTS PRO has been provided by the applicant in support of the registration of the product ULTIMUS (ADA102/0402208) in France.

The zRMS in charge of the evaluation of this product is France for field and greenhouse professional use and only France is concerned by this submission.

### 2.4.1 Acute toxicity

ULTIMUS (ADA102/0402208) 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.

### 2.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model<sup>8</sup>:

		Ferric Phosphate (Iron, Fe)	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL
<i>Outdoor, vehicle-mounted, granule, broadcast application</i>			
Application rate		4 x 0.078 kg Fe/ha	
<b>Granule application</b> (EFSA Calculator: PHED model; 75 <sup>th</sup> percentile) <ul style="list-style-type: none"> <li>Mixing and loading, and application.</li> <li>Area Treated: 50 ha</li> <li>Body weight: 60 kg</li> </ul>	Work wear (arms, body and legs covered) M/L and A + chemical resistant gloves	0.00158	0.39
<i>Outdoor, vehicle-mounted, granule, in-furrow application</i>			

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<sup>8</sup> AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

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		Ferric Phosphate (Iron, Fe)	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL
Application rate		4 x 0.078 kg Fe/ha	
<b>Granule application</b> (EFSA Calculator: PHED model; 75 <sup>th</sup> percentile) <ul style="list-style-type: none"> <li>Mixing and loading, and application.</li> <li>Area Treated: 50 ha</li> <li>Body weight: 60 kg</li> </ul>	Work wear (arms, body and legs covered) M/L and A + chemical resistant gloves	0.00158	0.39
<i>Outdoor, manual application of granules</i> <i>Indoor manual application of granules</i>			
Application rate		4 x 0.078 kg Fe/ha	
<b>Granule application</b> (EFSA Calculator: PHED model) Application. Area Treated: 1 ha Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A + chemical resistant gloves	0.0133	3.32

According to the model calculations, it can be concluded that the risk for the operator using ULTIMUS (ADA102/0402208) is acceptable with a working coverall and gloves during mixing/loading and application.

### 2.4.3 Worker exposure

Considering that the product is a ready-to-use bait product, the worker exposure assessment is not relevant.

### 2.4.4 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<sup>9</sup>.

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.”

According to the intended use (ready-to-use bait pellet applied on bare soil, in furrow), no spray drift, no fall out are expected. Therefore, zRMS considers that no exposure is expected for bystander.

<sup>9</sup> 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)

#### **2.4.5           Resident exposure**

According to the intended uses (professional use, 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.

The resident exposure in glasshouse is not relevant.

#### **2.4.6           Combined exposure**

Not relevant. The product contains only one active substance.

### **2.5               Residues and consumer exposure (Part B, Section 7)**

The respective intended uses on non-edible commodities 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 ULTIMUS (ADA102/0402208) 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 ULTIMUS (ADA102/0402208) 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 ULTIMUS (ADA102/0402208)

### Information on ULTIMUS (ADA102/0402208)

Crop	PHI for ULTIMUS (ADA102/0402208) proposed by applicant	PHI/ Withholding period* sufficiently supported for Ferric phosphate	PHI for ULTIMUS (ADA102/0402208) proposed by zRMS	zRMS Comments (if different PHI proposed)
Rapeseed	No PHI required	NR	3 days	/
Turnip				
Cereals				
Beets				
Pea, Beans				
Potato				
Lettuce				
Cauliflower				
Cabbage				
Brussels sprouts				
Strawberry				
Carrot				
Celery				
Leek				
Ornamentals Flower plants	NR		NR	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).

## 2.6 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 ( $1.86 \times 10^{-12}$  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.

## **2.7 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 conclusions for the active substance(s) and its/their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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

## **2.8 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.

## **3 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.

## **4 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”.

### **4.1.1 Post-authorisation monitoring**

None.

### **4.1.2 Post-authorisation data requirements**

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

- Shelf life study after 2 years at ambient temperature in commercial container
- A method for the determination of lead, cadmium and mercury in the product with LOQ in accordance with the maximum concentration limit.

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## Appendix 1 Copy of the product authorisation

DocuSign Envelope ID: 7D1AAB65-88AE-4022-941A-58F1F9BA9582



### 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 **ULTIMUS***

*de la société ADAMA FRANCE SAS*

*enregistrée sous le n°2020-2674*

*Vu les conclusions de l'évaluation de l'Anses du 15 novembre 2021,*

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.



