

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product code: 0302449**

**Product name(s): WARIOR EXTRA**

**Active Substance(s):**

**Metaldehyde, 50 g/kg**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(renewal of authorisation)**

**Applicant: KOLLANT S.r.l**

**Date: 2018-11-02**

## Table of Contents

<b>1</b>	<b>DETAILS OF THE APPLICATION.....</b>	<b>3</b>
1.1	APPLICATION BACKGROUND.....	3
1.2	ACTIVE SUBSTANCE APPROVAL.....	3
1.3	REGULATORY APPROACH.....	4
1.4	DATA PROTECTION CLAIMS.....	5
1.5	LETTER(S) OF ACCESS.....	5
<b>2</b>	<b>DETAILS OF THE AUTHORISATION.....</b>	<b>5</b>
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
<b>3</b>	<b>RISK MANAGEMENT.....</b>	<b>13</b>
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	13
3.1.1	<i>Physical and chemical properties.....</i>	<i>13</i>
3.1.2	<i>Methods of analysis.....</i>	<i>13</i>
3.1.3	<i>Mammalian Toxicology.....</i>	<i>13</i>
3.1.4	<i>Environmental fate and behaviour.....</i>	<i>17</i>
3.1.5	<i>Ecotoxicology.....</i>	<i>18</i>
3.1.6	<i>Efficacy.....</i>	<i>18</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT.....	19
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING.....	19
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.....	19
3.4.1	<i>Post-authorisation monitoring.....</i>	<i>19</i>
3.4.2	<i>Post-authorisation data requirements.....</i>	<i>19</i>
3.4.3	<i>Label amendments.....</i>	<i>19</i>
	<b>APPENDIX 1 – COPY OF THE FRENCH DECISION.....</b>	<b>20</b>
	<b>APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT.....</b>	<b>28</b>
	<b>APPENDIX 3 – LETTER(S) OF ACCESS.....</b>	<b>28</b>

## PART A – Risk Management

The company KOLLANT S.r.l has requested renewal of the marketing authorisation in France for the product WARIOR EXTRA (formulation code: 0302449; marketing authorisation n° 2030071), 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 WARIOR EXTRA (0302449) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of WARIOR EXTRA (0302449) 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 WARIOR EXTRA (0302449).

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 WARIOR EXTRA (0302449) in France as a molluscicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the renewal of authorisation after approval of the active substance of this product in France and in other MSs of the Southern zone.

### 1.2 Active substance approval

#### Metaldehyde

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

Specific provisions of Regulation (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).

### 1.3 Regulatory approach

The present application (2013-1835, 2015-5685, 2018-0055) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)<sup>1</sup> 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”)<sup>2</sup> – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4th May 2017<sup>3</sup> 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 1107/2009<sup>4</sup>, implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011<sup>5</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014<sup>6</sup> provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>7</sup> is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national

<sup>1</sup> French Food Safety Agency, Afssa, before 1 July 2010

<sup>2</sup> 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

<sup>3</sup> 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

<sup>4</sup> 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

<sup>5</sup> 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

<sup>6</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo>

<sup>7</sup> SANCO document “guidance document: - Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

mitigation measures.

#### 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of WARIOR EXTRA (0302449) 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

A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

## 2 DETAILS OF THE AUTHORISATION

### 2.1 Product identity

<b>Product name (code)</b>	WARIOR EXTRA (0302449)
<b>Authorisation number</b>	2030071
<b>Function</b>	molluscicide
<b>Applicant</b>	KOLLANT S.r.l
<b>Composition</b>	50 g/kg metaldehyde
<b>Formulation type (code)</b>	granular bait (GB)
<b>Packaging</b>	Bags in PELD (15 Kg and 20 Kg), paper bag (20 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

<b>Physical hazards</b>	-	
<b>Health hazards</b>	Eye damage, cat 1	
<b>Environmental hazards</b>		
<b>Hazard pictograms</b>		
<b>Signal word</b>	Danger	
<b>Hazard statements</b>	H318	Causes serious eye damage
<b>Precautionary statements –</b>	<i>For the P phrases, refer to the extant legislation</i>	
<b>Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)</b>		

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).
SPe 6	To protect birds and wild mammals remove spillages.

