

REGISTRATION REPORT

Part A

Risk Management

Product code: Metaldehyde 5 % GB

Product name(s): CEKUMETA 5

Active Substance(s):

Metaldehyde : 50 g/kg

COUNTRY: FRANCE

Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(renewal marketing authorisation)

Applicant: SHARDA EUROPE b.v.b.a

Date: 2018-11-02

Table of Contents

1	DETAILS OF THE APPLICATION.....	3
1.1	APPLICATION BACKGROUND.....	3
1.2	ACTIVE SUBSTANCE APPROVAL.....	3
1.3	REGULATORY APPROACH	3
1.4	DATA PROTECTION CLAIMS	5
1.5	LETTER(S) OF ACCESS	5
2	DETAILS OF THE AUTHORISATION	5
2.1	PRODUCT IDENTITY	5
2.2	CLASSIFICATION AND LABELLING.....	5
2.2.1	<i>Classification and labelling under Directive 99/45/EC</i>	<i>5</i>
2.2.2	<i>Classification and labelling in accordance with Regulation (EC) No1272/2008</i>	<i>5</i>
2.2.3	<i>Other phrases in compliance with Regulation (EU) No 547/2011</i>	<i>6</i>
2.2.4	<i>Other phrases linked to the preparation</i>	<i>6</i>
2.3	PRODUCT USES.....	7
3	RISK MANAGEMENT.....	11
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	11
3.1.1	<i>Physical and chemical properties</i>	<i>11</i>
3.1.2	<i>Methods of analysis</i>	<i>11</i>
3.1.3	<i>Mammalian Toxicology.....</i>	<i>11</i>
3.1.4	<i>Residues and Consumer Exposure</i>	<i>12</i>
3.1.5	<i>Environmental fate and behaviour.....</i>	<i>15</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>15</i>
3.1.7	<i>Efficacy</i>	<i>15</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT	16
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING	16
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	16
3.4.1	<i>Post-authorisation monitoring</i>	<i>16</i>
3.4.2	<i>Post-authorisation data requirements</i>	<i>16</i>
3.4.3	<i>Label amendments (see label in Appendix 2):</i>	<i>16</i>
	APPENDIX 1 – COPY OF THE FRENCH DECISION	17
	APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT	24
	APPENDIX 3 – LETTER(S) OF ACCESS	25

PART A – Risk Management

The company SHARDA EUROPE b.v.b.a has requested marketing authorisation in France for the product CEKUMETA 5 (Metaldehyde 5% GB), containing 50 g/kg metaldehyde for use as a molluscicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to CEKUMETA 5 (Metaldehyde 5% GB) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of CEKUMETA 5 (Metaldehyde 5% GB) 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 CEKUMETA 5 (Metaldehyde 5% GB).

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 SHARDA EUROPE b.v.b.a's application to market CEKUMETA 5 (Metaldehyde 5% GB) in France as a molluscicide (product uses described under point 2.3). France acted as a interzonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the renewal of authorisation after approval of the active substance of this product in France and in other MSs of the European Union.

1.2 Active substance approval

Metaldehyde

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

Specific provisions of regulation were as follows :

PART A

Only uses as molluscicide may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metaldehyde, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.

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

- the risk to operators and workers;
- the dietary exposure situation of consumers in view of future revisions of maximum residue levels;
- the acute risk and long term risk to birds and mammals.

Member States shall ensure that authorisations shall contain an effective dog repellent agent.

Conditions of use shall include risk mitigation measures, where appropriate.

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

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

1.3 Regulatory approach

The present application (2014-0112, 2013-1730) was evaluated by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ in the context of the voluntary zonal procedure for all Member States of the European Union taking into account the worst-case uses (“risk envelope approach”)². Where 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 2017³ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009⁴, implementing regulations and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

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

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

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

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 CEKUMETA 5 (Metaldehyde 5% GB), 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)	CEKUMETA 5 (Metaldehyde 5% GB)
Authorisation number	2030460
Function	Molluscicide
Applicant	SHARDA EUROPE b.v.b.a
Composition	50 g/kg metaldehyde
Formulation type (code)	Granular bait (GB)
Packaging	Paper bags/PE (100 g, 200 g, 250 g, 500 g, 750 g, 1 kg, 5 kg, 10 kg, 20 kg and 25 kg) Cardboard box/PE (100 g, 200 g, 250 g, 500 g, 750 g, 1 kg, 5 kg, 10 kg, 20 kg and 25 kg)

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

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

Hazard statements	-	-
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

See Part C for justifications of the classification and labelling proposals.

