

REGISTRATION REPORT

Part A

Risk Management

Product code: 0302443

Product name(s): CARAKOL 3

Active Substance(s):

Metaldehyde, 30 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: KOLLANT S.R.L.

Date: 2018/07/13

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PART A – Risk Management

The company KOLLANT S.R.L. has requested a marketing authorisation in France for the product CARAKOL 3 (formulation code: 0302443), containing 30 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 CARAKOL 3 (0302443) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of CARAKOL 3 (0302443) have been made using endpoints agreed in the EU peer review(s) of metaldehyde.

This document describes the specific conditions of use and labelling required for France for the registration of CARAKOL 3 (0302443).

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 KOLLANT S.R.L.'s application to market CARAKOL 3 (0302443) 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 (EU) No 540/2011 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 (2013-1375) 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 2017³ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight 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 2014⁶ 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 extrapolation⁷ 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/AGRGI632554A/jo/texte>

⁴ REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁵ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

⁷ 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 CARAKOL 3 (0302443), 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 letter(s) of access.


2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	CARAKOL 3 (0302443)
Authorisation number	2180260
Function	Molluscicide
Applicant	KOLLANT S.R.L.
Composition	30 g/kg metaldehyde
Formulation type (code)	granular bait (GB)
Packaging	PE (15 kg ; 20 kg)

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	Eye damage, cat 1	
Environmental hazards	-	
Hazard pictograms		
Signal word	Danger	
Hazard statements	H318	Causes serious eye damage
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.

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

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

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
SPe 6	To protect birds and wild mammals remove spillages.

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁸ : refer to the Decision in Appendix 1 for the details
Re-entry period ⁹ : not relevant
Pre-harvest interval ¹⁰ : <ul style="list-style-type: none">- Strawberry, garlic, tomato and aubergine (field and indoor), melon, watermelon, dry peas and beans (PIBSX and PHSVX), rapeseed, sunflower, soya bean, maize, millet, sorghum: F- Application must be made at growth stage BBCH 19 at the latest.- Sweet pepper (field and indoor): F- Application must be made at growth stage BBCH 49 at the latest.- Fresh peas and beans with and without pods: Application must be made at growth stage BBCH 50 at the latest. PHI 28 days.- Oats, wheat, triticale, rye, barley, buckwheat and other pseudo-cereals: F- Application must be made at growth stage BBCH 29 at the latest. PHI 60 days.- Sugar beet, fodder beet and others beets: F- Application must be made at growth stage BBCH 19 at the latest. PHI 90 days.- Flowering brassica: F- Application must be made at growth stage BBCH 49 at the latest. PHI 7 days.
Other mitigation measures: <ul style="list-style-type: none">- The formulation must be stored at temperature below 35°C.- Do not apply CARAKOL 3 (0302443) directly on harvestable parts of plants.
The label must reflect the conditions of authorisation.

⁸ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

⁹ The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

¹⁰ According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

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

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

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

PPP (product name/code): **CARAKOL 3 (0302443)** Formulation type: **GB** ^(a, b)
Active substance 1: Metaldehyde Conc. of as 1: **30 g/kg** ^(c)
Safener: N/A Conc. of safener: n.a
Synergist: N/A Conc. of synergist: n.a
Applicant: **KOLLANT S.r.l** Professional use: ☒
Zone(s): southern ^(d) Non professional use: ☐
Verified by MS: yes
Field of use: molluscicide

GAP, date: 2018-07-13

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 or L 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	Strawberry	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Acceptable
2	FR	Strawberry	G	Slugs and snails	Mechanica 1 spreading, directed to	BBCH 00-41	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Not acceptable (exceedance of MRL)

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 or L 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		
					the soil								
3	FR	Potato	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-93	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Not acceptable (no sufficient trials)
4	FR	Root and tuber vegetables except beets	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-45	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	20 days	Not acceptable (no sufficient trials)
5	FR	Onion, shallot	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Not acceptable (exceedance of MRL)
6	FR	Garlic	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Acceptable
5	FR	Tomato, aubergine	F/G	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Acceptable
6	FR	Sweet pepper	F/G	Slugs and snails	Mechanica 1	BBCH 00-49	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Acceptable

