REGISTRATION REPORT

Part A

Risk Management

Product name: LIMAGRI JARDIN

Active Substance:

metaldehyde, 50 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

Non-professional use
(marketing authorisation)

Applicant: SBM DEVELOPPEMENT

Date: 2018-06-20

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PART A – Risk Management

The company SBM DEVELOPPEMENT has requested marketing authorisation in France for the product LIMAGRI JARDIN, 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 LIMAGRI JARDIN where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of LIMAGRI 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 LIMAGRI 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 DEVELOPPEMENT's application to market LIMAGRI 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 (2013-1608) 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 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 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 extrapolation[6] 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

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

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 LIMAGRI 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)	LIMAGRI JARDIN
Authorisation number	Not applicable
Function	Molluscicide
Applicant	SBM DEVELOPPEMENT
Composition	50 g/kg metaldehyde
Formulation type (code)	Granules (GR)
Packaging	N/A: not registered in France.

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 –	***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

N/A: not registered in France.

2.2.4 Other phrases linked to the preparation

N/A: not registered in France.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 march 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date: 2018-06-20

PPP (product name/code):	**LIMAGRI JARDIN**	Formulation type:	**GR** (a, b)
Active substance 1:	metaldehyde	Conc. of as 1:	**50 g/kg** (c)
Applicant:	**SBM DEVELOPPEMENT**	Professional use:	☐
Zone(s):	Southern (d)	Non professional use:	☒
Verified by MS:	yes		

Field of use: molluscicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/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 beetroot	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-15	2	14	0,5 g/m²	0.25 kg as/ha	Not applicable	F	**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	2	14	0,5 g/m²	0.25 kg as/ha	Not applicable	F	**Not acceptable (physico-chemical properties** Stability and acetaldehyde formation above the

													limit acceptable)
3	FR	Brussels sprouts	F	Slugs, Snails	Spreading between rows (manually or by tractor)	BBCH 00-40	2	14	0,5 g/m²	0.25 kg as/ha	Not applicable	**F**	**Not acceptable (physico-chemical properties** Stability and acetaldehyde formation above the limit acceptable)
4	FR	Head cabbage	F	Slugs, Snails	Spreading between rows (manually or by tractor)	BBCH 00-40	2	14	0,5 g/m²	0.25 kg as/ha	Not applicable	**F**	**Not acceptable (physico-chemical properties** Stability and acetaldehyde formation above the limit acceptable)
5	FR	Cauliflower, broccoli and kohlrabi	F	Slugs, Snails	Spreading between rows (manually or by tractor)	BBCH 00-40	2	14	0,5 g/m²	0.25 kg as/ha	Not applicable	**F**	**Not acceptable (physico-chemical properties** Stability and acetaldehyde formation above the limit acceptable **and lack of residue trials** insufficient residue trials on broccoli and other Brassicacae kohlrabi and leafy brassica**)**
6	FR	Lettuce and other salad crops	F	Slugs, Snails	Spreading between rows (manually or by tractor)	BBCH 00-40	2	14	0,5 g/m²	0.25 kg as/ha	Not applicable	**F**	**Not acceptable (physico-chemical properties** Stability and acetaldehyde formation above the limit acceptable **and lack of residue trials** insufficient residue trials for other salad lettuce)
7	FR	Strawberry	F	Slugs, Snails	Spreading between rows (manually or by tractor)	BBCH 00-69	2	14	0,5 g/m²	0.25 kg as/ha	Not applicable	**F**	**Not acceptable (physico-chemical properties** Stability and acetaldehyde formation above the limit acceptable)

8	FR	All flowers crops and flower bulbs	F	Slugs, Snails	Spreading (manually or by tractor)	At the first infestation	2	14	0,5 g/m²	0.25 kg as/ha	Not applicable	Not applicable	**Not acceptable (physico-chemical properties** Stability and acetaldehyde formation above the limit acceptable)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No 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
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The formulation LIMAGRI JARDIN is a granule (GR) formulation. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of a blue extruded granular formulation. It is not explosive, has no oxidising properties and is not auto-flammable up to 400°C. In aqueous solution (1 %), it has a pH value 6.73 at 20°C. There is no effect of low temperature on the stability of the formulation. **The content of relevant impurity acetaldehyde is above the acceptable limit in the accelerated storage study (2 weeks at 54°C) and in the ambient shelf life study (initial). The formulation is considered to not be stable. 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.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