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe6	To protect birds and wild mammals remove spillages.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁷ : refer to the Decision in Appendix 1 for the details
Re-entry period: not relevant
Pre-harvest interval: <ul style="list-style-type: none"> - Cereals : F - Application must be made at growth stage BBCH 29 at the latest - Lettuce (outdoor uses) : F- Application must be made at growth stage BBCH 19 at the latest - Lettuce (indoor uses): F - Application must be made at growth stage BBCH 41 at the latest
Other mitigation measures: <ul style="list-style-type: none"> - Do not store at temperature above 35°C. - Do not apply CEKUMETA 5 (Metaldehyde 5% GB) directly on harvestable parts of plants.
The label may include the following recommendations: - The label must reflect the conditions of authorisation.

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

2.3 Product uses

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

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

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

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

GAP rev. 1, date 2018-11-02

PPP (product name/code): **CEKUMETA 5 (Metaldehyde 5% GB)**
Active substance 1: metaldehyde
Applicant: **SHARDA EUROPE b.v.b.a**
Zone(s): Southern ^(d)
Verified by MS: yes

Formulation type: **GB** ^(a, b)
Conc. of as 1: **50 g/kg** ^(c)
Professional use:
Non professional use:

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		
1	SEU	Straw Cereals (wheat, triticale, spelt, barley, oat, rye)	F	Slugs; snails	Applied at time of drilling and/or overall broadcast application	At planting to BBCH 29	(a) 1 (b) 2	7	(a) 7 (b) 14	(a) 0.35 (b) 0.70	N/A	F	

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		
2	SEU	Lettuce	F/G	Slugs; snails	Overall broadcast application	Outdoor uses: BBCH 00-19 Indoor uses: BBCH 00-41	a) 1 b) 2	7	a) 7 b) 14	a) 0.35 b) 0.70	N/A	F	Acceptable on lettuce only
3	SEU	Oilseed rape	F	Slugs; snails	Applied at time of drilling and/or overall broadcast application	At planting to BBCH 29	a) 2	7-10	a) 7 b) 14	a) 0.35 b) 0.70	N/A	N/A	Not acceptable (insufficient number of residue trials)
4	SEU	Potato	F	Slugs; snails	Overall broadcast application	At planting to BBCH 97	a) 2	7-10	a) 7 b) 14	a) 0.35 b) 0.70	N/A	N/A	Not acceptable (insufficient number of residue trials)
5	SEU	Berries	F/G	Slugs; snails	Overall broadcast application	At planting to BBCH 69	a) 2	7-10	a) 7 b) 14	a) 0.35 b) 0.70	N/A	N/A	Not acceptable (insufficient number of residue trials)
6	SEU	Brassicas (head, flowering, sprouts)	F	Slugs; snails	Overall broadcast application	At planting to BBCH 41	a) 2	7-10	a) 7 b) 14	a) 0.35 b) 0.70	N/A	N/A	Not acceptable (insufficient number of residue trials)
7	SEU	Grapes (wine and table)	F	Slugs; snails	Overall broadcast application	BBCH00- to BBCH 69	a) 2	7-10	a) 7 b) 14	a) 0.35 b) 0.70	N/A	N/A	Not acceptable (insufficient number of residue trials)
8	SEU	Maize	F	Slugs; snails	Applied at time of drilling and/or overall broadcast application	At planting +BBCH00- BBCH 15	a) 2	7-10	a) 7 b) 14	a) 0.35 b) 0.70	N/A	N/A	Not acceptable (insufficient number of residue trials)

