

REGISTRATION REPORT

Part A

Risk Management

Product code: FRU M3-00

Product name: LENTILLES ANTILIMACES

Active substance:

metaldehyde, 30 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(authorisation renewal)

Applicant: FRUNOL DELICIA GMBH

Date: 2020/06/19 (Decision)

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PART A – Risk Management

The company FRUNOL DELICIA GMBH has requested renewal of the marketing authorisation in France for the product LENTILLES ANTILIMACES (product code: FRU M3-00; marketing authorisation n° 2060175), containing 30 g/kg metaldehyde, for use as a molluscicide.

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 LENTILLES ANTILIMACES (FRU M3-00) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of LENTILLES ANTILIMACES (FRU M3-00) have been made using endpoints agreed in the EU peer review(s) of Metaldehyde.

This document describes the specific conditions of use and labelling required for France for the registration of LENTILLES ANTILIMACES (FRU M3-00).

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 FRUNOL DELICIA GMBH's application to market LENTILLES ANTILIMACES (FRU M3-00) in France as a molluscicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the renewal of authorisation after approval of the active substance of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Metaldehyde

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

Specific provisions of Regulation (EU) No 540/2011 were as follows :

PART A

Only uses as molluscicide may be authorised.

PART B

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 metaldehyde, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

- The risk to operators and workers;
- The dietary exposure situation of consumers in view of future revisions of maximum residue levels;
- The acute risk and long term risk to birds and mammals. Member States shall ensure that authorisations shall contain an effective dog repellent agent. Conditions of use shall include risk mitigation measures, where appropriate.

An EFSA conclusion is available (EFSA Journal 2010; 8(10): 1856).

A Review Report is available (SANCO/10474/2011 final, 11 March 2011).

1.3 Regulatory approach

The present applications (2013-1580 [authorisation renewal] and 2014-3305 [modification of the declared information]) were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ in the context of the voluntary zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)². When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4 May 2017³ 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 1107/2009⁴, 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)

¹ French Food Safety Agency, Afssa, before 1 July 2010

² 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

³ 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>

⁴ 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

No 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ 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, mainly based on the EU document on residue data extrapolation⁷ is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

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 LENTILLES ANTILIMACES (FRU M3-00), 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

The applicant has provided a letter of access.

⁵ 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

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo>

⁷ 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)	LENTILLES ANTILIMACES (FRU M3-00)
Authorisation number	2060175 (withdrawn in renewal process)
Function	Molluscicide
Applicant	FRUNOL DELICIA GMBH
Composition	30 g/kg metaldehyde
Formulation type (code)	Granular bait (GB)
Packaging	N/A: The product is no more authorised in France.

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No 1272/2008

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

N/A: withdrawn in France.

2.2.3 Other phrases linked to the preparation

N/A: The product is no more authorised in France.

2.3 Product uses

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

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

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

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

PPP (product name/code):	LENTILLES ANTILIMACES /FRU M3-00		GAP rev., date: 2020/06/19
Active substance 1:	metaldehyde	Formulation type:	GB ^(a, b)
Applicant:	FRUNOL DELICIA GMBH	Conc. of a.s. 1:	30 g/kg ^(c)
Zone(s):	southern ^(d)	Professional use:	<input checked="" type="checkbox"/>
Verified by MS:	yes	Non-professional use:	<input type="checkbox"/>
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)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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		

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)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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	France	Cereals	F	Slugs and snails	Spreading	From sowing up to BBCH 29	a) 3 b) 3	7	a) 3 b) 6	a) 90 b) 180	-	F – Application must be made at growth stage BBCH 29 at the latest	Not acceptable (physico-chemical properties)
2	France	Oilseed rape	F	Slugs and snails	Spreading	From sowing up to BBCH 29	a) 3 b) 3	7	a) 3 b) 6	a) 90 b) 180	-	F – Application must be made at growth stage BBCH 29 at the latest	Not acceptable (physico-chemical properties)