LIMAGRI JARDIN containing 50 g/kg metaldehyde has low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

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* human 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) x g/L	Spray dilution (used in formulation) x g/L
	Dermal absorption endpoints %	**0.23**	**Not relevant**

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases)

Crop	F/G[7]	Equipment	Application rate kg/L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Risk envelope	F and G	Manually	0.5 g/m² (250 g a.s./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 envelope	Manually	No PPE	1.65

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

3.1.3.3 Resident and bystander 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 LIMAGRI JARDIN 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 8 individual pellets are required to achieve an intake of metaldehyde which would be equivalent to the reference dose.
It is concluded that there is no unacceptable risk of residential exposure after incidental short-term exposure to LIMAGRI JARDIN.

LIMAGRI JARDIN is a granular formulation; no drift is expected. Therefore, bystander exposure estimation is considered to be not relevant.

3.1.3.4 Worker exposure

LIMAGRI JARDIN is intended to be used by non-professional user during home garden application. Moreover, LIMAGRI JARDIN is a granular formulation; no work is expected to be practiced after application. Therefore, worker exposure estimation is considered to be not relevant.

3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. An exceedance 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.

[7] Open field or glasshouse

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	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 According to the intended growth stage for the las application a PHI=F is more appropriate than a PHI of one day Extrapolation to broccoli not possible
Head cabbage	Yes	Yes	Yes	Yes	Yes	No		
Cauliflower	Yes	Yes	Yes	Yes	Yes	No		
Other Brassicacae	Yes	No	No	:	:	:		
Lettuce and other salad crops	Yes	Yes	Yes	Yes	Yes	No		
Strawberry	Yes	Yes	Yes	Yes	Yes	No		
All flowers 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, DT_{90} values of metaldehyde are below the trigger value of 100 days. Then, further investigation of residues in rotational crops is not required and relevant residues in rotational crops are not expected.

Dietary burden calculation is not considered relevant for garden uses.
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.

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.

LIMAGRI JARDIN 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 LIMAGRI GR and has been reproduced for LIMAGRI JARDIN.

The PEC of metaldehyde 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 soil and PECsw derived for the active substance and its metabolites are used for the eco-toxicological risk assessment.
PECgw for metaldehyde do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[8]. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.
Based on vapour pressure, information on volatilisation from plants and soil, and 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 LIMAGRI JARDIN in gardens, a bridging approach was followed. Detailed risk assessments have been conducted for the professional large scale applications and of the lead formulation LIMAGRI GR.

The risk assessment for birds taking into account that the repellency properties of LIMAGRI 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 and mammalian species (granivorous and slug-eating birds and mamals) from the application of LIMAGRI JARDIN to target crops according to the proposed GAP.
The risk assessment for aquatic organisms, honeybees, non-target arthropods, earthworms and other soil macro-organisms and non-target plant demonstrated that no unacceptable effects would be expected from using LIMAGRI JARDIN according to the proposed GAP.

Overall an acceptable risk for any non-target organisms can be concluded for applications of LIMAGRI JARDIN in gardens.

3.1.7 Efficacy

Considering the data submitted:
- the efficacy of LIMAGRI JARDIN when it is applied at the requested rate of 5 kg/ha to control slugs and snails on different crops is considered satisfactory for all requested uses.
- the selectivity of LIMAGRI JARDIN is considered negligible. To prevent eventual risk due to retention of the pellets on the crop, a recommendation on the label indicates to not apply LIMAGRI 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

[8] 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.

Taking into account the above assessment, considering the lack of stability at ambient temperature and that acetaldehyde formation is above the acceptable limit, an authorisation cannot be granted.

