

REGISTRATION REPORT

Part A

Risk Management

Product name: HELIXER JARDIN

Active Substance:
metaldehyde, 30 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

Non professional use
(marketing authorisation)

Applicant: SBM Développement

Date: 07/11/2017

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PART A – Risk Management

The company SBM Développement has requested marketing authorisation in France for the product HELIXER JARDIN (GR), containing 30 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 HELIXER JARDIN where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of HELIXER JARDIN 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 HELIXER JARDIN.

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 SBM Développement's application to market HELIXER JARDIN 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 first authorisation 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 (2013-1836 and 2014-1069) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)² – the highest application rates over the Southern Zone. 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 26 March 2014³ 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, 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

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

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

Where protection for data is being claimed for information supporting registration of HELIXER JARDIN, 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 the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. 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)	HELIXER JARDIN (no product code is stated)
Authorisation number	None (marketing authorisation refused)
Function	Molluscicide
Applicant	SBM Développement
Composition	30 g/kg metaldehyde
Formulation type (code)	Granules (GR)
Packaging	Cardboard containers with pouring spout holding 300 g, 500 g, 900 g and 2500 g product Cardboard container with polyethylene terephthalate/polyethylene (PET/PE) bag and dosing spoon holding 300 g, 500 g, 900 g and 2500 g product.

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	-
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)		
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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 product is not authorised.

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

2.2.4 Other phrases linked to the preparation

The product is not authorised.

2.3 Product uses

Please note:

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

PPP (product name/code): **HELIXER JARDIN** Formulation type: **GR** ^(a, b)
 Active substance 1: metaldehyde Conc. of a.s. 1: **30 g/kg** ^(c)
 Applicant: **SBM Développement** Professional use: ☐
 Zone(s): southern ^(d) Non-professional use: ☒
 Verified by MS: yes
 Field of use: molluscicide

GAP rev. 1, date: 2017-november-07

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, 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 or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Sugar and fodder beet / beetroot	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-15	3	14 days	7	0.21 kg a.s./ha	NA	NA	Not acceptable (physico-chemical properties Stability and acetaldehyde formation above the limit acceptable)
2	FR	Potatoes	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-45	3	14 days	7	0.21 kg a.s./ha	NA	NA	Not acceptable (physico-chemical properties Stability and acetaldehyde formation above the limit acceptable)

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, 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 ⁽ⁱ⁾
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
3	FR	Brussels sprouts	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-40	3	14 days	7	0.21 kg a.s./ha	NA	NA	Not acceptable (physico-chemical properties Stability and acetaldehyde formation above the acceptable limit and consumer safety insufficient residue trials for broccoli and other Brassicaceae kohlrabi and leafy brassica)
4	FR	Head cabbage	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-40	3	14 days	7	0.21 kg a.s./ha	NA	NA	Not acceptable (physico-chemical properties Stability and acetaldehyde formation above the acceptable limit and consumer safety insufficient residue trials for broccoli and other Brassicaceae kohlrabi and leafy brassica)

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, 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 ⁽ⁱ⁾
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
5	FR	Cauliflower	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-40	3	14 days	7	0.21 kg a.s./ha	NA	NA	Not acceptable (physico-chemical properties Stability and acetaldehyde formation above the acceptable limit and consumer safety insufficient residue trials for broccoli and other Brassicaceae kohlrabi and leafy brassica)
6	FR	Lettuce and other salad crops	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-40	3	14 days	7	0.21 kg a.s./ha	NA	NA	Not acceptable (physico-chemical properties Stability and acetaldehyde formation above the acceptable limit)
7	FR	Strawberry	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-69	3	14 days	7	0.21 kg a.s./ha	NA	NA	Not acceptable (physico-chemical properties Stability and acetaldehyde formation above the acceptable limit)
8	FR	All flowers crops flower bulbs	F	Slugs, Snails	Spreading (manually or by tractor)	At the first infestation	3	14 days	7	0.21 kg a.s./ha	NA	NA	Not acceptable (physico-chemical properties Stability and acetaldehyde formation above the acceptable limit)