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		
9	SEU	Ornamentals	F/G	Slugs; snails	Overall broadcast application	At planting to BBCH 99	(a) 1 (b) 2	7	(a) 7 (b) 14	(a) 0.35 (b) 0.70	N/A	N/A	acceptable
10	SEU	Pasture	F	Slugs; snails	Overall broadcast application	At planting to BBCH 15	(a) 2	7-10	(a) 7 (b) 14	(a) 0.35 (b) 0.70	N/A	N/A	Not acceptable (insufficient number of residue trials)
11	SEU	Strawberry	F/G	Slugs; snails	Overall broadcast application	At planting to BBCH 69	(a) 2	7-10	(a) 7 (b) 14	(a) 0.35 (b) 0.70	N/A	N/A	Not acceptable (insufficient number of residue trials)
12	SEU	Sugar beet, fodder beet	F	Slugs; snails	Applied at time of drilling and/or overall broadcast application	At planting to BBCH 15	(a) 2	7-10	(a) 7 (b) 14	(a) 0.35 (b) 0.70	N/A	N/A	Not acceptable (insufficient number of residue trials)
13	SEU	Turf		Slugs; snails	Overall broadcast application	At planting to BBCH 99	(a) 1 (b) 2	7	(a) 7 (b) 14	(a) 0.35 (b) 0.70	N/A	N/A	acceptable
14	SEU	Tomato, artichoke		Slugs, snails	Overall broadcast application	At planting to BBCH 41	(a) 2	7-10	(a) 7 (b) 14	(a) 0.35 (b) 0.70	N/A	N/A	Not acceptable (insufficient number of residue trials)
15	SEU	Orchards - Pome fruit trees, Stone fruit trees, Citrus fruit trees, Nut fruit trees	F	Slugs, snails	Overall broadcast application	BBCH00- to BBCH 69	(a) 2	7-10	(a) 7 (b) 14	(a) 0.35 (b) 0.70	N/A	N/A	Not acceptable (insufficient number of residue trials)

Remarks table heading:	<ul style="list-style-type: none"> (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 	<ul style="list-style-type: none"> (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:	<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> 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 product CEKUMETA 5 (Metaldehyde 5% GB) is a granular bait (GB) formulation. All studies have been performed in accordance with the current requirements. The appearance of the product is that of blue granular, with no odour. It is not explosive, has no oxidising properties and is not auto-flammable up to 240°C. In aqueous solution (1 %), it has a pH value around 6.9 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 12 weeks at 35°C. Neither the active ingredient content nor the technical properties were changed. The formulation is not classified for the physical-chemical part.

The formulation must be stored at temperature below 35°C.

3.1.2 Methods of analysis

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

Analytical methods are available in the 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, data on a.s:

- an analytical method (with a confirmatory method) and its ILV for the determination of metaldehyde residue 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

Endpoints used in risk assessment

Active Substance: METALDEHYDE			
ADI	0.02 mg kg bw/d	EU 2011	
ARfD	0.3 mg/kg bw		
AOEL	0.1 mg/kg bw/d		
Dermal absorption	Based on default value (expert judgement):		
		Concentrate (used in formulation) 50 g/kg	Spray dilution (used in formulation)
	Dermal absorption endpoints %	10	-

3.1.3.1 Acute Toxicity

Metaldehyde 5% GB (CEKUMETA 5) containing 50 g/kg metaldehyde has low acute oral and dermal toxicity and is not irritating to the rabbit eye or skin. The product is not considered to be a sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G ⁸	Equipment	Application rate
All crops	F/G	Tractor mounted equipment or Hand-held equipment	7 kg/ha (350 g as/ha)

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

Crop	Equipment	PPE and/or working coverall	% AOEL metaldehyde
All crops	Tractor mounted equipment	Gloves during loading and application	7.0
	Hand-held equipment		57

According to the model calculations, it can be concluded that the risk for the operator using Metaldehyde 5% GB (CEKUMETA 5) is acceptable with gloves during loading and application.

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

3.1.3.3 Bystander Exposure

Metaldehyde 5% GB (CEKUMETA 5) is a granular bait formulation; no drift is expected. Therefore, bystander exposure estimation is considered to be not relevant.

3.1.3.4 Worker Exposure

Metaldehyde 5% GB (CEKUMETA 5) is a granular bait formulation; no work is expected to be practiced after application. Therefore, worker exposure estimation is considered to be not relevant.

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

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) 396/2005 is not expected in cereals and lettuce.

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

As far as consumer health protection is concerned, France agrees with the authorization of the intended uses on straw cereals, indoor lettuce and proposed GAP on outdoor lettuce at BBCH 19.

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

Data gaps: For several intended uses, residue trials are missing. Therefore, they cannot be considered as fully supported in France (see table 8.11-1 below for details).