A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

N/A

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

3.4.1 Post-authorisation monitoring

N/A

3.4.2 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

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anses

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 règlementaire,

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

de la société *SBM DEVELOPPEMENT*

enregistrées sous les *n°2013-1608 et n°2014-2222*

Vu les conclusions de l'évaluation de l'Anses du 16 août 2017,

Considérant que le produit n'est pas stable au stockage à température ambiante, ce qui peut entrainer un dépassement de la limite acceptable en acétaldéhyde,

Considérant qu'en conséquence, les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 ne sont pas remplies

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

LIMAGRI JARDIN
AMM n°-

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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Informations générales sur le produit		
Noms du produit	LIMAGRI JARDIN SUPERLIMACIDE NOVAJARDIN	
Type de produit	Deuxième gamme	
Titulaire	SBM DEVELOPPEMENT 160, route de la Valentine CS70052 13374 MARSEILLE Cedex 11 FRANCE	
Formulation	Granulé (GR)	
Contenant	50 g/kg - métaldéhyde	
Produit de référence	Nom commercial	LIMAGRI GR
	N° AMM	9500135
Numéro d'intrant	9900-2013.01	
Numéro d'AMM	-	
Fonction	Molluscicide	
Gamme d'usages	Amateur / emploi autorisé dans les jardins	

A Maisons-Alfort, le 20 JUIN 2018

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)

LIMAGRI JARDIN
AMM n°-

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
16012901 Cultures légumières* Trt Sol*Limaces et escargots	0,5 g/m²	2/an	F
	Motivation du refus : L'usage est refusé en raison d'un manque de stabilité du produit au stockage à température ambiante pouvant entrainer un dépassement de la limite acceptable en acétaldéhyde, et d'un manque d'essais résidus sur certaines cultures (salades assimilées à la laitue, brocoli, chou feuillu et chou-rave) ne permettant pas d'exclure un risque de dépassement des limites maximales de résidus en vigueur.		
17402901 Cultures ornementales* Trt Sol*Limaces et escargots	0,5 g/m²	2/an	Non applicable
	Motivation du refus : L'usage est refusé en raison d'un manque de stabilité du produit au stockage à température ambiante pouvant entrainer un dépassement de la limite acceptable en acétaldéhyde.		
00701001 Plantes d'intérieur et balcons* Trt Substrats*Limaces et escargots	0,5 g/m²	2/an	Non applicable
	Motivation du refus : L'usage est refusé en raison d'un manque de stabilité du produit au stockage à température ambiante pouvant entrainer un dépassement de la limite acceptable en acétaldéhyde.		

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

LIMAGRI JARDIN®

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

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

Contient 50 g métaldéhyde /kg
Formulation : granulé prêt à l'emploi – (GR)

Emballage : Etui carton de 300 – 500 – 900g et 2.5 kg
Etui carton + sache PE de 0.3 à 2.5kg
Bidon PEHD de 300 – 500 et 900g

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

LIMAGRI JARDIN®

Informations réglementaires

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

Sans Classement

- 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.
- S46 : En cas d'ingestion, consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.
- S49 : Conserver uniquement dans le récipient d'origine.

- 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 Phyt'attitude, 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 métaldéhyde, substance active de LIMAGRI® JARDIN, est efficace sur les mollusques, principalement les limaces et les escargots. Le métaldéhyde agit par contact et par ingestion ; après sa pénétration dans le mollusque il est hydrolysé en acétaldéhyde lequel va agir sur 3 cibles cellulaires.
L'action du métaldéhyde empêche la réhydratation des mollusques et a également pour conséquence une importante sécrétion de mucus.

Règle à respecter
« L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, il est conseillé d'alterner, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents.»

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	0.5 g/m^2	2	Traitement du sol en plein Intervalle minimum entre applications : 14 jours.	F* , jusqu'au stade BBCH 45
16012091	Betterave potagères et fourragères	0.5 g/m^2	2	Traitement du sol en plein Intervalle minimum entre applications : 14 jours.	F* , jusqu'au stade BBCH 15
16012091	Choux	0.5 g/m^2	2	Traitement du sol entre les rangs Intervalle minimum entre applications : 14 jours.	1 jour
16012091	Laitue et autres salades similaires	0.5 g/m^2	2	Traitement du sol entre les rangs Intervalle minimum entre applications : 14 jours.	1 jour
16012091	Fraisier	0.5 g/m^2	2	Traitement du sol entre les rangs Intervalle minimum entre applications : 14 jours.	1 jour
17402901	Cultures florales et bulbes floraux Plantes Ornementales	0.5 g/m^2	2	Traitement du sol en plein ou en localisation sur la raie de semis ou de plantation. Intervalle minimum entre applications : 14 jours.	Non applicable