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization 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	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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 HELIXER JARDIN is a granule (GR) 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 260 °C. In aqueous solution (1 %), it has a pH value around 7.0 at ambient temperature. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and eight weeks at 40 °C neither the active substance content nor the technical properties were changed. **Nevertheless, the content of the relevant impurity, acetaldehyde, is above the acceptable limit after 18 and 24 months. The formulation is considered to not be stable after 18 months' storage. Nevertheless, the applicant attests that a new ambient shelf life study (6, 12, 18 and 24 months) will be provided in order to justify the shelf life of the formulation. However, these data are not currently available. Data provided in the dossier are insufficient to demonstrate the stability of the formulation. Consequently, the zRMS considers that the formulation is not stable.**

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

3.1.2 Methods of analysis

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

Analytical methods for the determination of residues of metaldehyde are available in the 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:

an analytical method (with a confirmatory method) and its ILV for the determination of metaldehyde residues in foodstuffs of animal origin 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

3.1.3.1 Acute Toxicity

According to the toxicity studies, HELIXER JARDIN has low acute oral and dermal toxicity and is not irritating to skin or eyes. It is not a skin sensitiser.

The dermal absorption value of metaldehyde in HELIXER JARDIN is 0.23 % for the formulation, based on *in vitro* studies with a similar preparation using human skin.

3.1.3.2 Operator Exposure

The acceptable operator exposure level (AOEL) of metaldehyde, in the context of its evaluation for approval, is 0.1 mg/kg bw/d. This is based on the no observed adverse effect level in a one-year oral dog toxicity study and a 100-fold assessment factor.

Estimated operator (i.e., user – non-professional) exposure to metaldehyde according to the French UPJ model (manual spreading) revealed that the risk is considered acceptable in homes and gardens without personal protective equipment.

3.1.3.3 Bystander Exposure

Since the formulation HELIXER JARDIN is a granular bait formulation, bystander exposure is considered to be not relevant.

3.1.3.4 Resident exposure

The Bream model is not adapted for this type of formulation (granule).

Infants are assumed to be one to three years old and have a body weight of 10 kg. The concentration of metaldehyde in HELIXER JARDIN is 3 % and the individual pellet weight is confirmed as 7.49 mg. The reverse reference approach shows that 14 individual pellets are required to achieve an intake of metaldehyde which would be equivalent to the reference dose.

Moreover, the HELIXER JARDIN formulation contains denatonium benzoate, a bittering agent, which prevents significant ingestion of the formulation. Consequently there is no unacceptable risk anticipated for toddlers accidentally ingesting a few granules of HELIXER JARDIN.

As a consequence, the risk is acceptable for the resident.

3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. An exceedence of the current MRL of metaldehyde as laid down in Reg. (EU) 400/2015 is not expected.

For vegetable crops, the application has to spread the product between the rows, to avoid contact with the consumable parts of the crops.

The chronic and short-term intakes of metaldehyde residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France, as zRMS, considers the proposed uses sufficiently 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 original RMS.

Summary for metaldehyde

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
Beetroot	Yes	Yes (nu	Yes	Yes	Yes		No	Inter-row application
Potato	Yes	Yes	Yes	Yes	Yes	No		Inter row application
Brussels sprout	Yes	Yes	Yes	Yes	Yes	No		Inter-row application
Head cabbage	Yes	Yes	Yes	Yes	Yes	No		According to the intended growth stage for the last application a PHI = F is more appropriate than a PHI of one day
Cauliflower	Yes	Yes	Yes	Yes	Yes	No		Inter row application According to the intended growth stage for the last application a PHI = F is more appropriate than a PHI of one day Extrapolation to broccoli not possible
Other Brassicaceae (leafy brassicae and Kohlrabi)	Yes	No	No	:	:	:		No data
Lettuce and other salad crops	Yes	Yes	Yes	Yes	Yes	No		Inter-row application According to the intended growth stage for the last application a PHI = F is more appropriate than a PHI of one day

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
Strawberry	Yes	Yes	Yes	Yes	Yes	No		Inter-row application According to the intended growth stage for the last application a PHI = F is more appropriate than a PHI of one day
All flower crops and flower bulbs	Ornamentals are used neither for human nor animal consumption, therefore no residue data are required.							