ADA102/0402208 / ULTIMUS  
Part A - National Assessment  
FRANCE

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Informations générales sur le produit	
Nom du produit	ULTIMUS
Type de produit	Produit de référence
Titulaire	ADAMA FRANCE SAS 33 rue de Verdun 92156 SURESNES France
Formulation	Appât prêt à l'emploi (RB)
Contenant	30 g/kg - phosphate ferrique
Numéro d'intrant	688-2020.01
Numéro d'AMM	2210940
Fonction	Molluscicide
Gamme d'usage	Professionnel
Mention particulière	Produit à faible risque au sens de l'article 47 du règlement (CE) 1107/2009

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

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

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

A Maisons-Alfort, le 24/11/2021

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)

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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
Sacs en polyéthylène	15 kg ; 16 kg ; 20 kg

Classification du produit
La classification retenue est la suivante : Sans classement.
Pour les phrases P se référer à la réglementation en vigueur.
<b>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.</b>

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Part A - National Assessment  
FRANCE

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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)	Mention abeilles
<b>11012903</b> Traitements généraux* Trit Sol*Limaces et escargots	7 kg/ha	4/an	-	Non applicable	-	-	-	-
Uniquement sur cultures non alimentaires. Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								
<b>11012903</b> Traitements généraux* Trit Sol*Limaces et escargots	7 kg/ha	4/an	-	3	-	-	-	-
Uniquement sur cultures alimentaires. Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								

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## Conditions d'emploi du produit

### Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

### Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un tracteur équipé d'un matériel d'épandage (ex. micro-granulateur)

#### • pendant le chargement du matériel d'épandage

- Gants en nitrile réutilisables certifiés EN ISO 374-1/A1 et EN 16523-1+A1 (type A);
- 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) certifié EN14605+A1 à porter par-dessus la combinaison précitée ;

#### • pendant l'épandage

- Gants en nitrile certifiés EN ISO 374-1/A1 et EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel d'épandage ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;

#### • pendant le nettoyage du matériel d'épandage

- Gants en nitrile réutilisables certifiés EN ISO 374-1/A1 et EN 16523-1+A1 (type A);
- 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) certifié EN14605+A1 à porter par-dessus la combinaison précitée.

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

- 6 heures pour les usages en plein champ et 8 heures pour les applications en milieu fermé.

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

#### Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

## Exigences complémentaires post-autorisation

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

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir les résultats de l'étude en cours de réalisation concernant la stabilité au stockage pendant 2 ans, à température ambiante.	24	-

ADA102/0402208 / ULTIMUS  
Part A - National Assessment  
FRANCE

## 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.

# ULTIMUS

**Phosphate ferrique 30 g/kg (3%)**

Traitement du sol

**Cultures**

Cultures alimentaires et non alimentaires, plein champ et sous abri.



La fiche de données de sécurité peut être obtenue gratuitement sur Internet [www.quickfds.com](http://www.quickfds.com) ou en écrivant à [fds@adama.com](mailto:fds@adama.com) ou par courrier à l'adresse postale d'ADAMA s.a.s ou en scannant le flashcode avec votre téléphone mobile.

Formulation : GB - Appât granulé prêt à l'emploi

AMM N° XXXXXXXX

Titulaire de l'AMM

ADAMA France s.a.s

33 rue de Verdun

92156 Suresnes Cedex

Tél. : 01 41 47 33 33

® Marque enregistrée par une société du groupe ADAMA



# ADAMA

**20 Kg**

### PREMIERS SECOURS

Inhalation : Transporter la victime à l'air frais. En cas de respiration irrégulière ou d'absence de respiration, pratiquer la respiration artificielle. Si les symptômes persistent, consulter un médecin.

### Protection de l'opérateur et du travailleur

### PROTECTION DE L'UTILISATEUR PENDANT LES PHASES DE :

APPLICATION AVEC :

DEROUTEUSE



**MOLLUSCICIDE**

PRODUCT NAME :	
<b>ULTIMUS</b>	
COUNTRY :	FRANCE
PACKAGE SIZE :	20 KG
LABEL CODE :	
LABEL DIMENSIONS :	L210MMXH297MM
LABEL DATE :	APRIL 2020
GEN CODE :	
<div> <div>CYAN</div> <div>MAJENTA</div> <div>JAUNE</div> <div>NOIR</div> </div>	

# ADA102/0402208 / ULTIMUS

## Part A - National Assessment

### FRANCE

#### PREMIERS SECOURS

**Inhalation :** Transporter la victime à l'air frais. En cas de respiration irrégulière ou d'absence de respiration, pratiquer la respiration artificielle. Si les symptômes persistent, consulter un médecin.

**Contact cutané :** Rincer immédiatement au savon et à grande eau en retirant les chaussures et vêtements contaminés. Si les symptômes persistent, consulter un médecin.

**Contact avec les yeux :** Rincer immédiatement et abondamment avec de l'eau. Après le rinçage initial, retirer les éventuelles lentilles de contact et continuer à rincer pendant au moins 15 minutes.