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
					spreading, directed to the soil								
7	FR	Cucumber, zucchini, gherkin	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Not acceptable (exceedance of MRL)
8	FR	Melon, watermelon	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Acceptable
9	FR	Flowering brassica	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-49	2/year	7	a) 8.75 kg/ha b) 17.5 kg/ha	a) 262.5 g/ha b) 525 g/ha	-	7	Acceptable
10	FR	Head brassica	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-49	2/year	7	a) 8.75 kg/ha b) 17.5 kg/ha	a) 262.5 g/ha b) 525 g/ha	-	3	Not acceptable (no sufficient trials and exceedance of MRL)
11	FR	Lettuces and salad plants, spinaches and similar leaves	F/G	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Not acceptable (no sufficient 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, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
12	FR	Peas and beans with and without pods	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-50	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	28	Acceptable
13	FR	Dry peas and beans (PIBSX and PHSVX)	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Acceptable
14	FR	Asparagus	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-41	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	20	Not acceptable (no sufficient trials)
15	FR	Artichoke	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-50	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	20	Not acceptable (no sufficient trials)
16	FR	Leek	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-50	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	20	Not acceptable (exceedance of MRL)
17	FR	Celery (APUGV and APUGR)	F	Slugs and snails	Mechanica 1 spreading, directed to	BBCH 00-19	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Not acceptable (no sufficient trials and exceedance of MRL)

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 or L 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		
					the soil								
18	FR	Rapeseed, sunflower, soya bean	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Acceptable
19	FR	Maize, millet, sorghum	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	F	Acceptable
20	FR	Oats, wheat, triticale, rye, barley, buckwheat and other pseudo-cereals	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-29	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	60	Acceptable
21	FR	Sugar beet, fodder beet and other beets	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	90	Acceptable
22	FR	Ornamentals, floricultural crops, nurseries, seedlings and plantations	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	spread in between (perennial) plants	2/year	7	a) 11.5 kg/ha b) 23 kg/ha	a) 345 g/ha b) 690 g/ha	-	N/A	Acceptable

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

CARAKOL 3 (0302443) is a granule (GB) formulation. All studies have been performed in accordance with the current requirements. The appearance of the product is a blue granular, with a characteristic odour. It is not explosive, has no oxidising properties and is not auto-flammable up to > 252°C. In aqueous solution, it has a pH value around 5.7 at ambient temperature.

There is no effect of high temperature on the stability of the formulation, since after 12 weeks at 35 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years.

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

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 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 monograph/this dossier and validated for the determination of residues of metaldehyde in plants, in soil in water (surface and drinking) and air.

To update:

- An analytical method (with a confirmatory method) and its ILV for the determination of metaldehyde residue in foodstuffs of animal origin should be provided in post authorization.
- Validation data of the method M858 for the determination the relevant impurity acetaldehyde in the formulation are provided. However, a validation of the method at the LOQ $\leq 0.004\%$ is missing and required.

The active substance are neither toxic nor very toxic hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment:

Active Substance: metaldehyde			
ADI	0.02 mg kg bw/d		EU agreed endpoint (Efsa 2010)
ARfD	0.3 mg/kg bw/d		EU agreed endpoint (Efsa 2010)
AOEL	0.1 mg/kg bw/d		EU agreed endpoint (Efsa 2010)
Dermal absorption	Based on an in vitro human study performed on a similar formulation :		
		Concentrate (tested) 50 g/kg	Spray dilution (tested)
	In vitro (human) %	0.39%±0.15%SD (0.54%)	-
		Concentrate (used in formulation) 30 g/kg	Spray dilution (used in formulation)
	Dermal absorption endpoints %	0.8 (pro rata)	-

3.1.3.1 Acute Toxicity

CARAKOL 3 (0302443) containing 30 g/kg of metaldehyde has a low toxicity in respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin and is not a skin sensitiser. However, due to the new formulation (refer to PART C), CARAKOL 3 (0302443) is classified for eye damage.

3.1.3.2 Operator Exposure

Operator exposure was assessed against the AOEL agreed in the EU review of metaldehyde. Data on dermal absorption of CARAKOL 3 (0302443) was provided and considered acceptable.