⁸ Open field or glasshouse

Summary of the evaluation

Use- No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) 2015/400	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Straw Cereals	Yes	Yes	Yes	Yes	Yes	No	No	
2	Lettuce	Yes	Yes	Yes	Yes	Yes		No	For outdoor uses: BBCH 19 proposed instead of BBCH 41
3	Oilseed rape	Yes	No	-	-	-	-	-	
4	Potato	Yes	No	-	-	-	-	-	
5	Berries	Yes	No	-	-	-	-	-	
6	Brassicas (head, flowering, sprouts)	Yes	No	-	-	-	-	-	
7	Grapes	Yes	No	-	-	-	-	-	
8	Maize	Yes	No	-	-	-	-	-	
9	Ornamentals	Not assessed , no alimentary crops							
10	Pasture	Yes	No	-	-	-	-	-	
11	Strawberry	Yes	No	-	-	-	-	-	
12	Sugar beet, fodder beet	Yes	No	-	-	-	-	-	
13	Turf	Not assessed , no alimentary crops							
14	Vegetables (general category) (artichoke and tomatoes)	Yes	No	-	-	-	-	-	
15	Orchards - Pome fruit trees, Stone fruit trees, Citrus fruit trees, semi tropical trees	Yes	No	-	-	-	-	-	

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

The effects of processing on the nature of metaldehyde residues have 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. Then, 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 and acute consumer exposures resulting from the uses proposed in the framework of this application were calculated. Based on EFSA PRIMo (rev2), chronic and acute exposures were considered as acceptable for all groups of consumers.

Summary for CEKUMETA 5 (Metaldehyde 5% GB)

Crop	BBCH for CEKUMETA 5 (Metaldehyde 5% GB) proposed by applicant	PHI/ Withholding period* sufficiently supported for	BBCH for CEKUMETA 5 (Metaldehyde 5% GB) proposed by zRMS	zRMS Comments (if different PHI proposed)
		metaldehyde		
Straw Cereals	BBCH 29	Yes		
Lettuce outdoor uses	BBCH 41	No	BBCH 19	Not sufficient trials at the intended BBCH for N dataset
Lettuce indoor uses	BBCH 41	Yes		

NR: not relevant

*Purpose of withholding period to be specified

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

Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for CEKUMETA 5 (Metaldehyde 5% GB)
Crop group	Led by metaldehyde	
N.R.	N.R.	

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 metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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

PEC soil and PEC_{SW} values derived for the active substance are used for the eco-toxicological risk assessment.

PEC_{GW} values for metaldehyde do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000⁹. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

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

3.1.6 Ecotoxicology

The risk assessment for birds shows that the repellency properties of Metaldehyde 5% GB (CEKUMETA 5), 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 Metaldehyde 5% GB (CEKUMETA 5) to target crops according to the proposed GAP.

In the same way, the risk assessment for mammals shows that the repellency properties of Metaldehyde 5% GB (CEKUMETA 5), 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 Metaldehyde 5% GB to target crops according to the proposed GAP.

The risk assessment for aquatic organisms, honeybees, earthworms and other soil macro-organisms and non-target plant demonstrated that no unacceptable effects would be expected from using Metaldehyde 5% GB (CEKUMETA 5) according to the proposed GAP. Nonetheless, acute effects on bird populations and seed-eating mammals must be monitored.

3.1.7 Efficacy

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

Since the risk of development of resistance to metaldehyde is low, the efficacy and selectivity data of the product Metaldehyde 5% GB (CEKUMETA 5) have still been valid.

The product should be applied at the same conditions of use already authorized in each cMS. Any change of conditions of the product application should be judged at national level.

The product complies with the Uniform Principles.

Considering the data submitted:

- As the risk of resistance development or appearance to metaldehyde in slug and snail populations is still considered low, the efficacy of the product Metaldehyde 5% GB (CEKUMETA 5), applied at the requested rate is still considered satisfying.
- In the absence of major change of agronomic practices, the selectivity and the impact of the preparation Metaldehyde 5% GB (CEKUMETA 5) on plants and plant products are still considered acceptable.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted as proposed 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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- monitor acute effects on bird populations and seed-eating mammals

3.4.3 Label amendments (see label in Appendix 2):

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

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

Appendix 1 – Copy of the French Decision



Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit phytopharmaceutique et des demandes associées

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

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

*Vu la demande de renouvellement de l'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique **CEKUMETA 5***

de la société SHARDA EUROPE B.V.B.A

enregistrées sous les n°2014-0112, n°2016-3135 et n°2013-1730

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

Vu le courrier d'intention de retrait de l'autorisation de mise sur le marché français pour la gamme d'usages « amateur » et de la mention « Emploi autorisé dans les jardins » de l'Anses en date du 15 janvier 2018,

Vu la décision du Directeur général de l'Anses du 13 juillet 2018,

Vu le recours gracieux formé le 2 août 2018 par la société SHARDA EUROPE B.V.B.A,

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

La présente décision abroge et remplace la décision du 13 juillet 2018 et s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.