### 2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment <sup>8</sup> : refer to the Decision in Appendix 1 for the details
Re-entry period <sup>9</sup> : not relevant
Pre-harvest interval <sup>10</sup> : <ul style="list-style-type: none"><li>- Strawberry (field), garlic, tomato (field &amp; greenhouse), aubergine (field &amp; greenhouse), melon, watermelon, peas and beans dry, rapeseed, sunflower, soybean, maize, millet, sorghum: F- Application must be made at growth stage BBCH [19] at the latest.</li><li>- Sugar beet: F- Application must be made at growth stage BBCH [19] at the latest. PHI 90 days.</li><li>- Pepper (field &amp; greenhouse): F- Application must be made at growth stage BBCH [49] at the latest.</li><li>- Peas with and without pods, beans with and without pods: Application must be made at growth stage BBCH [50] at the latest. PHI 28 days.</li><li>- Flowering brassica: F- Application must be made at growth stage BBCH [49] at the latest. PHI 7 days.</li><li>- Cereals (wheat, rye, triticale, barley, oats): F- Application must be made at growth stage BBCH [29] at the latest. PHI 60 days.</li></ul>
Other mitigation measures: <ul style="list-style-type: none"><li>- The formulation must be stored at temperature &lt; 35°C.</li></ul>
The label may include the following recommendations:
The label must reflect the conditions of authorisation.

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

<sup>9</sup> 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]

<sup>10</sup> 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:**

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.

GAP rev.1, date: 2018-11-02

PPP (product name/code): **WARIOR EXTRA (0302449)**  
Active substance 1: **metaldehyde**  
Applicant: **KOLLANT S.r.l**  
Zone(s): **southern**  
Verified by MS: **yes**  
Field of use: **molluscicide**

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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 <sup>(f)</sup>
					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		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													
1	France	Strawberry	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	<b>BBCH 00-19</b>	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	<b>Acceptable</b>
1 bis	France	Strawberry	G	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-41	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	<b>Non acceptable</b> (Exceedance of MRL)
2	France	Potatoes	F	Slugs and snails	Mechanica 1	BBCH 00-93	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	<b>Non acceptable</b> (lack of residue trials)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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								
3	France	Other root and tuber vegetables except sugar beet	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-45	2	7-14 days interval)	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	20	<b>Non acceptable</b> (lack of residue trials)
4	France	Onion, shallots	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	<b>Non acceptable</b> (lack of residue trials , exceedance of MRL)
4 bis	France	garlic	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	<b>Acceptable</b>
5	France	Tomatoes, aubergine	F/G	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	<b>Acceptable</b>
6	France	Pepper	F/G	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-49	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	<b>Acceptable</b>

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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		
7	France	Cucumber zucchini, gherkins	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	<b>Non acceptable</b> (Exceedance of MRL)
8	France	Melon, watermelon	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	<b>Acceptable</b>
9	France	Flowering brassica	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-49	2	7-14 days interval	a) 5.25 kg/ha b) 11.0 kg/ha	a) 262.5 g/ha b) 525 g/ha	-	7	<b>Acceptable</b>
10	France	Head brassica	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-49	2	7-14 days interval	a) 7.0 kg/ha b) 11.0 kg/ha	a) 350 g/ha b) 525 g/ha	-	3	<b>Non acceptable</b> (Exceedance of MRL)
11	France	Lettuce and other salad plants a incl. Brassicaceae, spinach and similar (leaves)	F/G	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	<b>Non acceptable</b> (lack of residue trials)
12	France	Legume (peas with and without pods, beans with and without pods)	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-50	2	(7-14 days interval)	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	28	<b>Acceptable</b>