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)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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		
3	France	Sugar and fodder beet	F	Slugs and snails	Spreading	From sowing up to BBCH 31	a) 3 b) 3	7 days	a) 3 b) 9	a) 90 b) 270	--	F - Application must be made at growth stage BBCH 31 at the latest	Not acceptable (physico-chemical properties)
4	France	Maize	F	Slugs and snails	Spreading	From sowing up to BBCH 19	a) 3 b) 3	7 days	a) 3 b) 6	a) 90 b) 180	--	F - Application must be made at growth stage BBCH 19 at the latest	Not acceptable (physico-chemical properties)
5	France	Sunflower	F	Slugs and snails	Spreading	From sowing up to BBCH 19	a) 3 b) 3	7 days	a) 3 b) 6	a) 90 b) 180	--	F - Application must be made at growth stage BBCH 19 at the latest	Not acceptable (physico-chemical properties)
6	France	Strawberry	F	Slugs and snails	Spreading	After infestation	a) 2 b) 2	7 days	a) 6 b) 12	a) 180 b) 360	--	1	Not acceptable (physico-chemical properties)
7	France	Ornamentals	F	Slugs and snails	Spreading	After infestation	a) 2 b) 2	7 days	a) 6 b) 12	a) 180 b) 360	--	Not applica- ble	Not acceptable (physico-chemical properties)

Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008 (c) g/kg or g/L	(d) Select relevant (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1 (f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1 Numeration necessary to allow references 2 Use official codes/nomenclatures of EU Member States 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure) 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application 8 The maximum number of application possible under practical conditions of use must be provided. 9 Minimum interval (in days) between applications of the same product 10 For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products. 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind". 13 PHI - minimum pre-harvest interval 14 Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The product LENTILLE ANTIILIMACES (FRU M3-00) is a granule (GB) formulation. All studies have been performed in accordance with the current requirements. The appearance of the product is that of blue granules, with a characteristic odour. It is not explosive, has no oxidising properties and is not auto-flammable up to 393 °C. In aqueous solution, it has a pH value around 5.3 at 20 °C.

An accelerated storage study (eight weeks at 40 °C) and an ambient shelf life study were provided. **The content of metaldehyde was determined by non-specific methodology. Moreover, there was no monitoring of the relevant impurity acetaldehyde during the storage to demonstrate the stability of the product.**

Data provided in the dossier are insufficient to demonstrate the stability of the formulation. Consequently, France considers that the formulation is not stable.

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

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of active substance and impurity in the technical active substance and for the determination of active substance in the formulation are available.

3.1.2.2 Analytical methods for residues

Analytical methods for the determination of residues of metaldehyde are available in the Draft Assessment Report (DAR)/this dossier and validated for the determination of residues of metaldehyde in plants, soil, water (surface and drinking) and air.

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: metaldehyde			
ADI	0.02 mg/kg bw/d		EU agreed endpoint (Efsa 2010)
ARfD	0.3 mg/kg bw		EU agreed endpoint (Efsa 2010)
AOEL	0.1 mg/kg bw/d		EU agreed endpoint (Efsa 2010)
Dermal absorption	Based on an <i>in vitro</i> human study performed on a similar formulation :		
		Concentrate (tested) 12.5 g/kg	Spray dilution (tested)
	<i>In vitro</i> (human) %	0.23	-
		Concentrate (used in formulation) 30 g/kg	Spray dilution (used in formulation)
Dermal absorption endpoints %		0.23	-

3.1.3.1 Acute Toxicity

LENTILLES ANTILIMACES (FRU M3-00), containing 30 g/kg metaldehyde, has a low acute oral and dermal toxicity and is not irritating to the rabbit skin or eye. It is not a skin sensitisier.

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

3.1.3.2 Operator Exposure

Operator exposure was assessed against the AOEL agreed in the EU review of metaldehyde. Data on dermal absorption of LENTILLES ANTILIMACES (FRU M3-00) were provided and are considered acceptable.