00701001	Plantes d'intérieur et de balcons	1 g/ 2m²	2	Traitement des substrats en plein ou en localisation. Intervalle minimum entre applications : 14 jours.	Non applicable

Information sur LIMAGRI JARDIN

LIMAGRI® JARDIN est fabriqué selon le procédé de formulation GRANUFAR®, breveté par SBM Développement. Grâce à ce procédé, LIMAGRI® JARDIN offre une très bonne résistance à l'humidité et une bonne tenue à la pluie.
Les granulés sont formulés par voie humide, permettant un séchage lent qui respecte les caractéristiques physiques et l'appétence des appâts. Ce procédé permet d'obtenir des granulés réguliers, dans lesquels la matière active est répartie de façon homogène.
LIMAGRI® JARDIN contient un répulsif pour les animaux domestiques et le gibier.

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.
- LIMAGRI® 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

Lonza

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France

AN
May 28, 2013

Letter of Access to Lonza's Annex II Studies for the registration of the Metaldehyde-based products Limagri Jardin and Anti-Limaces RA

Dear Sirs and Madam

Subject to the conditions and restrictions set out under **Section A** below, we, Lonza AG, acting also on behalf of its affiliates (hereinafter, collectively referred to as "Lonza"), hereby authorize you, the competent authority for plant protection products in France, to refer to the protected Annex II Studies (List of studies which are considered as relied upon for the evaluation with a view to Annex I inclusion of the Federal Office for Food Safety Austria, May 2011) concerning the active substance Metaldehyde and belonging to Lonza ("Annex II studies"), in order to allow the legal entity **SBM Développement**, a company incorporated under the laws of France, having its registered office at 160, Route de la Valentine, BP 90120, F-13 371 Marseille Cedex 11, France, to apply for the registration of its product Registrations identified under **Section B** below, following the inclusion of Metaldehyde in Annex I to Directive 91/414/EEC as laid down in Directive 2011/54/EU dated 20 April 2011.

The right granted to SBM Développement under this letter is hereinafter referred to as the "Right of Referral".

The Right of Referral concerns the Annex II studies and is subject to the following conditions which must be interpreted and applied strictly.

A. Conditions and restrictions

1. The Right of Referral is only valid in connection with the Annex II studies and in connection with the Registrations identified under **Section B** below.
2. The Rigth of Referral is only valid for the purpose of enabling SBM Développement to rely on the Annex II studies for the purpose of applying for the registration of its plant protection product Registrations as listed in **Section B** below.

2/3, May 28, 2013, Letter of Access to Lonza's Annex II Studies for the registration of the Metaldehyde-based products Limagri Jardin and Anti-Limaces RA

3. The Right of Referral is not granted in respect of any other persons, purposes, registrations or products.
4. The Right of Referral is not valid to support any other change, variation, extension or renewal of the Registrations identified under **Section B** below.
5. The Right of Referral is solely valid for SBM Développement. The Right of Referral is not capable of being transferred, assigned, sub-licensed or otherwise granted or extended to any other persons or companies. No sub-registrations or related registrations may be given by relying directly or indirectly on the Annex II studies and/or on this Letter of Access.
6. The Right of Referral is only valid in France.
7. SBM Développement shall not be permitted to receive any copy of or inspect or view all or any part of the Annex II studies.
8. There shall be no Right of Referral and the Right of Referral shall automatically and immediately cease to apply, if one or more of the following conditions are met:
    a. the Registration identified under **Section B** below is not a registration that is in the name of SBM Développement on the date of signature of this Letter of Access or thereafter;
    b. the Registration identified under **Section B** below does not contain Metaldehyde (META™ Metaldehyde) as supplied by Lonza; or
    c. the agreement between Lonza and SBM Développement pursuant to which this Letter of Access has been signed should terminate for any reason.
9. Lonza reserves the right to withdraw the Letter of Access and the related Right to Referral if any of the conditions set out in this letter is not or no longer met.