Operator exposure was modeled using the PHED model:

Parameters used in operator exposure assessment				
Crop	Equipment	Application rate kg product/ha (g a.s./ha)	Spray dilution (L/ha)	Model used
Open field				
Cereals (representative of all supported uses)	Vehicle-mounted equipment	11.5 kg product/ha (345 g metaldehyde/ha)	-	PHED
	Hand-held equipment			

These results show that for the use of a vehicle-mounted equipment, exposure to metaldehyde is estimated to be 6.3% of the AOEL with working coverall and gloves during mixing/loading and application.

For the use of a hand-held equipment, exposure to metaldehyde is estimated to be 7.0% of the AOEL with working coverall and gloves during mixing/loading and application.

According to the model calculations, it can be concluded that the risk for the operator using CARAKOL 3 (0302443) on field crops is acceptable with the use of personal protective equipment and with a coverall (90% protection factor).

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

3.1.3.3 Bystander Exposure

Since the formulation CARAKOL 3 (0302443) is a granular bait formulation, bystander exposure is considered as negligible and thus acceptable.

3.1.3.4 Worker Exposure

Worker exposure is considered as negligible.

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

3.1.4.1 Residues

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of metaldehyde as laid down in SANCO/10565/2014 voted on the 24th February of 2014 is not expected **except on indoor strawberry, head cabbage, zucchini, cucumber, gherkin, onion, shallot, leek and celery (APUGV) in NEU. The compliance of the intended GAP on potato, root and tuber vegetables except beets, lettuces and salad plants, spinaches and similar leaves, asparagus, artichoke, celeriac (APUGR) and Brussels sprout cannot be checked since numbers of submitted trials are not sufficient.**

For other crops, 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 proposed uses.

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

Data gaps

Noticed data gaps are:

Several uses are not acceptable in France **because of a lack of residue trials: potato, root and tuber vegetables other than beets, Brussels sprout, lettuces and salad plants, spinaches and similar leaves, asparagus, artichoke, celery.**

Summary of the evaluation

Summary for metaldehyde

Use- No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance SANCO 100565/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Strawberry	Yes	Field: Yes Indoor: No (4 indoor only)	BBCH41 Field : Yes Indoor: No	Yes	Field: Yes Indoor: No	No	No	MRL exceedance (indoor)
2	Potato	Yes	No (NEU: 0 SEU: 4)	BBCH49/93 No data set complete	Yes	Yes but data set not complete		No	4SEU trial <LOQ but in article 12 level of residue>LOQ at GAP 3x210 g/ha BBCH45. A zero residue situation cannot be accepted
3	Root and tuber vegetables except sugar beets	Yes	No (NEU: 4 on carrot SEU: 4 on carrot)	No data set not complete	Yes	Yes but data set not complete		No	Data set not complete on carrot so extrapolation to the whole group of “Root and tuber vegetables except sugar beet” cannot be made
4	Onion, Shallot, garlic	Yes	SEU: Yes (4 zero residue situation) NEU: No (2)	Yes in SEU	Yes	Yes	No	No	Only 2 NEU trial with one of them the level of residue > LOQ and the MRL. GAPs not fully supported in France for onion and shallot GAPs fully

Use- No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance SANCO 100565/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
									supported in France for garlic
5	Tomato, aubergine	Yes	Indoor: Yes Field: Yes,	Yes	Yes	Yes	No	No	
6	Sweet pepper	Yes	Indoor: Yes Field: Yes, one confirmatory SEU trial is asked in post registration	Yes	Yes	Yes	No	No	1 confirmatory SEU trial is required in post registration
7	Cucumber, zucchini, gherkin	Yes	Field Yes	Yes	Yes	No	No	No	MRL exceedance
8	Melon, watermelon	Yes	Yes	Yes	Yes	Yes	No	No	
9	Flowering brassica	Yes	NEU: Yes SEU : Yes	No -> 7 days proposed	Yes	NEU: Yes SEU : No	No	No	PHI 7 days proposed in France
10	Head brassica (head cabbage and Brussels sprout)	Yes	Head cabbage NEU: No (not compliant) SEU: Yes Brussels sprout: NEU: No (2) SEU: No(2)	Yes	Yes	Head cabbage NEU: No SEU: Yes Brussels sprout NEU: Yes SEU: Yes But data set not complete	No	No	GAP on head cabbage not supported in France (exceedance of MRL) GAP on Brussels sprout not supported in France (number of trials not sufficient)
11	Lettuces and salad plants, spinaches and similar leaves	Yes	NEU: No (4) SEU : Yes Indoor: No (4)	Yes	Yes	Yes	No	No	Not supported in France (number of trials not sufficient)
12	Peas and beans with and without pods	Yes	Yes	Yes	Yes	Yes	No	No	
13	Dry peas and beans	Yes	Yes	Yes	Yes	Yes	No	No	
14	Asparagus	Yes	NEU: No (0) SEU: Yes	Yes	Yes	Yes	No	No	Not supported in France (number of trials not sufficient)

