REGISTRATION REPORT

Part A

Risk Management

Product code: 1 90002 01

Product name(s): SPAHIS JARDIN

Active Substance(s):

metaldehyde, 50 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

Non-professional home and gardens use

(renewal of 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 SPAHIS JARDIN (formulation code: 1 90002 01), containing 50 g/kg metaldehyde for use as a molluscicide home garden (non-professional use).

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 SPAHIS JARDIN (1 90002 01) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of SPAHIS JARDIN (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 SPAHIS JARDIN (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 SPAHIS JARDIN (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 (2014-0119) 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 2017[3] 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 1107/2009[4], 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 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] 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
[6] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

mainly based on the EU document on residue data extrapolation[7] 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 SPAHIS JARDIN (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)	SPAHIS JARDIN (1 90002 01)
Authorisation number	2010324
Function	Molluscicide
Applicant	PHYTEUROP
Composition	50 g/kg metaldehyde
Formulation type (code)	Granular beat (GB)
Packaging	Bags paper / low density polyethylene (450 g, 1 kg, 1,5 kg) with pouring spout

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	-	-

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

Precautionary statements –	***For the P phrases, refer to the extant legislation***	
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 non-professional uses only to the following conditions:

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

2.2.4 Other phrases linked to the preparation

Re-entry period[8]: not relevant
Pre-harvest interval[9]: - Grape : F- Application must be made at growth stage BBCH [57] at the latest
Other mitigation measures: - Do not store above 40 °C. - Do not throw in the sink, the gutter or any other water point the unused funds - Do not leave containers open to pets and avoid applying the product in their presence.
The label may include the following recommendations: - The label must reflect the conditions of authorisation.

[8] The legal basis for this is **Titre I Article 3** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[9] According to the French Order of 12 September 2006, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
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)	**SPAHIS JARDIN (1 90002 01)**	**Formulation type:**	**GB**
active substance 1	**metaldehyde**	**Conc. of as 1:**	**50 g/kg**
Applicant:	**PHYTEUROP**	**professional use**	☐
Zone(s):	**southern**	**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)

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		
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)
Ornamen-tal, 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 SPAHIS JARDIN (1 90002 01) is a Granular beat (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 %) must be provided. It should be confirmed that the relevant impurity acetaldehyde is below 0.075g/kg in the stability studies.
- Provide an analytical method (with a confirmatory method) and its ILV for the determination of metaldehyde residue in foodstuffs of animal origin according to the EFSA conclusions (EFSA journal 2014 ;12 (5) :3682), must be provided.

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

SPAHIS JARDIN (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 eyes and is not a skin sensitiser.

The proposed packaging has been described in sufficient detail, and its compliance can therefore be finalised. In summary, compliance with the provisions of French Decree No. 2010-1755 of 30 December 2010 and Orders of 30 December 2010 relating to the use of certain plant protection products by non-professional users is considered to be finalised.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases) :

Crop	F/G[10]	Equipment	Application rate kg/L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Risk envelop	F	Manually	PPP : 0.7 g/ m² corresponding to 7 kg/ha (AS : 0.35532 g/10m² corresponding to 355.32 g/ha)	-	UPJ

Considering proposed uses, operator (i.e., user – non-professional) systemic exposure was estimated using the French study 2005 dedicated to amateur use:

Crop	Equipment	PPE and/or working coverall	% AOEL metaldehyde
Risk envelop	Manually	No PPE	1.67

According to the model calculations, it can be concluded that the risk for the operator (i.e., user – non-professional) using SPAHIS JARDIN (1 90002 01) is acceptable without personal protective equipment.

3.1.3.3 Bystander Exposure

SPAHIS JARDIN (1 90002 01) is a granular bait formulation; no drift is expected. Therefore, bystander exposure estimation is considered to be not relevant. Moreover, SPAHIS JARDIN (1 90002 01) is intended to be used by amateurs during home garden application.

3.1.3.4 Worker Exposure

SPAHIS JARDIN (1 90002 01) is intended to be used by amateurs during home garden application. In this case, the worker is also the operator and, it is concluded that the worker exposure is not exceeding operator exposure. To conclude, worker exposure is covered by operator exposure. Moreover, SPAHIS JARDIN (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.

3.1.3.5 Resident Exposure

Residential exposure was not assessed according to BREAM model because this model is not adapted for this type of formulation.

Using the reverse reference approach it is possible to calculate the number of SPAHIS JARDIN (1 90002 01) pellets that, if consumed by an infant would result in an exceedance of the ARfD of 0.3 mg/kg bw/day for metaldehyde.

The reverse reference approach shows that 4 individual pellets are required to achieve an intake of metaldehyde which would be equivalent to the reference dose.

[10] Open field or glasshouse

It is concluded that there is no unacceptable risk of residential exposure after incidental short-term exposure to SPAHIS JARDIN (1 90002 01).

3.1.4 Residues and Consumer Exposure

Overall conclusion

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 grapes and wine grapes)
6	Potato	Yes	No	No	/	/	/	/	
7	Lettuce cabbage	Yes	No	No	/	/	/	/	
8	Beans, peas, pulses,	Yes	No	No	/	/	/	/	

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
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 SPAHIS JARDIN (1 90002 01)

Crop	PHI for Product code proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for SPAHIS JARDIN (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.

SAPHIS JARDIN (1 90002 01) is a ready-to-use granular formulation for home and gardens. Only the evaluation of the risk of groundwater contamination is considered relevant in this case. However a complete evaluation has been provided for the identical preparation EXTRALUGEC and has been reproduced for SAPHIS JARDIN (1 90002 01).