B. Registration covered by this Letter of Access

Product name	Anti-Limaces RA
Registration reference n° / Year	2010604
Product name	Limagri Jardin
Registration reference n° / Year	n.a.
META™ Metaldehyde (content in g/kg)	50
Registration holder	SBM Développement
Marketing company	Novajardin

3/3, May 28, 2013, Letter of Access to Lonza's Annex II Studies for the registration of the Metaldehyde-based products Limagri Jardin and Anti-Limaces RA

If there are any questions or further information is needed, please contact Angela Noe at Lonza AG, Muenchensteinerstrasse 38, CH-4053 Basel, Switzerland (Email: angela.noe@lonza.com).

Yours sincerely
Lonza AG

Name: Elias Alonso
Title: Director Marketing & Sales
Date: May 28, 2013

Angela Noe
Registration Manager

Lonza

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AN
May 28, 2013

Letter of Access to Lonza's Annex III Studies for the registration of the Metaldehyde-based products Limagri Jardin and Anti-Limaces RA

Dear Sirs and Madam

Subject to the conditions and restrictions set out under **Section A** below, we, Lonza AG, acting also on behalf of Lonza GmbH, located in Nattermannallee 1, D-50829 Cologne, Germany (hereinafter, collectively referred to as "Lonza"), hereby authorize you, the competent authority for plant protection products in France, to refer to the Annex III Studies specified under **Section C** below in order to allow the legal entity **SBM Développement**, a company incorporated under the laws of France, having its registered office at 160, Route de la Valentine, BP 90120, F-13 371 Marseille Cedex 11, France, to apply for the registration of its formulations identified under **Section B** below following the inclusion of Metaldehyde in Annex I to Directive 91/414/EEC as laid down in Directive 2011/54/EU dated 20 April 2011.

The right granted to SBM Développement under this letter is hereinafter referred to as the "Right of Referral".

The Right of Referral concerns the Annex III Studies specified under **Section C** below and is subject to the following conditions which must be interpreted and applied strictly.

A. Conditions and restrictions

1. The Right of Referral is only valid in connection with the Annex III Studies specified under **Section C** below and in connection with the formulations identified under **Section B** below.
2. The Right of Referral is only valid for the Annex III Studies specified under **Section C** below used for the Annex I Decision according to Directive 91/414/EEC and for the

applications for the registration of the Lonza-formulation LON10001M/Axcela (product No. 220111777) and LON20001M/Desimo Duo (product no. 220111778) by Lonza Cologne GmbH in 2011.

3. The Right of Referral is only valid for the purpose of enabling SBM Développement to rely on the Annex III Studies specified under **Section C** below for the purpose of applying for the registration of its plant protection formulations as listed in **Section B** below.
4. The Right of Referral is not granted in respect of any other persons, purposes, registrations or products.
5. The Right of Referral is solely valid for SBM Développement. The Right of Referral is not capable of being transferred, assigned, sub-licensed or otherwise granted or extended to any other persons or companies. No sub-registrations or related registrations may be given by relying directly or indirectly on the Annex III Studies specified under **Section C** below and/or on this Letter of Access.
6. The Right of Referral is only valid in France.
7. SBM Développement shall not be permitted to receive any copy of or inspect or view all or any part of the Annex III Studies specified under **Section C** below.
8. There shall be no Right of Referral and the Right of Referral shall automatically and immediately cease to apply, if one or more of the following conditions are met:
    a. the formulation identified under **Section B** below does not contain Metaldehyde (META™ Metaldehyde) as supplied by Lonza; or
    b. the agreement between Lonza and SBM Développement pursuant to which this Letter of Access has been signed should terminate for any reason.
9. Lonza reserves the right to withdraw the Letter of Access and the related Right to Referral if any of the conditions set out in this letter is not or no longer met.