Informations générales sur le produit	
Noms du produit	CEKUMETA 5 METASH LIMA ORO 5% GB MATALUMA 5% GB SUPERDEHYDE ANTI L ECLOR WIFI 5
Type de produit	Produit de référence
Titulaire	SHARDA EUROPE B.V.B.A Heedstrat 58 1730 ASSE BELGIQUE
Formulation	Appât granulé (GB)
Contenant	50 g/kg - métaldéhyde
Numéro d'intrant	2030258
Numéro d'AMM	2030460
Fonction	Molluscicide
Gamme d'usages	Professionnel Mention « Amateur/emploi autorisé dans les jardins » retirée sans délai, conformément à l'article 4 point IV du décret n° 2012-755 du 9 mai 2012 relatif à la mise en conformité des dispositions nationales avec le droit de l'Union européenne en ce qui concerne la mise sur le marché et l'utilisation des produits phytopharmaceutiques.

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 mai 2024.

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

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le

02 NOV. 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)

CEKUMETA 5
AMM n°2030460

Page 2 sur 7



ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Boîtes en carton / polyéthylène basse densité	100 g ; 200 g ; 250 g ; 500 g ; 750 g ; 1 kg ; 5 kg ; 10 kg ; 20 kg ; 25 kg
Sacs multicouches en papier / polyéthylène basse densité	100 g ; 200 g ; 250 g ; 500 g ; 750 g ; 1 kg ; 5 kg ; 10 kg ; 20 kg ; 25 kg

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



Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Décal avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
11012903 Traitements généraux* Trt Sol* Limacés et escargots	7 kg/ha	2/an	entre les stades BBCH 00 et BBCH 41	F (BBCH 41)	-	-	-	-
	Uniquement sur laitue. Uniquement sous abri. Intervalle minimum entre les applications : 7 jours.							
11012903 Traitements généraux* Trt Sol* Limacés et escargots	7 kg/ha	2/an	entre les stades BBCH 01 et BBCH 19	F (BBCH 19)	-	-	-	-
	Uniquement sur laitue. Intervalle minimum entre les applications : 7 jours.							
11012903 Traitements généraux* Trt Sol* Limacés et escargots	7 kg/ha	2/an	entre les stades BBCH 00 et BBCH 99	Non applicable	-	-	-	-
	Uniquement sur cultures ornementales et gazons de graminées. Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
11012903 Traitements généraux* Trt Sol* Limacés et escargots	7 kg/ha	2/an	entre les stades BBCH 00 et BBCH 29	F (BBCH 29)	-	-	-	-
	Uniquement sur céréales à paille. Intervalle minimum entre les applications : 7 jours.							

CEKUMETA 5
AMM n° 2030460



Liste des usages retirés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Date limite accordée pour la vente et la distribution	Date limite accordée pour le stockage et l'utilisation des stocks
<p>11012903 Traitements généraux*Trt Sol*Limaces et escargots</p>	<p>7 kg/ha</p> <p>Motivation du retrait : L'usage est retiré sur "crucifères oléagineuses" avec un délai avant récolte F (BBCH 15), sur pomme de terre avec un délai avant récolte F (BBCH 97), sur baies et petits fruits ("framboisier", "cassisier", "petits fruits"), "vigne", fraisier, "agrumes", "fruits à pépins", "fruits à noyau" et "fruits à coque" avec un délai avant récolte F (BBCH 69) et sur "choux à inflorescences", "choux pommés", "tomate" et "artichaut" avec un délai avant récolte F (BBCH 41) en raison d'un nombre insuffisant d'essais résidus pour confirmer que les bonnes pratiques agricoles revendiquées en France permettront de respecter les limites maximales de résidus en vigueur pour le métaldehyde.</p>	2/an	-	13/01/2019	13/01/2020

CEKUMETA 5
AMM n°2030460

Page 5 sur 7



Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas stocker le produit dans un local où la température peut dépasser 35°C.

