

REGISTRATION REPORT

Part A

Risk Management

Product code: 1 90002 01

Product name(s): EXTRALUGEC SR

**Active Substance(s):
metaldehyde, 50 g/kg**

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(renewal marketing authorisation)

Applicant: PHYTEUROP

Date: 2018-07-30

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PART A – Risk Management

The company PHYTEUROP has requested marketing authorisation in France for the product EXTRALUGEC SR (formulation code: 1 90002 01), containing 50 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 EXTRALUGEC SR (1 90002 01) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of EXTRALUGEC SR (1 90002 01) have been made using endpoints agreed in the EU peer review of metaldehyde.

This document describes the specific conditions of use and labelling required for France for the registration of EXTRALUGEC SR (1 90002 01).

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 PHYTEUROP's application to market EXTRALUGEC SR (1 90002 01) 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 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 application (2014-0115) was evaluated 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.

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

The French Order of 4th May 2017³ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally 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, 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) No 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014 provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the Decision
- the “reference” and “linked” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order,

¹ 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 adjuvants 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/AGRG1632554A/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

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

mainly based on the EU document on residue data extrapolation⁶ is to supply “minor” crops with registered plant protection products.

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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of EXTRALUGEC SR (1 90002 01), 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

Phyteurop is part of the metaldehyde task force.

A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	EXTRALUGEC SR (1 90002 01)
Authorisation number	9000753
Function	Molluscicide
Applicant	PHYTEUROP
Composition	50 g/kg metaldehyde
Formulation type (code)	Granular bait (GB)
Packaging	Bags paper / low density polyethylene (1 kg, 5 kg, 10 kg, 15 kg ; 20 kg, 25 kg, 30 kg)

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	No classification	
Health hazards	No classification	
Environmental hazards	No classification	
Hazard pictograms	-	
Signal word	-	
Hazard statements	-	-

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

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.

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

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

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.
SPe 6	To protect wild birds and mammals, recover any accidentally spilled product.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁷ : refer to the Decision in Appendix 1 for the details
Re-entry period: not relevant
Pre-harvest interval: - Grape : F- Application must be made at growth stage BBCH [57] at the latest
Other mitigation measures: - Do not stored above 40 °C. - Do not apply EXTRALUGEC SR (1 90002 01) on harvestable parts of plants.
The label may include the following recommendations: -
The label must reflect the conditions of authorisation.

⁷ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

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.

GAP rev. 1, date: 2018-07-30

PPP (product name/code) **EXTRALUGEC SR (1 90002 01)**
active substance 1 **metaldehyde**

Formulation type: **GB**
Conc. of as 1: **50 g/kg**

Applicant: **PHYTEUROP**
Zone(s): **southern**

professional use
non professional use

Verified by MS: **yes**

Crop and/or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Potato	France	1 90002 01	F	Mollusc (snails and slugs)	GB	50 g/kg (5%) metaldehyd	Soil application (spreading)	-	2	7 days	/	/	0.35	NR	Not acceptable (insufficient number of residue trials)
Beetroot	France	1 90002 01	F	Mollusc (snails and slugs)	GB	50 g/kg (5%) metaldehyd	Soil application (spreading)	BBCH 00-15	2	7 days	/	/	0.35	NR	Not acceptable (insufficient number of residue trials)
Maize	France	1 90002 01	F	Mollusc (snails and slugs)	GB	50 g/kg (5%) metaldehyd	Soil application (spreading)	BBCH 00-15	2	7 days	/	/	0.35	NR	Not acceptable (insufficient number of residue trials)