B. Formulation covered by this Letter of Access

Product name	Anti-Limaces RA
Registration reference n° / Year	2010604
Product name	Limagri Jardin
Registration reference n° / Year	n.a.
META™ Metaldehyde (content in g/kg)	50
Registration holder	SBM Développement
Marketing company	Novajardin

3/13, May 28, 2013, Letter of Access to Lonza's Annex III Studies for the registration of the Metaldehyde- based products Limagri Jardin and Anti-Limaces RA

C. Annex III Studies covered by this Letter of Access

- Section B2 "Analytical Methods"

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA 5.3.1/01	Todd, M.	2009	Metaldehyde - Validation of Methodology for the determination of Metaldehyde in Oilseed Rape (Plant, Seed and Straw), Wheat (Plant, Grain and Straw), Broccoli, Orange and Sugar beet Huntingdon Life Sciences Ltd., Cambridgeshire, United Kingdom Report No.: LR 4335 SCI0119 GLP, unpublished	Y	Lonza
KIIIA 5.3.1/02	Burton, D.	2009	Metaldehyde - Validation of Methodology for the Determination of Metaldehyde in Lettuce, Strawberry, Potato and Head Cabbage Huntingdon Life Sciences Ltd., Cambridgeshire, United Kingdom Report No.: LR 4363 LZA0391 GLP, unpublished	Y	Lonza

- Section B3 "Mammalian Toxicology"

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA 7.6/01	Page, L.	2009	The in-vitro percutaneous absorption of radiolabelled metaldehyde through human skin Charles River, Edinburgh, UK Doc: 511-001 GLP, unpublished	Y	Lonza

4/13, May 28, 2013, Letter of Access to Lonza's Annex III Studies for the registration of the Metaldehyde- based products Limagri Jardin and Anti-Limaces RA

- Section B4 "Metabolism and Residue"

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA 8.1.1/01	Burton, D.	2010	Metaldehyde – Stability of Metaldehyde residues in various crops during storage at -20°C for approximately 12 months. HLS, Suffolk, UK Report No. : LR 4596 GLP, unpublished	Y	Lonza
KIIIA 8.3.1/01	Wilson, A.	2009	Metaldehyde - Residue Study (decline) with a granular bait formulation containing 30 g/kg Metaldehyde applied to strawberries in Germany, Northern France and the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4491 ACI09-008 GLP, unpublished	Y	Lonza
KIIIA 8.3.1/02	Wilson, A.	2011	Metaldehyde - Residue study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to Strawberries in Germany, Northern France and the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4639 ACI10-010 GLP, unpublished	Y	Lonza
KIIIA 8.3.1/03	Ferrando, J.	2009	Metaldehyde - Residue Study (decline) with a granular bait formulation containing 30 g/kg Metaldehyde applied to strawberries in Spain, Italy and Southern France AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4492 ACI09-009 GLP, unpublished	Y	Lonza

5/13, May 28, 2013, Letter of Access to Lonza's Annex III Studies for the registration of the Metaldehyde- based products Limagri Jardin and Anti-Limaces RA

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA 8.3.1/04	Ferrando, J.	2010	Metaldehyde - Residue study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to Strawberries in Spain, Italy and Southern France AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4640 ACI10-011 GLP, unpublished	Y	Lonza
KIIIA 8.3.2/01	Wilson, A.	2010	Metaldehyde - Residue study (decline) with a granular bait formulation containing 30 g/kg Metaldehyde applied to Potatoes in Germany, Northern France and the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4561 ACI09-010 GLP, unpublished	Y	Lonza
KIIIA 8.3.2/02	Wilson, A.	2010	Metaldehyde - Residue study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to Potatoes in Germany, Northern France and the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4647 ACI10-012 GLP, unpublished	Y	Lonza
KIIIA 8.3.2/03	Ferrando, J.	2009	Metaldehyde - Residue Study (decline) with a granular bait formulation containing 30 g/kg Metaldehyde applied to potatoes in Italy, Southern France and Spain AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4481 ACI09-011 GLP, unpublished	Y	Lonza

6/13, May 28, 2013, Letter of Access to Lonza's Annex III Studies for the registration of the Metaldehyde- based products Limagri Jardin and Anti-Limaces RA