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, 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		
13	France	Pulses (peas and beans, dry)	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2	(7-14 days interval)	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	<b>Acceptable</b>
14	France	Asparagus	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	-	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	20	<b>Non acceptable</b> (lack of residue trials)
15	France	Artichoke	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	-	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	20	<b>Non acceptable</b> (lack of residue trials)
16	France	Leek	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	-	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	20	<b>Non acceptable</b> (lack of residue trials)
17	France	Celery	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	-	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	<b>Non acceptable</b> (lack of residue trials, exceedance of MRL)
18	France	Rapeseed, sunflower, soya bean	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	<b>Acceptable</b>

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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		
19	France	Maize, millet, sorghum	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	F	Acceptable
20	France	Cereals (wheat, rye, triticale, barley, oats)	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-29	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	60	Acceptable
21	France	Sugar beet	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-19	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	a) 350 g/ha b) 700 g/ha	-	90	Acceptable
22	France	Ornamentals, floricultural crops, nurseries, seedlings and plantations	F	Slugs and snails	Mechanica 1 spreading, directed to the soil	BBCH 00-99	2	7-14 days interval	a) 7.0 kg/ha b) 14.0 kg/ha	- a) 350 g/ha b) 700 g/ha	-	-	Acceptable

**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008  
 (c) g/kg or g/L

(d) Select relevant  
 (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
 (f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

<b>Remarks</b>	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
<b>columns:</b>	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 <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

### 3 RISK MANAGEMENT

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

##### 3.1.1 Physical and chemical properties

WARIOR EXTRA (0302449) is a granule bait (GB) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a blue granular, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable and is not auto-flammable at ambient temperature.

In aqueous solution (1%), it has a pH value of 9.22 at 22°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 stability data indicate a shelf life of at least 2 years at ambient temperature when stored in LDPE.

Its technical characteristics are acceptable for a granular bait (GB) formulation.

The formulation is not classified for the physical-chemical part.

The formulation must be stored at temperature  $\leq 35^{\circ}\text{C}$ .

##### 3.1.2 Methods of analysis

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

Analytical methods for the determination of residues of metaldehyde are available in the monograph/Draft Assessment Report/this dossier and validated for the determination of residues of metaldehyde in plants, in soil in water (surface and drinking) and air.

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

To update:

According to the EFSA conclusions, 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.

In order to confirm that acetaldehyde is below the acceptable maximum limit, validation of the analytical method M858 at the  $\text{LOQ} \leq 0.007\%$  (w/w) for the determination of relevant impurity acetaldehyde in the formulation should be provided in post-authorisation.

##### 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 an in vitro human study performed on formulation :		
		Concentrate (tested) 50 g/kg	Spray dilution (tested)
	In vitro (human) %	0.6	-
	Concentrate	Spray dilution	

		(used in formulation) 50 g/L	(used in formulation)
	<b>Dermal absorption endpoints %</b>	<b>0.6</b>	-

### 3.1.3.1 Acute Toxicity

WARIOR EXTRA (0302449) containing 50 g/kg metaldehyde has a low toxicity in respect to acute oral and dermal toxicity. No acute inhalation study has been conducted because WARIOR EXTRA (0302449) is considered nearly dust free and none of the co-formulants are classified toxic by inhalation. The formulation is not irritating to skin, not a skin sensitiser, by calculation method. However, due to the new formulation (refer to PART C), WARIOR EXTRA (0302449) is classified for eye damage.

### 3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G <sup>11</sup>	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	6.4
	Hand-held equipment		6.0

According to the model calculations, it can be concluded that the risk for the operator using WARIOR EXTRA (0302449) 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

WARIOR EXTRA (0302449) is a granular bait formulation; no drift is expected. Therefore, bystander exposure estimation is considered not relevant.

### 3.1.3.4 Worker Exposure

WARIOR EXTRA (0302449) is a granular bait formulation; no work is expected to be practiced after application. Therefore, worker exposure estimation is considered not relevant.