The effects of processing on the nature of metaldehyde residues have not been investigated because no study was available. 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 original RMS. 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. Therefore 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.

Crop	PHI for HELIXER JARDIN requested by applicant (in days if not otherwise stated)	PHI/ Withholding period* sufficiently supported for	PHI for HELIXER JARDIN proposed by zRMS	zRMS Comments (if different PHI proposed)
		metaldehyde		
Sugar beet, beetroot	BBCH15, PHI = F	Yes	/	/
Potato	BBCH 45, PHI = F	Yes	BBCH 40, PHI = F	Inter-row application According the intended growth stage for the las application a PHI = F is more appropriate than a PHI of one day
Brussels sprout	BBCH 40, PHI = 1	Yes	BBCH 40, PHI = F	

Crop	PHI for HELIXER JARDIN requested by applicant (in days if not otherwise stated)	PHI/ Withholding period* sufficiently supported for	PHI for HELIXER JARDIN proposed by zRMS	zRMS Comments (if different PHI proposed)
		metalddehyde		
Head cabbage	BBCH 40, PHI = 1	Yes	BBCH 40, PHI = F	Inter-row application According the intended growth stage for the last application a PHI = F is more appropriate than a PHI of one day
Cauliflower	BBCH 40, PHI = 1	Yes	BBCH 40, PHI = F	Inter-row application According the intended growth stage for the last application a PHI = F is more appropriate than a PHI of one day
Lettuce and other salad	BBCH 40, PHI = 1	Yes	BBCH 69, PHI = F	Inter-row application According the intended growth stage for the last application a PHI = F is more appropriate than a PHI of one day
Strawberry	BBCH 69, PHI = 1	Yes	BBCH 40, PHI = F	Inter-row application According the intended growth stage for the last application a PHI = F is more appropriate than a PHI of one day

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 concentrations (PECs) 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.

HELIXER JARDIN is a ready-to-use granular formulation for homes and gardens. Only the evaluation of the risk of groundwater contamination is considered relevant in this case.

The PEC of metalddehyde in groundwater has 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_{gw} values for metalddehyde do not exceed the trigger of 0.1 µg/L. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

3.1.6 Ecotoxicology

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

The risk assessment for birds shows that the repellency properties of HELIXER JARDIN, 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 HELIXER JARDIN to target crops according to the proposed GAP.

In the same way, the risk assessment for mammals shows that the repellency properties of HELIXER JARDIN, 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 HELIXER JARDIN 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 expected from using HELIXER JARDIN according to the proposed GAP.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy of HELIXER JARDIN when it is applied at the requested rate of 7 kg/ha or twice at 3.5 kg/ha to control slugs and snails on different crops is considered satisfactory.
- the selectivity of HELIXER JARDIN is considered acceptable. To prevent eventual risk due to retention of the pellets on the crop, a recommendation on the label indicates to not apply HELIXER JARDIN directly on harvestable parts of plants.
- 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 low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation cannot be granted (due to unacceptable stability and acetaldehyde formation above the acceptable limit; plus insufficient residues data for certain crops)**. 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

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

Not applicable.

3.4.1 Post-authorisation monitoring

N/A

3.4.2 Post-authorisation data requirements

N/A

3.4.3 Label amendments (see label in Appendix 2):

N/A

Appendix 1 – Copy of the French Decision



Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et réglementaire,

*Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique **HELIXER JARDIN***

de la société **SBM Développement**

enregistrées sous les **n°2013-1836 et 2014-1069**

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

Considérant que la teneur en impureté pertinente après stockage du produit est supérieure à la limite acceptable,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.



Informations générales sur le produit		
Noms du produit	HELIXER JARDIN ANTI LIMACE 3%	
Type de produit	Deuxième gamme	
Titulaire	SBM Développement 160, route de la Valentine CS 70052 13374 MARSEILLE Cedex 11 FRANCE	
Formulation Contenant	Granulé (GR)	
	30 g/kg - métaldéhyde	
Produit de référence	Nom commercial	HELIXER
	N° AMM	-
Numéro d'intrant	909-2013.01	
Numéro d'AMM	-	
Fonction	Molluscicide	
Gamme d'usages	Amateur / emploi autorisé dans les jardins	