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un tracteur équipé d'un microgranulateur ou lors d'une application à l'aide d'un matériel d'épandage

• pendant le chargement du matériel d'épandage

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester/coton 65 %/35 % (combinaison ou ensemble veste + pantalon) ;
- Blouse ou tablier à manches longues de catégorie III type 3 (PB) porté sur la combinaison de travail ;

• pendant l'épandage

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

• pendant le nettoyage du matériel d'épandage

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester/coton 65 %/35 % (combinaison ou ensemble veste + pantalon) ;
- Combinaison catégorie III Type 5/6 ou blouse ou tablier à manches longues de catégorie III type 3 (PB) porté sur la combinaison de travail.

Déla

- Non pertinent pour ce type d'application.

Respect des limites maximales de résidus (LMR)

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

- Ne pas appliquer le produit directement sur les parties récoltées des plantes.

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.



Protection de la faune

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

Le produit peut être utilisé sur les usages autorisés, conformément aux conditions d'emploi antérieures jusqu'au 13 janvier 2019.

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Date limite	Réurrence (mois)
Fournir un suivi des effets aigus sur les populations d'oiseaux et de mammifères granivores.	13/07/2020	-

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

CEKUMETA 5

Appâts granulés (GB) contenant 5% p/p de Métaldéhyde
AMM n°203460 délivrée par le Ministère de l'agriculture, de
l'agroalimentaire et de la forêt

PRODUIT CONTRE LES LIMACES ET LES ESCARGOTS

NOTICE D'EMPLOI
IMPORTANT: Ces informations font parties de l'étiquette du produit CEKUMETA 5. Toutes les instructions de cette section doivent être lues attentivement.

RECOMMANDATIONS:
Lire attentivement et respecter strictement le mode d'emploi.

PRECAUTIONS:
Stockage: Conserver le produit dans son emballage d'origine, dans des locaux fermés, hors de portée des enfants. Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.
Après utilisation: éliminer les emballages via les collectes organisées par les distributeurs partenaires de la filière AIVALOR (08 10 12 18 85, numéro Azur prix d'un appel local).

MODE D'EMPLOI:
Pour une efficacité optimum, appliquer CEKUMETA 5 de préférence par temps doux et humide, quand les limaces et les escargots sont les plus en activité. Ne pas appliquer avant de fortes précipitations. Cela peut réduire la persistance des granules et donc l'efficacité du produit.
Une application tardive des granules sur les plantes feuillues peut avoir comme conséquence le logement des granules dans le feuillage. Un soin particulier doit être pris pour éviter ceci, notamment en ce qui concerne les cultures destinées à la consommation humaine et animale.
Appliquer CEKUMETA 5 sur le sol ou aux pieds des cultures traitées en utilisant un appareil d'épandage des granules approprié.
Appliquer CEKUMETA 5 juste avant ou juste après le semis. Pour les cultures émergées ou établies, appliquer dès l'apparition des dommages.

MATERIEL D'EPANDAGE DES GRANULES:
Etalonner et contrôler le matériel d'application/d'épandage. Les réglages de l'année précédente sont à vérifier. Faire un test à poste fixe (en récupérant les granules utilisés).

Produit non classé comme dangereux
Symbole de danger: aucun
Phrase de risque: aucune
Conseils de prudence:
S2: Conserver hors de la portée des enfants
S13: Conserver à l'écart des aliments et boissons, y compris ceux pour animaux

USAGES ET DOSES AUTORISEES:
CEKUMETA 5 peut être utilisé pour l'usage et la dose d'application suivante:

Code d'usage	Usage	Dose d'emploi	Nombre maximum d'applic.	Délai avant récolte (jours)
11012903	Traitements généraux* Trait. du sol** Mollusques escargots	7 kg/ha	2	-

NOTES GÉNÉRALES:
Consulter les procédures de nettoyage des réservoirs sur les étiquettes de tous produits associés et être sûr d'utiliser le procédé le plus rigoureux et recommandé. Respecter les bonnes pratiques agricoles.

CONDITIONS DE VENTE:
Tous nos produits sont de haute qualité et sont appropriés aux usages recommandés. Toutefois nous ne pouvons contrôler les conditions dans lesquels ils seront stockés, manipulés, mélangés ou utilisés ni contrôler les conditions climatiques dans lesquels ils seront employés. Ces différents paramètres précités peuvent affecter la performance du produit. C'est pourquoi, notre société et nos revendeurs déclineront toute responsabilité quant à la qualité des produits qui serait altérée par de mauvaises conditions de stockage, de manipulation ou d'application par l'utilisateur.

CEKUMETA 5 est un molluscicide à usage agricole et professionnel.