Endpoint used in assessment for LENTILLES ANTILIMACES (FRU M3-00)	
Metaldehyde	
Systemic AOEL :	0.1 mg/kg bw/d
Dermal absorption of undiluted product:	0.23 %

Operator exposure was modelled using PHED model:

Crop (Open field)	Equipment	Application rate of product (active substance)
Cereals		
Oilseed rape		
Beet	Tractor-mounted equipment	
Maize		6 kg/ha
Sunflower	Hand-held equipment	(180 g a.s./ha)
Strawberry (risk envelope)		
Ornamentals		

According to the model calculations, it may be concluded that the risk for the operator using LENTILLES ANTILIMACES (FRU M3-00) on field crops is acceptable with the use of gloves during loading and application.

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

3.1.3.3 Bystander Exposure

Since the formulation LENTILLES ANTILIMACES (FRU M3-00) is a granular bait, bystander exposure is considered negligible and thus acceptable.

3.1.3.4 Worker Exposure

LENTILLES ANTILIMACES (FRU M3-00) is a granular bait formulation applied directly on to soil on crops where there is no need to re-enter the treated area after application. Worker exposure is considered to be not relevant.

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

3.1.4 Residues and Consumer Exposure

Overall conclusion

The data available are considered sufficient for risk assessment. Any exceedence of the current MRL of metaldehyde as laid down in SANCO/10565/2014 voted on 24 February 2014 is not expected in France.

The chronic and short-term intakes of metaldehyde residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

As far as consumer health protection is concerned, France considers the proposed uses fully supported.

According to the available data, no specific mitigation measures should apply.

Data gaps

As required in Efsa's opinion on the review of MRLs, a hydrolysis study investigating the effect of sterilisation on the nature of residues of metaldehyde should be submitted to the RMS.

Table 1: Summary for metaldehyde

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance SANCO 100565/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Cereals	Yes	Yes	Yes	Yes	Yes	No	No	
2	Oilseed rape	Yes	Yes	Yes	Yes	No		No	
3	Sugar and fodder beet	Yes	NEU : Yes SEU : No (0)	Yes	Yes	Yes		No	
4	Maize	Yes	Yes	Yes	Yes	No		No	Yes
5	Sunflower	Yes	Yes	Yes	Yes	No		No	Yes
6	Strawberry	Yes	No (2)	No for no PHI and PHI = 1 day proposed	Yes	Yes		No	GAP fully supported if pellets are applied between rows and that it has to be ensured that pellets do not rest on or become trapped in the leaves or on fruit

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The effects of processing on the nature of metaldehyde residues have been investigated. No study investigating the magnitude of residues in processed commodities was reported; no processing factors for enforcement and risk assessment could be derived.

According to the soil degradation studies evaluated in the framework of the peer review, DT₉₀ values of metaldehyde are below the trigger value of 100 days. Further investigation of residues in rotational crops is not required and relevant residues in rotational crops are not expected.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated

for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin are therefore not necessary.

Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated. Based on EFSA PRIMo (rev2), chronic and acute exposures were considered acceptable for all groups of consumers.

Summary for LENTILLES ANTILIMACES (FRU M3-00)

Table 1: Information on LENTILLES ANTILIMACES (FRU M3-00)

Crop	PHI for LENTILLES ANTILIMACES (FRU M3-00) requested by applicant	PHI/withholding period* sufficiently supported for	PHI for LENTILLES ANTILIMACES (FRU M3-00) proposed by zRMS	zRMS Comments (if different PHI proposed)
		metaldehyde		
Cereals	BBCH 29, PHI=F	Yes		
Oilseed rape	BBCH 29, PHI=F	Yes		
Sugar and fodder beet	BBCH 31, PHI=F	Yes		
Maize	BBCH 19, PHI=F	Yes		
Sunflower	BBCH 19, PHI=F	Yes		
Strawberry	After infestation	No	After infestation and pellets are applied between rows and it must be ensured that pellets do not rest on or become trapped in the leaves or on fruit Proposed PHI: 1 day	Zero-residue situation not accepted for broadcast applications when the consumable parts are formed

NR: not relevant

* Purpose of withholding period to be specified

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

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate predicted environmental concentration (PEC) values for the active substance and its metabolite 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.