A Maisons-Alfort, le 07 NOV. 2017

Françoise WEBER
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

HELIXER JARDIN
AMM n°-

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
16012901 Cultures légumières* Trt Sol* Limaces et escargots	0,7 g/m ²	3/an	F (BBCH 45)
	Motivation du refus : L'usage sur pomme de terre est refusé en raison de la formation pendant le stockage d'acétaldéhyde en quantité supérieure aux limites acceptables.		
	0,7 g/m ²	3/an	F (BBCH 15)
	Motivation du refus : Les usages sur betteraves potagères et fourragères sont refusés en raison de la formation pendant le stockage d'acétaldéhyde en quantité supérieure aux limites acceptables.		
	0,7 g/m ²	3/an	F (BBCH 40)
	Motivation du refus : Les usages sur choux, laitue et autre salades similaires sont refusés en raison de la formation pendant le stockage d'acétaldéhyde en quantité supérieure aux limites acceptables et en raison de l'absence d'essai résidus sur brocoli, chou feuillu et chou rave ne permettant pas de garantir le respect des limites maximales de résidus.		
	0,7 g/m ²	3/an	F (BBCH 69)
	Motivation du refus : L'usage sur fraiser est refusé en raison de la formation pendant le stockage d'acétaldéhyde en quantité supérieure aux limites acceptables.		
17402901 Cultures ornementales* Trt Sol* Limaces et escargots	0,7 g/m ²	3/an	Non applicable
	Motivation du refus : L'usage est refusé en raison de la formation pendant le stockage d'acétaldéhyde en quantité supérieure aux limites acceptables.		

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
00701001 Plantes d'intérieur et balcons* Trit Substrats* Limaces et escargots	0,7 g/m ²	3/an	Non applicable
Motivation du refus : L'usage est refusé en raison de la formation pendant le stockage d'acétaldéhyde en quantité supérieure aux limites acceptables.			

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

HELIXER Jardin®

Molluscicide-multicultures à base d'appâts granulés prêts à l'emploi

Destiné à l'emploi en jardins (Home & Garden)

Contient 30 g métaldehyde / kg

Formulation: granulé prêt à l'emploi (GR)

Emballage:

- Etui carton/PE de 0.3 à 2.5kg
- Etui carton + sac PE de 0.3 à 2.5kg
- Etui carton de 0.3 à 2.5kg

Distribution:

Producteur:

SBM Développement

160 Route de la Valentine,

CS 70052

13374 Marseille cedex 11

® Marque déposée SBM Développement, France

Date de fabrication: XXXXX

N° de lot: XXXXX

Saut de page

HELIXER Jardin®

Informations réglementaires

→ SSCL: Sans Classement

Respectez les instructions d'utilisation pour éviter les risques pour l'homme, les animaux et l'environnement.

- S1/2: Conserver sous clé et hors de portée des enfants
- S13: Conserver à l'écart des aliments et boissons, y compris ceux pour animaux
- S20/21: Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation
- S40: En cas d'ingestion: consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette

SP1: 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 et des routes.

→ Sans Classement

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

- P101: En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette
- P102: Tenir hors de portée des enfants
- P220: Stocker à l'écart des aliments et boissons y compris ceux pour animaux
- P301 + P310: EN CAS D'INGESTION: appeler immédiatement un CENTRE ANTIPOISON ou un médecin
- P501: Eliminer le contenu le récipient conformément à la réglementation locale/nationale

SP1: Ne pas polluer l'eau avec le produit ou son emballage.

Fiche de données de sécurité disponible sur <http://www.quickfds.com>

Information santé

Appel en cas d'urgence: appeler le 15 ou le centre antipoison de Paris: 01 40 05 48 48.

Puis signalez vos symptômes au réseau PhytAttitude, n° vert 0800 887 887 (appel gratuit depuis un poste fixe).

Emballage

Réemploi de l'emballage interdit; rincer soigneusement l'emballage en veillant à verser l'eau de rinçage sur le terrain venant de recevoir le produit.

Éliminer les emballages vides via une collecte organisée par un service de collecte spécifique.