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

### 3.1.4.1 Residues

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of metaldehyde as laid down in Reg (EU) n° 2015/400 is not expected except in indoor strawberry, cucumber, zucchini, gherkins, onion, shallots, celery and head cabbage in NEU (France).

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.

<sup>11</sup> Open field or glasshouse

**Data gaps**

Several uses are not acceptable in France because of a lack of residue trials: potato, root and tuber vegetables other than sugarbeet, Brussels sprout, onion, shallot, lettuce and other salad plants, spinach and similar, asparagus, artichoke, celery.

**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)	BBCH19 Field : Yes Indoor: No	Yes	Field: Yes Indoor: No	No	No	MRL exceedance indoor
2	Potatoes	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	Other root and tuber vegetables except sugar beet	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 "other root and tuber vegetables except sugar beet" cannot be made
4	Onion, Shallots, garlic	Yes	SEU: Yes (4 zero residue situation) NEU: No (2)	Yes in SEU	Yes	Yes	No	No	Only 2NEU trial with one of them the level of residue > LOQ and the MRL. GAPs not fully supported in France for onion and shallots  GAPs fully 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	Yes	Yes	Yes	No	No	
7	Cucumber, zucchini, gherkins	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	<b>Head cabbage</b> NEU: No (not compliant) SEU: Yes <b>Brussels sprout:</b> NEU: No (2) SEU: No(2)	Yes	Yes	<b>Head cabbage</b> NEU: No SEU: Yes <b>Brussels sprout</b> NEU: Yes SEU: Yes	No	No	GAP on head cabbage not supported in France GAP on Brussels sprout not supported in France

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
11	Lettuce and other salad plants including brassicaceae, spinach, and similar leaves	Yes	NEU: No (4) SEU : Yes Indoor: No (4)	Yes	Yes	Yes	No	No	Not supported in France
12	Legume (peas with and without pods, beans with and without pods)	Yes	Yes	Yes	Yes	Yes	No	No	
13	Pulses (peas and beans dry)	Yes	Yes	Yes	Yes	Yes	No	No	
14	Asparagus	Yes	NEU: No (0) SEU: Yes	Yes	Yes	Yes	No	No	Not supported in France
15	Artichoke	Yes	NEU: No (0) SEU: Yes	Yes	Yes	Yes	No	No	Not supported in France
16	Leek	Yes	NEU: No (4) SEU: Yes (4)	Yes	Yes	NEU : No SEU: Yes	No	No	Not supported in France
17	Celery	Yes	NEU: No (2) SEU: Yes	Yes	Yes	Yes	No	No	Not supported in France
18	Rapeseed, sunflower, soya bean	Yes	Yes	Yes	Yes	Yes	No	No	
19	Maize, millet, sorghum	Yes	Yes	Yes	Yes	Yes	No	No	
20	Cereals (wheat, rye, triticale, barley, oats)	Yes	Yes	Yes	Yes	Yes	No	No	
21	Sugar beet	Yes	Yes	Yes	Yes	Yes	No	No	
22	Ornamentals, floricultural crops, nurseries, seedings 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, DT<sub>90</sub> 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.

### Information on WARIOR EXTRA (0302449) (KCA 6.8)

Crop	PHI for WARIOR EXTRA (0302449) proposed by applicant	PHI/ Withholding period* sufficiently supported for	zRMS Comments (if different PHI proposed)
		metaldehyde	
strawberry	BBCH 41, PHI=F	Yes for field only at BBCH 19	No residue trials available at BBCH 41
Onion, shallots, garlic (2 x 345 g a.s./ha)	BBCH 19, PHI=F	No except garlic	Onion and shallots 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	
Cauliflower, broccoli (2x262.5 g/ha) France only	BBCH 49 , PHI=3 d	Yes	According to residue trials
Legume (pea with and without pod, bean with and without pod) (2 x 345 g a.s./ha)	BBCH 50, PHI=28 d	Yes	
Pulses (pea and bean dry) (2 x 345 g a.s./ha)	BBCH19, PHI=F	Yes	
Rapeseed, sunflower, saya, bean, (2 x 345 g a.s./ha)	BBCH19, PHI=F	Yes	
Maize, miller, sorghum (2 x 345 g a.s./ha)	BBCH 19, PHI=F	Yes	
Cereals (wheat, rye, triticale, barley, oats) (2 x 345 g a.s./ha)	BBCH 29, PHI=60 d	Yes	
Sugar beet (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<sub>SOIL</sub> and PEC<sub>SW</sub> derived for the active substance and its metabolite are used for the eco-toxicological risk assessment.