The PEC values of metaldehyde and its metabolite in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU review or agreed in the assessment based on new data provided.

PEC_{SOIL} and PEC_{SW} values derived for the active substance and its metabolite are used for the ecotoxicological risk assessment.

PEC_{GW} values for metaldehyde do not exceed the trigger of 0.1 µg/L. Therefore no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

The risk assessment for birds shows that the repellence property of LENTILLE ANTILIMACES (FRU M3-00), the field studies and the weight of evidence allow it to be concluded that there is no unacceptable acute or reproductive risk to avian species (granivorous and slug-eating birds) from the application of LENTILLE ANTILIMACES (FRU M3-00) to target crops according to the proposed GAP.

In the same way, the risk assessment for mammals shows that the repellency property of LENTILLE ANTILIMACES (FRU M3-00), the field studies and the weight of evidence allow it to be concluded that there is no unacceptable acute or reproductive risk to mammalian species (granivorous and slug-eating mammals) from the application of LENTILLE ANTILIMACES (FRU M3-00) to target crops according to the proposed GAP.

The risk assessment for aquatic organisms, honeybees, earthworms and other soil macro-organisms and non-target plants demonstrated that no unacceptable effects would be anticipated from LENTILLE ANTILIMACES (FRU M3-00) used according to the proposed GAP.

3.1.7 Efficacy

Considering the data submitted for the re registration of the preparation LENTILLES ANTILIMACES:

- The efficacy of LENTILLES ANTILIMACES (FRU M3-00) is considered satisfactory for all the requested uses.
- The level of phytotoxicity of LENTILLES ANTILIMACES (FRU M3-00) is considered negligible for all the uses.
- The risk of negative impact (on yield, quality, transformation processes, propagation, succeeding and adjacent crops) is considered negligible.
- The risk of resistance developing or appearing is considered to be very low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation can no longer be granted**. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

N/A.

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

N/A.

3.4.2 Label amendments

N/A.

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 et la demande associée du produit phytopharmaceutique **LENTILLES ANTILIMACES***

de la société **FRUNOL DELICIA GMBH**
enregistrées sous les n°2013-1580 et 2014-3305

Vu les conclusions de l'évaluation de l'Anses du 18 septembre 2019,

*Vu le courrier de l'Anses du 14 janvier 2020 d'intention de retrait de l'autorisation de mise sur le marché du produit **LENTILLES ANTILIMACES**,*

Considérant que les données disponibles ne permettent pas de garantir la stabilité du produit pendant le stockage,

Considérant que, lors de la dégradation de la substance active, il ne peut pas être garanti que la limite acceptable spécifiée en acétaldéhyde sera respectée,

Considérant qu'en conséquence, les exigences mentionnées à l'article 29 paragraphe 1 point h) du règlement (CE) n°1107/2009 susvisé ne sont plus remplies,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **est retirée** en France dans les conditions précisées dans la présente décision.



Informations générales sur le produit

Noms du produit	LENTILLES ANTILIMACES LIMADISQUE LIMADISQUE JARDIN METAPADS METADISQUE MOLLUSTOP 3% MOLLUSTOP JARDIN CONTRE LIMACE 3% CONTRE LIMACE JARDIN
Type de produit	Produit de référence
Titulaire	FRUNOL DELICIA GMBH HANSASTRASSE 74 59425 UNNA Allemagne
Formulation Contenant	Appât granulé (GB) 30 g/kg - métaldéhyde
Numéro d'intrant	2060115
Numéro d'AMM	2060175
Fonction	Molluscicide
Gamme d'usage	Professionnel

A Maisons-Alfort le,

19 JUIN 2020

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)