Use- No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance SANCO 100565/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
15	Artichoke	Yes	NEU: No (0) SEU: Yes	Yes	Yes	Yes	No	No	Not supported in France (number of trials not sufficient)
16	Leek	Yes	NEU: No (4) SEU: Yes (4)	Yes	Yes	NEU : No SEU: Yes	No	No	Not supported in France (exceedance of MRL)
17	Celery	Yes	NEU: No (2) SEU: Yes	Yes	Yes	Yes	No	No	GAP on celery (APUGV) not supported in France (exceedance of MRL) GAP on celeriac (APUGR) not supported in France (number of trials not sufficient)
18	Rapeseed, sunflower, soya bean	Yes	Yes	Yes	Yes	Yes	No	No	
19	Maize, millet, sorghum	Yes	Yes	Yes	Yes	Yes	No	No	
20	Oats, wheat, triticale, rye, barley, buckwheat and other pseudo-cereals	Yes	Yes	Yes	Yes	Yes	No	No	
21	Sugar beet, fodder beet and other beets	Yes	Yes	Yes	Yes	Yes	No	No	
22	Ornamentals, floricultural crops, nurseries, seedlings and plantations	Not assessed, no alimentary crops							

The effects of processing on the nature of metaldehyde residues have been investigated. 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 is 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 is 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 CARAKOL 3 (0302443)

Information on CARAKOL 3 (0302443)

Crop	PHI for CARAKOL 3 (0302443) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CARAKOL 3 (0302443) proposed by zRMS	zRMS Comments (if different PHI proposed)
		metalddehyde		
Strawberry	BBCH 41, PHI=F	Yes for field only at BBCH 19		No residue trials available at BBCH 41
Onion, shallot, garlic (2 x 345 g a.s./ha)	BBCH 19, PHI=F	No except garlic		Onion and shallot not supported
Tomato, aubergine (2 x 345 g a.s./ha) field and indoor	BBCH 19, PHI=F in field and glasshouse	Yes		
Sweet pepper (2 x 345 g a.s./ha) field and indoor	BBCH 49, PHI=F in field and glasshouse	Yes		
Melon, watermelon (2 x 345 g a.s./ha)	BBCH 19, PHI=F	Yes		
Flowering brassica (2x262.5 g/ha) France only	BBCH 49, PHI=3 d	Yes	7 days	According to residue trials
Peas and beans with and without pods (2 x 345 g a.s./ha)	BBCH 50, PHI=28 d	Yes		
Dry peas and beans (PIBSX and PHSVX) (2 x 345 g a.s./ha)	BBCH19, PHI=F	Yes		
Rapeseed, sunflower, soya, bean, cotton seed (2 x 345 g a.s./ha)	BBCH19, PHI=F	Yes		
Maize, millet, sorghum (2 x 345 g a.s./ha)	BBCH 19, PHI=F	Yes		
Oats, wheat, triticale, rye, barley, buckwheat and other pseudo-cereals (2 x 345 g a.s./ha)	BBCH 29, PHI=60 d	Yes		
Sugar beet, fodder beet and other beets (2 x 345 g a.s./ha)	BBCH 19 PHI=90 days	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).

3.1.4 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs 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.

The PEC of metaldehyde and its metabolite 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} derived for the active substance and its metabolite are used for the eco-toxicological risk assessment.