The PEC 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 221/2000[11]. 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 DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

With regard to possible adverse effects on non-target organisms after applications of SAPHIS JARDIN (1 90002 01) in gardens, a bridging approach was followed. Detailed risk assessments have been conducted for the professional large scale applications of the similar formulation EXTRALUGEC SR (dRR submitted which covered all the intended professional and non-professional uses).

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 SAPHIS JARDIN (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 SAPHIS JARDIN (1 90002 01) according to the proposed GAP.

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 (fractionnable)	In accordance	

Considering the data submitted:

- the efficacy of SAPHIS JARDIN (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 SAPHIS JARDIN (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.

[11] 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.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted only on grapevine, ornamental 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

No further information is required.

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

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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 règlementaire,

Vu la demande de renouvellement de l'autorisation de mise sur le marché du produit phytopharmaceutique ***SPAHIS JARDIN***

de la société *PHYTEUROP*

enregistrée sous le *n°2014-0119*

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

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est renouvelée** en France 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.

SPAHIS JARDIN
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Informations générales sur le produit		
Noms du produit	SPAHIS JARDIN TRADIALIM JARDIN	
Type de produit	Deuxième gamme	
Titulaire	PHYTEUROP 55, rue Raspail - CS 80105 92594 Levallois-Perret Cedex FRANCE	
Formulation	Appât granulé (GB)	
Contenant	50 g/kg - métaldéhyde	
Produit de référence	Nom commercial	EXTRALUGEC SR
	N° AMM	9000753
Numéro d'intrant	2010324	
Numéro d'AMM	2010324	
Fonction	Molluscicide	
Gamme d'usages	Amateur / emploi autorisé dans les jardins	

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 JUIL. 2018

La directrice générale déléguée
en charge du pôle des produits réglementés

Françoise WEBER

SPAHIS JARDIN
AMM n°2010324

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agence nationale de sécurité sanitaire alimentation, environnement, travail

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 avec bec verseur	450 g ; 1 kg ; 1,5 kg

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

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
11012903 Traitements généraux*Trt Sol*Limaces et escargots	**0,7 g/m²**	**2/an**	-	Non applicable	-	-	-	-
	Uniquement sur gazons et cultures florales. Intervalle minimum entre les applications : 7 jours.							
	0,7 g/m²	**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 BBBCH 57 conformément aux données résidus disponibles.							

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Liste des usages retirés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
11012903 Traitements généraux*Trt Sol*Limaces et escargots	0,7 g/m²	2/an	-
	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.		

SPAHIS JARDIN

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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.

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

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

Protection de la faune

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

- Ne pas laisser les contenants accessibles aux animaux domestiques et éviter toute application du produit en leur présence.

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)	Récurrence (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 ≤ 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	-

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

ANTI-LIMACES

Des cultures légumières et ornementales

NOM COMMERCIAL :	SPAHIS JARDIN
N° d'AMM :	2010324 (emploi autorisé dans les jardins)
DETENTEUR DE L'AMM :	PHYTEUROP - 53, rue Raspail 92594 Levallois-Perret Cedex
TYPE d'ACTION :	Molluscicide
FORMULATION :	Appât granulé (GB)
COMPOSITION :	50 g/kg (5 %) métaldéhyde

Culture	Organisme nuisible	Dose	Nombre max. d'application	DAR	ZNT
Traitements généraux / traitement du sol	mollusques, escargots	7 g/10m²	2	3 jours	5 mètres

- 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.

SPAHIS JARDIN

Sans classement.

P102 Tenir hors de portée des enfants.

P270 Ne pas manger, boire ou fumer en manipulant ce produit.

P271 Utiliser seulement en plein air ou dans un endroit bien ventilé.

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.]

EUH401 Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

Définition et mode d'action

SPAHIS JARDIN titrant 5% de métaldéhyde est un appât granulé antilimaces prêt à l'emploi à longue durée d'action. Le métaldéhyde provoque une destruction irréversible des cellules muqueuse (tube digestif, pied, ...) qui entraîne la mort rapide des mollusques. Sa formulation lui confère une très bonne résistance à l'humidité et permet une bonne régularité d'épandage. Utilisé sur cultures légumières et ornementales, SPAHIS JARDIN agit sur les limaces grises, rouges ou noires, et les escargots par contact et ingestion.

Période et doses d'emploi

J F M A M J J A S O N D

Période optimale
Période favorable

Les traitements se font en préventif ou en curatif dès l'apparition des premiers dégâts. Afin de garantir une efficacité optimale, il est recommandé d'utiliser SPAHIS JARDIN à la dose de 70 g/100 m² soit 30 à 35 granulés par m². En cas de pression plus faible, la dose peut être diminuée à 50 g/100 m² correspondant à 20 à 25 granulés par m².
Epandre régulièrement les granulés sur le sol. Ne pas faire de tas. Réaliser le traitement de préférence le soir, après arrosage ou par temps humide.
SPAHIS JARDIN contient un amérisant et un répulsif. Il répond aux exigences actuelles de sécurité en diminuant le risque de consommation par les animaux.

Précautions à prendre

- Dangereux pour les chiens et/ou les chats.
- Contient un additif diminuant le risque de consommation pour les chiens et les chats durant une période très limitée après l'ouverture des emballages.
- Ne pas appliquer sur des légumes prêts à être consommés.
- Bien refermer l'emballage après utilisation.
- Conserver le produit à l'écart des aliments et boissons y compris ceux pour animaux, et hors de la portée des enfants.
- Toujours conserver le produit dans son emballage d'origine. Le stocker à l'abri du gel et de la chaleur.

Elimination du produit et de l'emballage :

- Emballage vide : réemploi interdit. Bien vider l'emballage lors de la dernière utilisation.
- Eliminer les emballages, avec ou sans reliquat de produit, dans une déchèterie.

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.

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

Poids net : **1 kg**

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

Not applicable.