Mode d'action

Le métaldehyde, substance active de HELIXER Jardin®, est efficace sur les mollusques, principalement les limaces et les escargots. Le métaldehyde agit par contact et par ingestion; après sa pénétration dans le mollusque il va provoquer la sécrétion d'une importante quantité de mucus causant la déshydratation irréversible des mollusques cibles.

Usages et doses sur limaces et escargots

Usages	Cultures	Doses	Nombre d'application	Méthode d'application	Délai-Avant Récolte - Stade d'application
16012091	Pomme de Terre	0.7 g/m ²	3	Traitement du sol en plein Intervalle minimum entre applications: 14 jours La dose 0.7 g/m ² peut être remplacée par 2 applications à 0.35 g/m ² réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	F*, jusqu'au stade BBCH 45
16012091	Betterave potagères et fourragères	0.7 g/m ²	3	Traitement du sol en plein Intervalle minimum entre applications: 14 jours La dose 0.7 g/m ² peut être remplacée par 2 applications à 0.35 g/m ² réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	F*, jusqu'au stade BBCH 15
16012091	Choux	0.7 g/m ²	3	Traitement du sol entre les rangs Intervalle minimum entre applications: 14 jours La dose 0.7 g/m ² peut être remplacée par 2 applications	1 jour

				à 0.35 g/m ² réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	
16012091	Laitue et autres salades similaires	0.7 g/m ²	3	Traitement du sol entre les rangs Intervalle minimum entre applications: 14 jours La dose 0.7 g/m ² peut être remplacée par 2 applications à 0.35 g/m ² réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	1 jour
16012091	Fraisier	0.7 g/m ²	3	Traitement du sol entre les rangs Intervalle minimum entre applications: 14 jours La dose 0.7 g/m ² peut être remplacée par 2 applications à 0.35 g/m ² réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	1 jour
17402901	Cultures florales et bulbes floraux Plantes Ornementales	0.7 g/m ²	3	Traitement du sol en plein ou en localisation sur la raie de semis ou de plantation Intervalle minimum entre applications: 14 jours La dose 0.7 g/m ² peut être remplacée par 2 applications à 0.35 g/m ² réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	Non applicable
00701001	Plantes d'intérieur et de balcons	1.4 g/2m ²	3	Traitement des substrats en plein ou en localisation Intervalle minimum entre applications: 14 jours	Non applicable

Information sur HELIXER Jardin®

HELIXER Jardin® est fabriqué selon le procédé de formulation GRANUFAR®, breveté par SBM Développement. Grâce à ce procédé, HELIXER Jardin® offre une résistance élevée à l'humidité et une bonne tenue à la pluie; ce procédé garantit des granulés sans poussières.

Les granulés sont formulés par voie humide, permettant un séchage lent qui respecte les caractéristiques physiques et l'apparence. Ce procédé permet d'obtenir des granulés réguliers, dans lesquels la matière active est répartie de façon homogène.

HELIXER Jardin® contient du Bitrex®, un agent d'amertume qui vise à réduire le risque de consommation par l'homme (enfant et adulte), et un répulsif pour les animaux domestiques et le gibier.

Utilisation d'HELIXER Jardin®

- Appliquer après un arrosage, une pluie ou par temps de pluie, de préférence le soir.
- Epancher régulièrement les granulés sur les zones à protéger, sans toucher les feuilles des cultures. Ne pas appliquer directement sur les cultures prêtes à être consommées.
- Pour contrôler les escargots blancs, disperser les granulés autour du tronc d'arbre, plutôt en préventif (mars, avril).
- Lors d'infestations importantes ou en période de fortes pluies, appliquer une dose réduite de 0,35 g/m² et renouveler tous les 7 jours.

Important

Respecter les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage. Elles ont été déterminées en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé.

Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...

Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.

Précautions à prendre

- Stocker le produit dans un local phytosanitaire conforme et fermé à clé, il est recommandé de ne pas stocker la préparation à plus de 35°C.
- HELIXER Jardin® est dangereux pour les chiens et les chats.
- Bien lire l'étiquette et les précautions avant l'utilisation.
- Ne pas contaminer les cours d'eau et fossés en eau.

Appendix 3 – Letter(s) of Access

The letters of access are available and have been removed for confidentiality reasons.