**Maintenir l'œil grand ouvert pendant le rinçage.** Si les symptômes persistent, consulter un médecin.

**Ingestion :** Rincer la bouche. Boire beaucoup d'eau. Si les symptômes persistent, consulter un médecin.

#### EN CAS D'URGENCE

Composer le 15 ou le 112 ou contacter le centre antipoison le plus proche.

Puis signalez vos symptômes au réseau Phyt'attitude, N° Vert : 0 800 887 887 (appel gratuit depuis un poste fixe).

#### DESRIPTIF DU PRODUIT

Tableau des usages autorisés

Cultures	Dose d'emploi	Nombre d'applications	Dose max annuelle
Cultures alimentaires	7 kg/ha	4 appl/an	28 kg/ha/an
Cultures non alimentaires	7 kg/ha	4 appl/an	28 kg/ha/an

ADAMA France ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées dans le tableau ci-dessus et, à ce titre, décline toute responsabilité concernant l'élargissement de son utilisation à d'autres cultures et cibles telles que prévues par le catalogue des usages fixé par l'arrêté du 26 mars 2014.

Ainsi, l'attention de l'utilisateur est attirée sur les risques éventuels de non-conformité de cet élargissement permis par ce catalogue.

Délai de rentrée des travailleurs sur la parcelle : 6 heures après traitement conformément à l'arrêté du 4 mai 2017 modifié par l'arrêté du 27 décembre 2019.

Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database>

#### MISE EN ŒUVRE RÉGLEMENTAIRE ET BONNES PRATIQUES

##### Stockage du produit

Conserver le produit uniquement dans son emballage d'origine, dans un local phytosanitaire conforme à la réglementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées.

#### Protection de l'opérateur et du travailleur

Caractéristiques des EPI	PROTECTION DE L'UTILISATEUR PENDANT LES PHASES DE :				PROTECTION DU TRAVAILLEUR
	MÉLANGE/CHARGEMENT	APPLICATION AVEC :		NETTOYAGE	
		TRACTEUR ÉQUIPÉ D'UN MICROGRANULATEUR OU MICROGRANULATEUR MANUEL : APPLICATION VERS LE BAS	TRACTEUR AVEC CABINE	TRACTEUR SANS CABINE	
<b>GANTS EN NITRILE</b> réutilisables (certifiés EN 374-3) ou à usage unique (certifiés EN 374-2)	Réutilisables	A usage unique*	A usage unique*	Réutilisables	
<b>EPI VESTIMENTAIRE</b> conforme à la norme NF EN ISO 27065	EPI vestimentaire ET			EPI vestimentaire ET	
<b>EPI PARTIEL</b> blouse ou tablier à manches longues catégorie III type PB3 certifié EN 14605+A1	EPI partiel			EPI partiel	
<b>COMBINAISON DE PROTECTION CHIMIQUE</b> catégorie III type 3 ou 4 certifiée EN 14605+A1:2009	OU Type 3 ou 4			OU Type 3 ou 4	

\* EN CAS D'INTERVENTION À L'EXTÉRIEUR ; DANS CE CAS, LES GANTS DOIVENT ÊTRE STOCKÉS ET PORTÉS À L'EXTÉRIEUR DE LA CABINE.

##### Nettoyage du matériel

Après la vidange des appareils, ramasser les granules et les épandre sur une surface traitée.

##### Élimination du produit, de l'emballage

Réemploi de l'emballage interdit. Apporter les emballages vidés et plés aux collectes organisées par les distributeurs partenaires de la filière ADIVALOR ou tout autre service de collecte spécifique.

##### AVERTISSEMENT

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces, la pression parasitaire... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché. Compte-tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées protégées ou issues de cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. ADAMA France s.a.s ne saurait être tenu en aucun cas responsable des conséquences inhérentes à toute copie (totale ou partielle) de cette étiquette, à sa diffusion ou son utilisation non autorisée.

## ULTIMUS

AMM N° XXXXXXX

GB - Appât granulé prêt à l'emploi

Phosphate ferrique 30 g/kg (3%)

EUH210 : Fiche de données de sécurité disponible sur demande.

Délai de rentrée des travailleurs sur la parcelle : 6 heures après traitement.

P102 : Tenir hors de portée des enfants.

SPI : Ne pas polluer l'eau avec le produit ou son emballage.

RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL.  
Consulter le livret avant toute utilisation.

RÉEMPLOI DE L'EMBALLAGE INTERDIT.

Produit fabriqué en Union Européenne

N° de lot	VOIR SUR L'EMBALLAGE
Date de fabrication	

## **Appendix 3 Letter of Access**

[Available upon request.](#)