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA 8.3.2/04	Ferrando, J.	2010	Metaldehyde - Residue study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to Potatoes in Spain, Italy and Southern France AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4648 ACI10-013 GLP, unpublished	Y	Lonza
KIIIA 8.3.3/01	Wilson, A.	2009	Metaldehyde - Residue Study (decline) with a granular bait formulation containing 30 g/kg Metaldehyde applied to brussels sprouts in Germany and the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4432 ACI09-004 GLP, unpublished	Y	Lonza
KIIIA 8.3.3/02	Wilson, A.	2010	Metaldehyde - Residue study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to brussels sprouts in Germany, North France and the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4601 ACI10-006 GLP, unpublished	Y	Lonza
KIIIA 8.3.4/01	Wilson, A.	2010	Metaldehyde - Residue Study (decline) with a granular bait formulation containing 30 g/kg Metaldehyde applied to head cabbages in Germany, North France and the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4598 ACI09-001 GLP, unpublished	Y	Lonza

7/13, May 28, 2013, Letter of Access to Lonza's Annex III Studies for the registration of the Metaldehyde- based products Limagri Jardin and Anti-Limaces RA

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA 8.3.4/02	Wilson, A.	2010	Metaldehyde - Residues study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to head cabbages in Germany, Northern France and the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4620 ACI10-001 GLP, unpublished	Y	Lonza
KIIIA 8.3.4/03	Ferrando, J.	2010	Metaldehyde - Residue Study (decline) with a granular bait formulation containing 30 g/kg Metaldehyde applied to head cabbages in Italy and South France AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4562 ACI09-017 GLP, unpublished	Y	Lonza
KIIIA 8.3.4/04	Ferrando, J.	2010	Metaldehyde - Residue study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to head cabbages in Italy and Spain AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4619 ACI10-002 GLP, unpublished	Y	Lonza
KIIIA 8.3.5/01	Wilson, A.	2009	Metaldehyde - Residue Study (decline) with a granular bait formulation containing 30 g/kg Metaldehyde applied to cauliflowers in Germany, North France and the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4430 ACI09-003 GLP, unpublished	Y	Lonza

8/13, May 28, 2013, Letter of Access to Lonza's Annex III Studies for the registration of the Metaldehyde- based products Limagri Jardin and Anti-Limaces RA

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA 8.3.5/02	Wilson, A.	2010	Metaldehyde - Residues study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to cauliflowers in Germany, Northern France and the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4623 ACI10-005 GLP, unpublished	Y	Lonza
KIIIA 8.3.5/03	Ferrando, J.	2009	Metaldehyde - Residue Study (decline) with a granular bait formulation containing 30 g/kg Metaldehyde applied to cauliflowers in Spain and South France AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4494 ACI09-002 GLP, unpublished	Y	Lonza
KIIIA 8.3.5/04	Ferrando, J.	2010	Metaldehyde - Residue study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to cauliflowers in Spain and Italy AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4622 ACI10-004 GLP, unpublished	Y	Lonza
KIIIA 8.3.6/01	Wilson, A.	2009	Metaldehyde - Residue study (decline) with a granular bait formulation containing 30 g/kg Metaldehyde applied to Lettuces in Germany, North France and the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4482 ACI09-006 GLP, unpublished	Y	Lonza

9/13, May 28, 2013, Letter of Access to Lonza's Annex III Studies for the registration of the Metaldehyde- based products Limagri Jardin and Anti-Limaces RA

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA 8.3.6/02	Wilson, A.	2010	Metaldehyde - Residue study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to Lettuces in Germany, Northern France and the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4643 ACI10-008 GLP, unpublished	Y	Lonza
KIIIA 8.3.6/03	Ferrando, J.	2009	Metaldehyde - Residue study (decline) with a granular bait formulation containing 30 g/kg Metaldehyde applied to Lettuces in Spain, Italy and South France AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4495 ACI09-007 GLP, unpublished	Y	Lonza
KIIIA 8.3.6/04	Ferrando, J.	2010	Metaldehyde - Residue study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to Lettuces in Spain, Italy and Southern France AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4644 ACI10-009 GLP, unpublished	Y	Lonza
KIIIA 8.3.9/01	Wilson, A.	2010	Metaldehyde - Residue study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to Sugar beet in Germany, Northern France and the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4565 ACI09-012 GLP, unpublished	Y	Lonza

10/13, May 28, 2013, Letter of Access to Lonza's Annex III Studies for the registration of the Metaldehyde- based products Limagri Jardin and Anti-Limaces RA