CEKUMETA 5 se présente sous la forme d'appâts granulés (GB) contenant 5% p/p de Métaldéhyde.

Poids net: XXXXX

Numéro de lot: XXXXX

Détenteur d'homologation:
Sharda Europe b.v.b.a
Jozef Mertensstraat 142
1702 Dilbeek
Belgique

Distributeur:
XXXXXX
XXXXXX
XXXXXX
XXXXXX

En cas d'urgence, appeler le 15 ou le centre antipoison puis signalez vos symptômes au réseau "PhytoAttitude" n°vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Appendix 3 – Letter(s) of Access

*Rec. = V. An
29/12/11*

Lonza

REGISTERED
Agence Nationale de Sécurité Sanitaire de
l'Alimentation, de l'Environnement e du Travail (ANSES)
Att. Mr. BITAUD Bertrand
253 avenue du Général Leclerc
94700 Maisons Alfort Cedex
FRANCE
Tel + 01 49 77 21 28
e-mail: Bertrand.BITAUD@anses.fr

Lonza AG
Münchensteinerstrasse 38
CH-4053 Basel, Schweiz

Angela Noe
Lonza Life Science Ingredients
Regulatory Compliance Europe

Tel +41 61 316 8793
Fax +41 61 316 9793
angela.noe@lonza.com

AN
December 28, 2011

Letter of Access - Directive 91/414/EEC and Implementing Directive 2011/54/EU - Metaldehyde

Dear Sir

By this Letter of Access, Lonza AG ("Data Owner"), acting also on behalf of the notifier Lonza GmbH, located in Nattermannallee 1, D-50829 Cologne, Germany (hereinafter, collectively referred to as "Lonza"), certifies that your organization is authorised by Data Owner to cite, refer to, rely on and make use of the data listed exhaustively under Section A herein below for the purpose of granting or renewing an authorization for the products containing Metaldehyde as active substance which are explicitly listed under Section B herein below, following the entry into force of the inclusion of Metaldehyde in Annex I to Directive 91/414/EEC (as amended), for the benefit of Sharda Worldwide Exports Pvt Ltd ("Sharda") any of its Affiliates in the EU as specified under Section C herein below.

Such right of reference is effective to the extent permitted without requirement of further reference or confirmation from Data Owner during the period of data protection provided for the below listed studies. Lonza reserves the right to verify and withdraw this Letter of Access if the conditions under which it was granted are not or no longer met or if the active substance contained in the Products mentioned herein below is not technically equivalent to the one listed in Annex I to Directive 91/414/EEC (as amended). In such a case the registrations granted on the basis to this Letter of Access shall be immediately cancelled upon written request from Lonza.

2/3, December 28, 2011, Letter of Access - Directive 91/414/EEC and Implementing Directive 2011/54/EU - Metaldehyde

Section A : List of studies for which Lonza grants a letter of Access for the Products mentioned under Section B below for the benefit of the legal entities mentioned under Section C below

IIA 5.3.2	52-week chronic toxicity study of metaldehyde by repeated oral administration via the diet to Beagle dogs Doc.No. 537-003, Lonza Report No. 3657 (Leuschner J2003)
IIA 5.3.2	P0071: Ninety day sub-chronic oral (dietary) toxicity study in the rat Doc.No. 533-003, Lonza Report No. 2974 (Thomas O., Bartlett A., Brooks P. 1998)
IIA 5.8	Acute neurotoxicity study in rats by oral administration of metaldehyde LPT Report No. 23443, Doc. No.: 541-002 (Haferkorn J.2009)

Section B : Registrations for which Lonza grants a Letter of Access to the studies mentioned under Section A above for the benefit of the legal entities mentioned under Section C below

Name	Ref.	Holder
Anti-Limace Eclor	5900368	Sharda Europe B.V.B.A
CEKUMETA 5	2030268	Sharda Europe B.V.B.A

3/3, December 28, 2011, Letter of Access - Directive 91/414/EEC and Implementing Directive 2011/54/EU - Metaldehyde

Section C. Legal entities to which Lonza grants a Letter of Access to the studies mentioned under Section A above for the Products mentioned under Section B above

Name	Address
Sharda Europe B.V.B.A.	Heedstraat 58 1730 Asse Belgium Tel. +32 24 66 44 44 FAX +32 24 63 36 58