(a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		

Oil seed	France	1 90002 01	F	Mollusc (snails and slugs)	GB	50 g/kg (5%) metaldehyd	Soil application (spreading)	BBCH 00- 16	2	7 days	/	/	0.35	NR	Not acceptable (insufficient number of residue trials)
Cereals (wheat, barley, oat, rye, triticale)	France	1 90002 01	F	Mollusc (snails and slugs)	GB	50 g/kg (5%) metaldehyd	Soil application (spreading)	BBCH 00- 29	2	7 days	/	/	0.35	NR	Not acceptable (insufficient number of residue trials)
Grapevine	France	1 90002 01	F	Mollusc (snails and slugs)	GB	50 g/kg (5%) metaldehyd	Soil application (spreading)	BBCH 09- 57	2	7 days	/	/	0.35	NR	Acceptable
Strawberry, small fruit and berries	France	1 90002 01	F	Mollusc (snails and slugs)	GB	50 g/kg (5%) metaldehyd	Soil application (spreading)	BBCH 09- 69	2	7 days	/	/	0.35	NR	Not acceptable (insufficient number of residue trials)
Vegetables crops (lettuce, cabbage)	France	1 90002 01	F	Mollusc (snails and slugs)	GB	50 g/kg (5%) metaldehyd	Soil application (spreading)	BBCH 10- 40	2	7 days	/	/	0.35	NR	Not acceptable (insufficient number of residue trials)
Vegetables crops (beans, peas, pulses)	France	1 90002 01	F	Mollusc (snails and slugs)	GB	50 g/kg (5%) metaldehyd	Soil application (spreading)	BBCH 10- 15	2	7 days	/	/	0.35	NR	Not acceptable (insufficient number of residue trials)

Crop and/or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		

Grassland	France	1 90002 01	F	Mollusc (snails and slugs)	GB	50 g/kg (5%) metaldehyd	Soil application (spreading)	/	2	7 days	/	/	0.35	NR	Not acceptable (insufficient number of residue trials)
Ornamentals, Turf	France	1 90002 01	F	Mollusc (snails and slugs)	GB	50 g/kg (5%) metaldehyd	Soil application (spreading)	/	2	7 days	/	/	0.35	NR	Acceptable

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
 - (f) All abbreviations used must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at 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
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) 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 EXTRALUGEC SR (1 90002 01) is a granular bait (GB) formulation. All studies have been performed in accordance with the current requirements. The appearance of the product is that of blue granular, with no odour. It is not explosive, has no oxidising properties and is not auto-flammable up to 423 °C. In aqueous solution (1 %), it has a pH value around 7.1 at 20.8 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 8 weeks at 40 °C. Neither the active ingredient content nor the technical properties were changed. The formulation is not classified for the physico-chemical aspect.

The formulation must be stored at temperature below 40°C.

3.1.2 Methods of analysis

Analytical methods for the determination of active substance and its relevant impurity (acetaldehyde) in the formulation are available and validated.

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

To update, post authorisation:

- Provide a validation of the analytical method for the determination of acetaldehyde in the formulation (study report No. 13-919022-012) at the LOQ ≤ 0.075 g/kg (0.0075 %). It should be confirmed that the relevant impurity acetaldehyde is below 0.075g/kg in the stability studies.
- Establish monitoring of acute effects on bird populations and granivorous mammals.

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	
ARfD	0.3 mg/kg bw/d	EU agreed endpoint	
AOEL	0.1 mg/kg bw/d	EU agreed endpoint	
Dermal absorption	Based on an in vitro rat study performed on a similar formulation:		
		Concentrate (tested) 50 g/L	Spray dilution (tested)
	In vitro (human) %	0.23	Not relevant
		Concentrate (used in formulation) 50 g/L	Spray dilution (used in formulation)
	Dermal absorption endpoints %	0.23	Not relevant

3.1.3.1 Acute Toxicity

EXTRALUGEC SR (1 90002 01) containing 50 g/kg metaldehyde has low acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases) :

Crop	F/G ⁸	Equipment	Application rate kg/L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Risk envelop	F	Tractor mounted equipment	7 kg/ha (355.3 g technical as/ha equivalent to 350 g pure as/ha)	/	PHED
Risk envelop	F	Hand-held application	7 kg/ha (355.3 g technical as/ha equivalent to 350 g pure as/ha)	/	PHED

Considering proposed uses, operator systemic exposure was estimated using the PHED model:

Crop	Equipment	PPE and/or working coverall	Treated surface (Ha)	% AOEL metaldehyde
Risk envelop	Tractor mounted equipment	Working coverall and gloves during mixing/loading and application	25	3.24
Risk envelop	Tractor mounted equipment	Working coverall and gloves during mixing/loading and application	50	6.47
Risk envelop	Hand-held application	Working coverall and gloves during mixing/loading and application	1	4.05

According to the model calculations, it can be concluded that the risk for the operator using EXTRALUGEC SR (1 90002 01) is acceptable with a working coverall (90% protection factor).