PEC_{GW} for metaldehyde do not exceed the trigger of 0.1 µg/L. 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 DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.5 Ecotoxicology

The risk assessment for birds shows that the repellence property of CARAKOL 3 (0302443), the field studies and the weight of evidence allow to conclude that there is no unacceptable acute or reproductive risk to avian species (granivorous and slug-eating birds) from the application of CARAKOL 3 (0302443) to target crops according to the proposed GAP.

On the same way, the risk assessment for mammals shows that the repellency property of CARAKOL 3 (0302443), the field studies and the weight of evidence allow to conclude that there is no unacceptable acute or reproductive risk to mammalian species (granivorous and slug-eating mammals) from the application of CARAKOL 3 (0302443) 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 plants demonstrated that no unacceptable effects would be anticipated of CARAKOL 3 (0302443) according to the proposed GAP.

3.1.6 Efficacy

The product complies with the Uniform Principles.

Considering the data submitted:

- the efficacy of CARAKOL 3 (0302443) is considered as satisfying.
- the selectivity of CARAKOL 3 (0302443) is considered as satisfying.
- the risk of negative impact (yield, quality, transformation processes, propagation, succeeding crops, adjacent crops) is considered as negligible.
- the risk of resistance development or appearance is considered as very low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted excepted for indoor strawberry, potato, onion, shallot, cucumber, zucchini, gherkin, lettuces and salad plants, spinaches and similar leaves, asparagus, artichoke, leek, celery, head brassica 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:

- An analytical method (with a confirmatory method) and its ILV for the determination of metaldehyde residue in foodstuffs of animal origin.
- Validation data of the method M858 for the determination the relevant impurity acetaldehyde in the formulation are provided. However, a validation of the method at the LOQ $\leq 0.004\%$ is missing and required.
- 1 SEU trial conducted on tomato at the intended GAP;
- 1 SEU trial conducted on sweet pepper at the intended GAP;

3.4.3 Label amendments

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

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

Appendix 1 – Copy of the French Decision



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

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

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

*Vu la demande d'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique **CARAKOL 3***

*de la société **KOLLANT S.R.L.***

enregistrées sous les n°2013-1375, 2013-1376, 2013-1377, 2013-1378, 2015-5770

Vu les conclusions de l'évaluation de l'Anses du 7 mai 2018,

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

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

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

(Signature)
Régis GENEI

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Informations générales sur le produit	
Noms du produit	CARAKOL 3 SURIKATE OPPOSUM GUSTO 3
Type de produit	Produit de référence
Titulaire	KOLLANT S.R.L. Via Trieste, 49/53 35121 PADOVA ITALIE
Formulation	Appât granulé (GB)
Contenant	30 g/kg - métaldéhyde
Numéro d'intrant	9891-2013.01
Numéro d'AMM	2180260
Fonction	Molluscicide
Gamme d'usages	Professionnel

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

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

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

A Maisons-Alfort, le 13 JUIL. 2018

Le Directeur Général

Roger GENET

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Sacs en polyéthylène	15 kg ; 20 kg

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Lésions oculaires graves et irritation oculaire - Catégorie 1	H318 : Provoque des lésions oculaires graves
Pour les phrases P se référer à la réglementation en vigueur.	
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.	



Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitee arthropodes non ciblés (mètres)	Zone Non Traitee plantes non ciblés (mètres)	Mention abelles
11012903 Traitements généraux* Trit Sol*Limaces et escargots	11,5 kg/ha Uniquement sur « Tomate ». Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.	2/an	entre les stades BBCH 00 et BBCH 19	F (BBCH 19)	-	-	-
11012903 Traitements généraux* Trit Sol*Limaces et escargots	11,5 kg/ha Uniquement sur Poivron. Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.	2/an	entre les stades BBCH 00 et BBCH 49	F (BBCH 49)	-	-	-
11012903 Traitements généraux* Trit Sol*Limaces et escargots	11,5 kg/ha Uniquement sur Haricots et Pois non écosés frais. Intervalle minimum entre les applications : 7 jours.	2/an	entre les stades BBCH 00 et BBCH 50	28	-	-	-
11012903 Traitements généraux* Trit Sol*Limaces et escargots	11,5 kg/ha Uniquement sur Ail, Melon, Pastèque, Haricots et pois secs, Colza, Tournesol, Soja, Maïs, Millet, Sorgho. Intervalle minimum entre les applications : 7 jours.	2/an	entre les stades BBCH 00 et BBCH 19	F (BBCH 19)	-	-	-
11012903 Traitements généraux* Trit Sol*Limaces et escargots	11,5 kg/ha Uniquement sur Céréales à paille. Intervalle minimum entre les applications : 7 jours.	2/an	entre les stades BBCH 00 et BBCH 29	60	-	-	-
11012903 Traitements généraux* Trit Sol*Limaces et escargots	11,5 kg/ha Uniquement sur Betterave potagère et Betterave industrielle et fourragère. Intervalle minimum entre les applications : 7 jours.	2/an	entre les stades BBCH 00 et BBCH 19	90	-	-	-

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Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
11012903 Traitements généraux* Trit Sol/Limaces et escargots	11,5 kg/ha Uniquement sur traisier. Intervalle minimum entre les applications : 7 jours. Modification du stade d'application maximum de BBCH 41 à BBCH 19 en raison d'un risque de dépassement des limites maximales de résidus de méthaldéhyde en vigueur. L'usage sous abri est refusé en raison d'un risque de dépassement des limites maximales de résidus de méthaldéhyde en vigueur.	2/an	entre les stades BBCH 00 et BBCH 19	F (BBCH 19)	-	-	-	-
11012903 Traitements généraux* Trit Sol/Limaces et escargots	8,75 kg/ha Uniquement sur cultures ornementales. Intervalle minimum entre les applications : 7 jours.	2/an	-	Non applicable	-	-	-	-
11012903 Traitements généraux* Trit Sol/Limaces et escargots	8,75 kg/ha Uniquement sur choux à inflorescences. Intervalle minimum entre les applications : 7 jours.	2/an	entre les stades BBCH 00 et BBCH 49	7	-	-	-	-

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Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
11012903 Traitements généraux* Trt Sol/Limaces et escargots	11,5 kg/ha	2/an	F
Motivation du refus : Les usages sur « Laitue », « Epinard », Cèleri, Oignon, Echalote, Concombre, Courgette, Cornichon, Pomme de terre sont refusés en raison d'un risque de dépassement des limites maximales de résidus de métaldéhyde en vigueur.			
11012903 Traitements généraux* Trt Sol/Limaces et escargots	8,75 kg/ha	2/an	3
Motivation du refus : L'usage sur « Choux pommés » est refusé en raison d'un risque de dépassement des limites maximales de résidus de métaldéhyde en vigueur.			
11012903 Traitements généraux* Trt Sol/Limaces et escargots	11,5 kg/ha	2/an	20
Motivation du refus : L'usage sur Asperge, Poireau, Artichaut, Légumes racines et légumes tubercules autres que Betterave, sont refusés en raison d'un risque de dépassement des limites maximales de résidus de métaldéhyde en vigueur.			

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas stocker 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 à l'aide d'un tracteur équipé d'un microgranulateur ou d'un microgranulateur manuel

• pendant le chargement du matériel d'épandage

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

• pendant l'application

- Gants en nitrile certifiés EN 374-2 à usage unique (dans le cas d'utilisation d'un tracteur à cabine, le port de gants pendant l'application n'est nécessaire que lors d'interventions sur le matériel de pulvérisation et les gants doivent être stockés à l'extérieur de la cabine) ;
- Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant.

• pendant le nettoyage du matériel d'épandage

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

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

- Non applicable 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 consommables 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.

Exigences complémentaires post-autorisation

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

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir une méthode analytique validée pour la détermination des résidus de méthaldéhyde dans les denrées d'origine animale.	24	-
Fournir les données de validation d'une méthode pour la détermination de l'impureté pertinente (acétaldéhyde) dans le produit.	24	-
Fournir les résultats des essais résidus (un par culture) réalisés sur Tomate et Poivron dans la zone Sud de l'Europe.	24	-

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



Appendix 3 – Letter(s) of Access

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