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA 8.3.9/02	Wilson, A.	2010	Metaldehyde - Residue study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to Sugar Beet in the United Kingdom AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4641 ACI10-014 GLP, unpublished	Y	Lonza
KIIIA 8.3.9/03	Ferrando, J.	2010	Metaldehyde - Residue study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to sugar beet in Italy, Southern France and Spain AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4566 ACI09-018 GLP, unpublished	Y	Lonza
KIIIA 8.3.9/04	Ferrando, J.	2010	Metaldehyde - Residue study (harvest) with a granular bait formulation containing 30 g/kg Metaldehyde applied to Sugar Beet in Italy AgroChemex International Ltd, Essex, United Kingdom Report No.: LR 4642 ACI10-015 GLP, unpublished	Y	Lonza

11/13, May 28, 2013, Letter of Access to Lonza's Annex III Studies for the registration of the Metaldehyde- based products Limagri Jardin and Anti-Limaces RA

- Section B6 "Ecotoxicological Studies"

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA 10.1	Wilkens, S. Frese, I.	2009a	Metaldehyde slug bait: field study on exposure and effects on birds in treated cereals fields in Germany, France and Great Britain. GLP, unpublished	Y	Lonza
KIIIA 10.1	Wilkens, S.	2009	Metaldehyde slug bait: Field study on exposure and effects on birds in treated cereal fields in Germany, France and Great Britain. GLP, unpublished	Y	Lonza
KIIIA 10.1	Wilkens, S. Frese, I.	2009b	Metaldehyde slug bait: field study on exposure and effects on birds in treated OSR fields in Germany, France and Great Britain. GLP, unpublished	Y	Lonza
KIIIA 10.1	Münderle, M. Ludwigs, J.-D.	2011	Expert statement - Field studies on exposure and effects of Metarex slug bait on birds and mammals. GLP, unpublished	Y	Lonza
KIIIA 10.1	Watkins, R.J.	2004	Palatability of Metarex slug pellets to house sparrows (Passer domesticus) under realistic worst case conditions. GLP, unpublished	Y	Lonza
KIIIA 10.1	Thompson, HM.	2007a	Metarex - Avoidance test to assess exposure of grey partridges (Perdix perdix) to Metarex slug pellets GLP, unpublished	Y	Lonza
KIIIA 10.1	Thompson, HM.	2007b	Metarex - Avoidance test to assess exposure of common pheasants (Phasianus colchicus) to Metarex slug pellets. GLP, unpublished		Lonza

12/13, May 28, 2013, Letter of Access to Lonza's Annex III Studies for the registration of the Metaldehyde- based products Limagri Jardin and Anti-Limaces RA

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KIIIA 10.2	Klein, O.	2007	Field study to evaluate residues of Metaldehyde in slugs and slug baits following the application of Metarex (50g metaldehyde/kg). GLP, unpublished	Y	Lonza
KIIIA 10.3	Gilham, A.M.	2001	Palatability of Metarex slug pellets to wood mice (*Apodemus silvaticus*). GLP, unpublished	Y	Lonza
KIIIA 10.3	Thompson, H.M.	2007	Metarex: avoidance test to assess exposure of bank vole (*Clethrionomys glareolus*) to Metarex slug pellets. GLP, unpublished	Y	Lonza
KIIIA 10.3	Hoeller, D.	2009a	Shrews in drilled OSR fields - detection of focal species. GLP, unpublished	Y	Lonza
KIIIA 10.3	Hoeller, D.	2009b	Shrews in drilled cereal fields - detection of focal species. GLP, unpublished	Y	Lonza
KIIIA 10.3	Hoeller, D.	2009c	Metaldehyde slug bait: field study on exposure and effects on rodents in treated OSR fields in Germany. GLP, unpublished	Y	Lonza
KIIIA 10.3	Hoeller, D.	2009d	Metaldehyde slug bait: field study on exposure and effects on rodents in treated cereal fields in Germany. GLP, unpublished	Y	Lonza

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If there are any questions or further information is needed, please contact Angela Noe at Lonza AG, Muenchensteinerstrasse 38, CH-4053 Basel, Switzerland (Email: angela.noe@lonza.com).

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