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

3.1.3.3 Bystander Exposure

EXTRALUGEC SR (1 90002 01) is a granular bait formulation; no drift is expected. Therefore, bystander exposure estimation is considered to be not relevant.

3.1.3.4 Worker Exposure

EXTRALUGEC SR (1 90002 01) is a granular bait formulation; no work is expected to be practiced after application. Therefore, worker exposure estimation is considered to be not relevant.

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

3.1.3.5 Resident Exposure

EXTRALUGEC SR (1 90002 01) is a granular bait formulation; no drift is expected. Therefore, resident exposure estimation is considered to be not relevant.

3.1.4 Residues and Consumer Exposure

Overall conclusion

⁸ Open field or glasshouse

The data available are considered sufficient for risk assessment only for grape. No SEU residues trials are available on cereals and oilseeds therefore, data are not sufficient on those crops. No residues data are available on maize, beetroot, strawberry, small fruits and berries, potato, lettuce, cabbage, bean, pea, pulses and grassland, therefore those uses could not be assessed.

An exceedance of the current MRL for metaldehyde as laid down in Reg. (EU) 396/2005 is not expected on grapevine.

The chronic and the short-term intakes of metaldehyde residues resulting from the intended use on grapevine are unlikely to present a public health concern.

As far as consumer health protection is concerned, France as zRMS agrees with the authorization of the intended use on grapevine only, however with a proposed application stage at BBCH 57 instead of 69 initially requested.

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

Data gaps

For several intended uses, residue trials are missing. Therefore, they cannot be considered as fully supported in France and/or in the Southern zone (see table 8.11-1 below for details).

Summary for metaldehyde

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg 400/2015	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Beetroot	Yes	No (0)	No	/	/	/	/	
2	Oil seed	Yes	No (11 NEU 0 SEU)	No	Yes	Yes : NEU only SEU : no data	No	No	
3	Cereals (Wheat, barley, oat, rye, triticale)	Yes	No (16 NEU 0 SEU)	No	Yes	Yes : NEU only SEU : no data	No	No	
4	Maize	Yes	No	No	/	/	/	/	
5	Grapevine Strawberry, small fruit and berries	Yes	Yes grape vine only	Yes grape vine only	Yes	Yes	No	No	Grapevine only (table and wine grapes)
6	Potato	Yes	No	No	/	/	/	/	
7	Lettuce cabbage	Yes	No	No	/	/	/	/	
8	Beans, peas, pulses,	Yes	No	No	/	/	/	/	
9	Grassland	Yes	No	No	/	/	/	/	
10	Ornamental, Turf	No human or animal consumption; therefore no residue assessment needed.							

As residues of metaldehyde in grape do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Further investigation of residues in rotational crops is not required since grapevine is a permanent crop.

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 as acceptable for all groups of consumers.

Summary for EXTRALUGEC SR (1 90002 01)

Crop	PHI for EXTRALUGEC SR (1 90002 01) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for EXTRALUGEC SR (1 90002 01) proposed by zRMS	zRMS Comments (if different PHI proposed)
		metaldehyde		
grapevine	Last application up to BBH69 , PHI=F	Yes	Last application up to BBH57, PHI=F	As far as consumer health protection is concerned, France agrees with the authorization of the intended use on grapevine with a proposed last application stage at BBCH 57 instead of 69 initially requested

NR: not relevant

** 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

3.1.5 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 PECs (predicted environmental concentrations) for the active substance and its metabolites 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 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 are used for the eco-toxicological risk assessment.

PEC_{GW} values for metaldehyde do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000⁹. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses. However in order to confirm this conclusion, further data on the release rate of the formulated product are required within 2 years as recommended in EFSA journal (2010).

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

⁹ Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

3.1.6 Ecotoxicology

The risk assessment for birds and mammals shows that there is no unacceptable acute or reproductive risk to avian and mammalian species (granivorous and slug-eating birds/mammals) from the application of EXTRALUGEC SR (1 90002 01) to target crops according to the proposed GAP.