LENTILLES ANTILIMACES
AMM n°2060175

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
16012901 Cultures légumières*Trit Sol* Limaces et escargots	6 kg/ha	2/an	-
Motivation du refus : L'usage est refusé en raison de l'instabilité du produit lors du stockage pouvant entraîner, lors de la dégradation de la substance active, un dépassement de la limite acceptable spécifiée en acétaldéhyde. L'usage est également refusé sur fraisier en raison d'un risque de dépassement de la limite maximale de résidus pour des applications « en plein ».			
17402901 Cultures ornementales*Trit Sol* Limaces et escargots	6 kg/ha	2/an	-
Motivation du refus : L'usage est refusé en raison de l'instabilité du produit lors du stockage pouvant entraîner, lors de la dégradation de la substance active, un dépassement de la limite acceptable spécifiée en acétaldéhyde.			
15102901 Grandes cultures*Trit Sol* Limaces et escargots	3 kg/ha	2/an	-
Motivation du refus : L'usage est refusé en raison de l'instabilité du produit lors du stockage pouvant entraîner, lors de la dégradation de la substance active, un dépassement de la limite acceptable spécifiée en acétaldéhyde.			



Liste des usages retirés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks
11012903 Traitements généraux* Trt Sol* Limaces et escargots	6 kg/ha	2/an	-	6 mois à compter de la présente décision	18 mois à compter de la présente décision

Motivation du retrait :
L'usage est retiré sur fraisier (seul usage revendiqué et donc transformé en l'usage n°13012901 mieux adapté à la revendication) en raison de l'instabilité du produit lors du stockage pouvant entraîner, lors de la dégradation de la substance active, un dépassement de la limite acceptable spécifiée en acétaldéhyde.
L'usage est également retiré en raison d'un risque de dépassement de la limite maximale de résidus pour des applications « en plein ».

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

Lentilles Antilimaces®

Le nouvel appât breveté en forme de lentille pour une lutte encore plus efficace contre les limaces et les escargots dans toutes les cultures.

Les avantages de l'Innovation Lentilles Antilimaces :

Grâce à leur formulation unique, les lentilles *Delicia® Lentilles Antilimaces®* sont plus attractives et sont ainsi garantes d'une lutte antilimace encore plus efficace par rapport aux antilimaces traditionnels. L'association d'un procédé d'extrusion exclusif et de l'emploi de blé de la plus haute qualité (Qualité-E) avec un taux de protéine de 14% minimum fait de *Delicia® Lentilles Antilimaces®* un appât extrêmement attractif pour les limaces et les escargots. Ceci à une dose de 3 à 6 kg/ha soit 30 à 60 lentilles / m². Les lentilles *Delicia® Lentilles Antilimaces®* sont absolument sans poussière et très résistantes à la pluie et à l'humidité pendant plusieurs jours. Les bords minces de la lentille facilitent la prise par la limace, et spécialement les jeunes limaces. L'appât se gonfle en présence d'humidité sans se déliter ce qui le rend résistant à la pluie et à l'humidité. La matière active métaldéhyde détruit les cellules qui sécrètent le mucus et les limaces meurent par déshydratation. L'effet est irréversible.

Cela signifie:

- lutte plus efficace contre les limaces
- quantité de substance active et dose épandue réduites
- réduction des coûts de main d'oeuvre, de matériel et d'énergie en comparaison aux produits de lutte antilimace traditionnels.

Recommandations d'emploi :

Les limaces sont essentiellement actives la nuit, c'est pourquoi il est recommandé d'effectuer le traitement en fin d'après-midi. Les lentilles *Delicia® Lentilles Antilimaces®* doivent être épandues régulièrement sur la surface à traiter ou entre les plants cultivés afin de s'assurer que toutes les limaces soient atteintes. Les petits tas d'appâts sont à proscrire absolument. Ne pas épandre en dehors du périmètre du champ à traiter et exclure les bordures de cours d'eau, les bandes enherbées, les fossés et les talus.

Consultez les tables de réglages auprès du fabricant d'épandeur ou contactez nous via info@frunol-delicia.de.