PEC<sub>GW</sub> for metaldehyde do not exceed the trigger of 0.1µg/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, type of formulation and DT<sub>50</sub> 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 WARIOR EXTRA (0302449), the field studies and the weight of evidence allow concluding that there is no unacceptable acute or reproductive risk to avian species (granivorous and slug-eating birds) from the application of WARIOR EXTRA (0302449) to target crops according to the proposed GAP.

On the same way, the risk assessment for mammals shows that the repellency property of WARIOR EXTRA (0302449), the field studies and the weight of evidence allow concluding that there is no unacceptable acute or reproductive risk to mammalian species (granivorous and slug-eating mammals) from the application of WARIOR EXTRA (0302449) 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 WARIOR EXTRA (0302449) according to the proposed GAP.

### 3.1.6 Efficacy

Considering the data submitted for the re registration of the preparation WARIOR EXTRA (0302449):

- ✓ The efficacy of WARIOR EXTRA (0302449) is still considered satisfactory in the claimed conditions,
- ✓ The selectivity of WARIOR EXTRA (0302449) is still considered acceptable in the claimed conditions, However, to prevent eventual risk of negative impact on quality due to retention of the pellets on the crop (negative impact on visual aspect), it is recommended not applying the preparation directly on harvested parts of plants.
- ✓ The risk of negative impact (yield, quality, transformation processes, propagation, succeeding crops, adjacent crops) is considered negligible,
- ✓ The risk of resistance development or appearance is considered low.

### **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**

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

#### **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
- In order to confirm that acetaldehyde is below the acceptable maximum limit, validation of the analytical method M858 at the LOQ  $\leq 0.007\%$  (w/w) for the determination of relevant impurity acetaldehyde in the formulation

#### **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 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 les demandes de renouvellement de l'autorisation de mise sur le marché, de changement de composition et d'ajout d'un nouvel emballage du produit phytopharmaceutique **WARIOR EXTRA***

*de la société KOLLANT S.R.L.*

*enregistrées sous les n°2013-1835, n°2015-5685 et n°2018-0055*

*Vu les conclusions de l'évaluation de l'Anses du 1<sup>er</sup> décembre 2017 relatives à la demande de renouvellement de l'autorisation et à la demande de changement de composition,*

*Vu les conclusions de l'évaluation de l'Anses du 14 juin 2018 relatives à la demande d'ajout d'un emballage,*

*Vu la décision du Directeur général de l'Anses du 11 juillet 2018,*

*Vu le recours gracieux formé le 16 août 2018 par la société ADAMA France SAS,*

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

La présente décision abroge et remplace la décision du 11 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	WARIOR EXTRA WARIOR BLUE CARAKOL BLUE METALIXON BLUE SKAELIM BLUE LIMARION B HELITOX B WARIOR QDX CARAKOL HELITOX QDX KOLFLOR LIMARION METALIXON SKAELIM
Type de produit	Produit de référence
Titulaire	KOLLANT S.R.L. Via Trieste 49/53 35121 PADOVA ITALIE
Formulation	Appât granulé (GB)
Contenant	50 g/kg - métaldéhyde
Numéro d'intrant	2030071
Numéro d'AMM	2030071
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 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)