The risk assessment for aquatic organisms, honeybees, earthworms and other soil macro-organisms and non-target plant demonstrated that no unacceptable effects would be anticipated of EXTRALUGEC SR (1 90002 01) according to the proposed GAP.

Nonetheless, acute effects on populations of granivorous birds and mammals must be monitored.

3.1.7 Efficacy

Crop	Pest	Method of application	Dose of use (max per appli)	Max nb of appl. per use	Opinion of France for efficacy section	Comments (e.g. monitoring ...)/ additional demands
All crops	Slugs and snails	Soil application (spreading)	7 kg/ha	2	In accordance	

Considering the data submitted:

- the efficacy of EXTRALUGEC SR (1 90002 01) is considered as satisfying on the basis of trials on oilseed rape, winter wheat, spring barley, maize, sunflower, grapevine, potato, lettuce and cabbage against slugs (*Deroceras reticulatum*). This large panel of crop is representative of crops diversity, so it is possible to extrapolate the results to all crops.
- the selectivity of EXTRALUGEC SR (1 90002 01) is considered as satisfying.
- the risk of negative impact (yield, quality, transformation processes, propagation, succeeding crops) is considered as acceptable.
- the risk of resistance development or appearance is considered low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted only on grapevine, ornamentals and turf (insufficient number of residue trials for other crops). A copy of the decision issued can be found in Appendix 1.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

Establish monitoring of acute effects on bird populations and granivorous mammals.

3.4.2 Post-authorisation data requirements

The following data would have been required to update the dossier:

Provide a validation of the analytical method for the determination of acetaldehyde in the formulation (study report No. 13-919022-012) at the LOQ ≤ 0.075 g/kg (0.0075 %). It should be confirmed that the relevant impurity acetaldehyde is below 0.075g/kg in the stability studies.

3.4.3 Label amendments

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision



Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit phytopharmaceutique et de la demande associée

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 de changement de composition du produit phytopharmaceutique **EXTRALUGEC SR***

*de la société **PHYTEUROP***

*enregistrées sous les **n°2014-0115 et n°2014-1147***

Vu les conclusions de l'évaluation de l'Anses du 11 août 2017,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **est renouvelée** en France, en intégrant la nouvelle composition, pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

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.



Informations générales sur le produit	
Noms du produit	EXTRALUGEC SR JUDGE COPALIM SR LIMATIC EXTRA COPALIM PRO SEMALIM PRO PRIMEDIC SR HELUGEC SR SUPER LIMASTOP NP COPALDEHIDE SEMALIM SR GASTROTOX SR COPALIM SEMALIM EXTRALUGEC GRANULES EXTRALUGEC GRANULES TECHN'O GENESIS TECHN'O
Type de produit	Produit de référence
Titulaire	PHYTEUROP 55, rue Raspail - CS 80105 92594 Levallois-Perret Cedex FRANCE
Formulation	Appât granulé (GB)
Contenant	50 g/kg - métaldéhyde
Numéro d'intrant	9000753
Numéro d'AMM	9000753
Fonction	Molluscicide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 mai 2022.

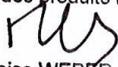
Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour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

30 JUL. 2018

La directrice générale déléguée
en charge du pôle des produits réglementés


Françoise WEBER

EXTRALUGEC SR
AMM n°9000753

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Sacs en papier / polyéthylène basse densité	1 kg ; 5 kg ; 10 kg ; 15 kg ; 20 kg ; 25 kg ; 30 kg

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



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)	Mention abeilles		
11012903 Traitements généraux*Trt Sol*Limaces et escargots	7 kg/ha	2/an	-	Non applicable	-	-	-	-		
	Uniquement sur gazons et cultures florales. Intervalle minimum entre les applications : 7 jours.									
	7 kg/ha	2/an	entre les stades BBCH 09 et BBCH 57	F (BBCH 57)	-	-	-	-		
Uniquement sur vigne (raisin de cuve et raisin de table). Intervalle minimum entre les applications : 7 jours. Modification du stade maximal d'application de BBCH 69 à BBCH 57 conformément aux données résidus disponibles.										