Informations réglementaires

Nom commercial autorisé : LENTILLES ANTILIMACES

Détenteur de l'autorisation de mise sur le marché :

frunol delicia GmbH

Hansastraße 74 b – 59425 Unna, Allemagne

N° AMM : 2060175 délivrée le 28.06.2006

Substance active: Métaldéhyde 30 g / kg (3%)

Quantité nette de produit : 18 kg

Formulation : Appât granulé prêt à l'emploi

Type d'action du produit : molluscicide

N° de lot : Indiqué sous le sac

TABLEAU DES USAGES AUTORISÉS

Culture/organisme nuisible (code d'usage)	Dose	Nombre maximum d'applications	Délai avant récolte (DAR)	Zone non traitée (ZNT)
Grandes cultures (céréals, colza, maïs, tournesol)* Trt Sol * Limaces et escargots Code d'usage n° 15102901	3 kg produit/ha	2	Pas requis	Pas requis
Grandes cultures (betterave sucrière, betterave fourragère) * Trt Sol * Limaces et escargots Code d'usage n° 15102901	3 kg produit/ha	3	Pas requis	Pas requis
Cultures ornemental * Trt Sol * Limaces et escargots Code d'usage n° 17402901	6 kg produit/ha	2	Pas requis	Pas requis
Grandes cultures (fraise) * Trt Sol * * Limaces et escargots Code d'usage n° 15102901	6 kg produit/ha	2	Pas requis	Pas requis

Les limites maximales de résidus sont consultables à l'adresse suivante : <http://e-phy.agriculture.gouv.fr>

Mesures de précaution:

A utiliser seulement pour la lutte antilimace et conformément au mode d'emploi. Conserver au frais et à l'abri de l'humidité. Conserver uniquement dans son emballage d'origine. A n'utiliser dans les zones habitées que si les animaux domestiques peuvent être maintenus éloignés. Maintenir éloigné des animaux domestiques. Après l'épandage, se laver soigneusement les mains et les parties du corps concernées avec de l'eau et du savon. Ne pas traiter par grand vent.

Premiers secours:

En cas de contact avec la peau, laver les zones touchées à l'eau et au savon. En cas de contact avec les yeux, rincer abondamment.

Élimination et traitement des déchets:

Déposer les restes de produit dans les lieux de traitement des déchets prévus à cet effet. Emballages vides: réemploi interdit. Bien vider. Eliminer les emballages vides via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR ou un autre service de collecte spécifique.



Stockage :

En dehors de la période d'utilisation, les sacs doivent être stockés dans un local fermé à clé et sur une palette en bois. Après l'utilisation, les sacs ouverts et non vidés doivent être refermés et stockés dans le local phyto.

Etant donné que l'utilisation du produit se trouve en dehors de notre zone d'influence, nous nous portons uniquement responsables de la qualité irréprochable du produit au moment de sa livraison.

Delicia® et *Lentilles Antilimaces*® sont des marques déposées de frunol delicia GmbH
META® est une marque déposée de Lonza.



Etikette muss wenn möglich 74 x 105 mm Abmessung haben (3 – 50 Liter Verpackung)

LENTILLES ANTILIMACES

frunol delicia® GmbH
Hansastraße 74 b
59425 Unna (Allemagne)
www.frunol-delicia.de
Tél: 00 49 (0)2303 253 60 17

Phrases de Sécurité

- S 2 Conserver hors de portée des enfants
- S 13 Conserver à l'écart des aliments et boissons, y compris ceux pour animaux
- S 20/21 Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation
- S 37 Porter des gants appropriés
- S 46 En cas d'ingestion, consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette
- SPe 6 – Pour protéger les oiseaux/les mammifères sauvages, récupérer tout produit accidentellement répandu.
- SP 1 Ne pas polluer l'eau avec le produit ou son emballage – Ne pas nettoyer le

PRODUIT POUR LES PROFESSIONNELS

**Fiche de Données de Sécurité disponible
sur simple appel au 00 49 2303 253 60 17
ou sur internet : www.quickfds.com**

En cas d'urgence, appeler le 15 ou le centre anti-poison puis signalez vos symptômes
au réseau « Phyt'attitude », n° vert 0 800 887 887 (appel gratuit depuis un poste fixe)

Appendix 3 – Letter(s) of Access

Provided upon request.