Yours sincerely
Lonza AG


Name: Elias Alonso
Title: Director Marketing & Sales
Date: December 28, 2011


Angela Noe
Registration Manager

Lonza

DHL

ANSES-DPR-UIA
14 rue Pierre et Marie Curie
94701 MAISONS-ALFORT Cedex
France

Lonza AG
Münchensteinerstrasse 38
CH-4053 Basel, Schweiz

Nicole Hänel
Lonza Life Science Ingredients
Regulatory Compliance Europe

Tel +41 61 316 8349
Nicole.haenel@lonza.com

NH
March 23, 2016

**Letter of Access - Directive 91/414/EEC and Implementing Directive 2011/54/EU -
Metaldehyde**

Dear Sirs and Madam

By this Letter of Access, Lonza AG ("Data Owner"), acting also on behalf of the notifier Lonza GmbH, located in Nattermannallee 1, D-50829 Cologne, Germany (hereinafter, collectively referred to as "Lonza"), certifies that your organization is authorised by Data Owner to cite, refer to, rely on and make use of the data listed exhaustively under Section A herein below for the purpose of granting or renewing an authorization for the products containing Metaldehyde as active substance which are explicitly listed under Section B herein below, following the entry into force of the inclusion of Metaldehyde in Annex I to Directive 91/414/EEC (as amended), for the benefit of Sharda Europe bvba ("Sharda") any of its Affiliates in the EU as specified under Section C herein below.

Such right of reference is effective to the extent permitted without requirement of further reference or confirmation from Data Owner during the period of data protection provided for the below listed studies. Lonza reserves the right to verify and withdraw this Letter of Access if the conditions under which it was granted are not or no longer met or if the active substance contained in the Products mentioned herein below is not technically equivalent to the one listed in Annex I to Directive 91/414/EEC (as amended). In such a case the registrations granted on the basis of this Letter of Access shall be immediately cancelled upon written request from Lonza.

2/3, March 23, 2016, Letter of Access - Directive 91/414/EEC and Implementing Directive 2011/54/EU - Metaldehyde

Section A : List of studies for which Lonza grants a letter of Access for the Products mentioned under Section B below for the benefit of the legal entities mentioned under Section C below

Annex III, 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 RIFCon GmbH, Heidelberg, Germany Report No.: 056 R08067 Doc. No.: 865-003
Annex III, 10.1	Wilkens, S. Frese, I.	2009	Metaldehyde slug bait: Field study on exposure and effects on birds in treated cereal fields in Germany, France and Great Britain RIFCon GmbH, Heidelberg, Germany Report No.: 070 R08175-4 Doc. No.: 865-006
Annex III, 10.1	Wilkens, S. Frese, I.	2009	Metaldehyde slug bait: Field study on exposure and effects on birds in treated OSR fields in Germany, France and Great Britain RIFCon GmbH, Heidelberg, Germany Report No.: 068 R08175-2 Doc. No.: 865-004
Annex III, 10.3	Hoeller, D.	2009	Metaldehyde slug bait: Field study on exposure and effects on rodents in treated OSR fields in Germany RIFCon GmbH, Heidelberg, Germany Report No.: 067 R08175-1 Doc. No.: 865-005
Annex III, 10.3	Hoeller, D.	2009	Metaldehyde slug bait: Field study on exposure and effects on rodents in treated cereal fields in Germany RIFCon GmbH, Heidelberg, Germany Report No.: 069 R08175-3 Doc. No.: 865-007

3/3, March 23, 2016, Letter of Access - Directive 91/414/EEC and Implementing Directive 2011/54/EU - Metaldehyde

Section B : Registrations for which Lonza grants a Letter of Access to the studies mentioned under Section A above for the benefit of the legal entities mentioned under Section C below

Name	N° Intransit	AMM	Holder
CEKUMETA 5	2030258	2030460	SHARDA EUROPE BVBA, Josef Merlenstraat 142, 1702 Dilbeek, Belgium

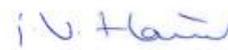
Section C. Legal entities to which Lonza grants a Letter of Access to the studies mentioned under Section A above for the Products mentioned under Section B above

Name	Address
Sharda Europe B.V.B.A.	Jozef Merlenstraat 142 1702 Dilbeek Belgium Tel. +32 24 66 44 44 FAX +32 24 63 36 58

Yours sincerely
Lonza AG



Name: Elias Alonso
Title: Product Manager META
Date: March 23, 2016



Nicole Hänel
Registration Manager