EXTRALUGEC SR
AMM n°9000753



Liste des usages retirés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
<p>11012903 Traitements généraux*Trt Sol*Limaces et escargots</p>	7 kg/ha	2/an	-
<p>Motivation du retrait : L usage est retiré sur pomme de terre, betterave (sucrière, fourragère, potagère), navet, rutabaga, maïs, maïs doux, sorgho, millet, graines oléagineuses, céréales à paille (blé, seigle, orge, avoine, triticale), fraise, baies, petits fruits : fruits de ronces (mûres), framboises, myrtilles, groseilles, cassis, laitues, scarole, mâche, épinard, pourpier, feuille de bette, fines herbes (ciboulette, persil, fines herbes), brassicacées (chou-fleur, brocoli, chou pommé, chou de Bruxelles), légumineuses potagères fraîche (haricot vert, haricot frais écossé, pois non écossé, petit pois écossé, lentille fraîche), légumineuses séchées (pois, haricot, lentille, lupin) et prairies en raison d'un nombre insuffisant d'essais résidus pour confirmer que les bonnes pratiques agricoles permettront de respecter les limites maximales de résidus en vigueur.</p>			

EXTRALUGEC SR
AMM n°9000753



Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas stocker le produit dans un local où la température peut dépasser 40°C.

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 microgranulateur

• pendant le chargement du matériel d'épandage

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester 65 % / coton 35% (combinaison ou ensemble veste + pantalon) ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

• pendant l'épandage

- Gants certifiés EN 374-2 à usage unique en cas d'intervention sur semoir, épandeur à engrais ou microgranulateur ;
- Combinaison de travail polyester 65 % / coton 35% (combinaison ou ensemble veste + pantalon) ;

• pendant le nettoyage du matériel d'épandage

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester 65 % / coton 35 % (combinaison ou ensemble veste + pantalon) ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

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

- Non applicable.

Respect des limites maximales de résidus (LMR)

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

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.

Protection de la faune

- SPe 6 : Pour protéger les oiseaux et les mammifères sauvages, récupérer tout produit accidentellement répandu.

Le produit peut être utilisé sur les usages autorisés, y compris sur les cultures qui seraient exclues de la portée par la présente décision, conformément aux conditions d'emploi antérieures pendant une période de 6 mois.



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)	Réurrence (mois)
Fournir une validation de la méthode analytique pour la détermination de l'acétaldéhyde dans la formulation (rapport d'étude No. 13-919022-012) à une LOQ $\leq 0,075$ g/kg (0,0075 %) afin de confirmer que l'impureté pertinente acétaldéhyde est inférieure à 0,075 g/kg dans les études de stabilité.	24	-
Mettre en place un suivi des effets aigus sur les populations d'oiseaux et de mammifères granivores.	24	-

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

Molluscicide

Traitement du sol

<p>NOM COMMERCIAL : XXXX N° d'AMM : 9000753 DETENTEUR DE L'AMM : PHYTEUROP - 53, rue Raspail 92594 Levallois-Perret Cedex</p> <p>TYPE d'ACTION : Molluscicide FORMULATION : Appât granulé (GB) COMPOSITION : 50 g/kg (5 %) métaldéhyde</p>	<p>XXXX</p> <p>Sans classement.</p> <p>SP1 Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.]</p> <p>EUH 401 Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.</p>
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Usage	Organisme nuisible	Dose	Nombre max. d'application	DAR	ZNT
Traitements généraux / traitement du sol	Limaces, escargots	7 kg/ha	2	Voir conditions d'emploi	5 mètres

L'utilisation de ce produit sur ses usages autorisés n'est recommandée que sur les cultures et cibles indiquées dans le tableau ci-dessous. PHYTEUROP décline en conséquence toute responsabilité en cas d'utilisation du produit sur des cultures ou pour des cibles non recommandées.

- Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : http://ec.europa.eu/sanco_pesticides/public/index.cfm
- Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur.

Définition et mode d'action

XXXX est un appât granulé tirant 5% de métaldéhyde. Le métaldéhyde provoque une destruction irréversible des cellules muqueuses (tube digestif, pied, ...) qui entraîne la mort rapide des mollusques (limaces noires et grises, escargots).

Performances

XXXX est résistant à l'humidité, ce qui évite le délitage et l'apparition de moisissures. La formulation XXXX répond aux exigences actuelles de sécurité grâce à l'incorporation d'une substance diminuant les risques de consommations éventuelles de produit par les animaux domestiques, le gibier...

Conditions d'emploi

XXXX peut être employé sur les cultures ci-dessous, pour détruire les limaces et les escargots.

Cultures	DAR / Périodes d'application
Pomme de terre	7 jours
Betterave (sucrière, fourragère, potagère), navet et rutabaga	BBCH 00 à BBCH 15
Mais, maïs doux, sorgho, millet	BBCH 00 à BBCH 15
Cultures oléagineuses (lin, pavot, sésame, tournesol, colza, soja, moutarde, autre oléagineux sauf arachides)	BBCH 00 à BBCH 16
Céréales à paille (blé, seigle, orge, avoine, triticale)	BBCH 00 à BBCH 29
Vigne (raisin de cuve et raisin de table)	BBCH 09 à BBCH 69
Fraise, baies et petits fruits : fruits de ronces (mûres), framboises, myrtilles, groseilles, cassis, myrtilles, etc.)	BBCH 09 à BBCH 69
Laitues et autres salades similaires (laitue, scarole, mâche, etc., y compris les brassicacées), épinard et similaires (épinard, pourpier, feuille de bette, etc.) et fines herbes (ciboulette, persil, et autres fines herbes consommées fraîches)	BBCH 10 à BBCH 40
Brassicacées (chou-fleur, brocoli, chou pommé, chou de Bruxelles)	BBCH 10 à BBCH 40
Légumineuses potagères fraîches (haricot vert, haricot frais écossé, pois non écossé, petit pois écossé, lentille fraîche), légumineuses séchées (pois, haricot, lentille, lupin)	BBCH 10 à BBCH 15
Prairies, gazons, cultures florales	Délai de rentrée du bétail : 49 jours

Les meilleures efficacités sont obtenues par des traitements préventifs avant ou au moment du semis. En cas d'infestations prolongées de limaces, il peut être nécessaire de renouveler les applications pendant la période de sensibilité des cultures. XXXX peut être appliqué sur de grandes largeurs avec des épandeurs d'engrais centrifuges ou des épandeurs spécifiques d'anti-limaces.

Précautions à prendre

- Lors de la vidange des appareils, ne pas laisser de granulés en tas sur le sol. Les récupérer et les disperser sur la surface traitée.
- Dangereux pour les animaux domestiques (chiens et chats) et pour le gibier.
- Contient un additif diminuant le risque de consommation pour les chiens et les chats durant une période très limitée après l'ouverture des emballages.
- Conserver le produit à l'écart des aliments et boissons y compris ceux pour animaux, et hors de la portée des enfants.
- Toujours conserver les produits dans leur emballage d'origine. Les stocker dans un local réservé à cet usage, frais, sec, bien ventilé et fermant à clé, à l'abri du gel et de la chaleur.
- Les manipulateurs doivent porter une tenue de travail.
- Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.
- Se laver les mains et le visage dès le travail terminé et avant de prendre toute nourriture.
- Réservé à un usage professionnel.

Élimination du produit et de l'emballage :

- Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.
- Réemploi de l'emballage interdit. Bien les vider. Éliminer les emballages vides via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR.

Premiers soins :

- Enlever immédiatement les vêtements contaminés par le produit.
- Après inhalation : Donner de l'air frais.
- Après contact avec la peau : Laver immédiatement et abondamment à l'eau et au savon. Bien rincer.
- Après contact avec les yeux : Rincer les yeux pendant plusieurs minutes, sous l'eau courante en écartant bien les paupières.
- Après ingestion : Rincer la bouche à l'eau. Ne pas faire vomir.

Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.

La fiche de données de sécurité peut être obtenue gratuitement sur Internet à l'adresse suivante : www.quickfds.com.

Poids net : Y kg

EMB : 49215 F
Date de fabrication : voir sur l'emballage.

Distribué par : PHYTEUROP – 53, rue Raspail – 92594 Levallois-Perret Cedex
 Tél. : 01 47 59 77 27 – Fax : 01 47 37 54 52

Appendix 3 – Letter(s) of Access
Provided.