WARIOR EXTRA  
AMM n°2030071

Page 2 sur 8



## ANNEXE I : Modalités d'autorisation du produit

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

<b>Classification du produit</b>	
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.	
<b>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.</b>	



**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 arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
11012903 Traitements généraux*Trt Sol*Limaces et escargots	7 kg/ha	2/an	entre les stades BBCH 00 et BBCH 19	90	-	-	-
	Uniquement sur betterave industrielle. Intervalle minimum entre les applications : 7 jours						
	7 kg/ha	2/an	entre les stades BBCH 00 et BBCH 19	F (BBCH 19)	-	-	-
	Uniquement sur ail, tomate, aubergine, melon, pastèque, pois et haricots secs, colza, tournesol, soja, maïs, millet, sorgho et fraisier. Également autorisé sous abri sur tomate et aubergine. Intervalle minimum entre les applications : 7 jours. Sur fraisier, diminution du stade maximal d'application de BBCH 41 à BBCH 19 et fixation d'un délai avant récolte de type F conformément aux essais résidus fournis. L'usage est retiré sur fraisier sous abri, oignon et échalote en raison d'un risque inacceptable de dépassement des LMR en vigueur pour le méthaldéhyde.						
	7 kg/ha	2/an	entre les stades BBCH 00 et BBCH 49	F (BBCH 49)	-	-	-
	Uniquement sur pois/vivron. Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.						
	7 kg/ha	2/an	entre les stades BBCH 00 et BBCH 99	Non applicable	-	-	-
	Uniquement sur cultures ornementales, floriculture et pépinière. Intervalle minimum entre les applications : 7 jours.						
	7 kg/ha	2/an	entre les stades BBCH 00 et BBCH 29	60	-	-	-
	Uniquement sur céréales à paille. Intervalle minimum entre les applications : 7 jours.						

WARIOR EXTRA  
AMM n°2030071



**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 arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
11012903 Traitements généraux**Trt Sol*Limaces et escargots	7 kg/ha	2/an	entre les stades BBCH 00 et BBCH 50	28	-	-	-
	Intervalle sur pois écosés frais, haricots écosés frais, haricots et pois non écosés frais. Intervalle minimum entre les applications : 7 jours.	5,25 kg/ha	2/an	entre les stades BBCH 00 et BBCH 49	7	-	-
	Uniquement sur chou à inflorescence. Intervalle minimum entre les applications : 7 jours. Le délai avant récolte est modifié de 3 jours à 7 jours conformément aux données résidus fournies. L'usage sur choux pommés est retiré en raison d'un risque inacceptable de dépassement des LMR en vigueur pour le méthaldéhyde.						

WARIOR EXTRA  
AMM n°2030071



**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><b>11012903</b> Traitements généraux*Trt Sol/Limacés et escargots</p>	7 kg/ha	2/an	-	11/01/2019	11/01/2020
<p><b>Motivation du retrait :</b> L'usage est retiré sur concombre, courgette et comichon avec un délai avant récolte F (BBCH19) en raison d'un risque inacceptable de dépassement des LMR en vigueur pour le métaldéhyde. L'usage est retiré laitue et autres salades, épinard et similaires et céleri-branche avec un délai avant récolte F (BBCH19), sur légumes racines et tuberculés avec un délai avant récolte F (BBCH45), sur pomme de terre avec un délai avant récolte F (BBCH93) et sur asperge, poireau et artichaut avec un délai avant récolte de 20 jours en raison d'un nombre insuffisant d'essais résidus fournis et d'un risque de dépassement des LMR en vigueur pour le métaldéhyde.</p>					

WARIOR EXTRA  
AMM n°2030071



## 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 dans le cadre d'une application effectuée à l'aide d'un microgranulateur manuel**

#### **• pendant le chargement du matériel d'épandage**

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester/coton 65 %/35 % (combinaison ou ensemble veste + pantalon) ;
- EPI partiel (blouse ou tablier à manches longues) 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'épandage**

- Gants certifiés EN 374-2 à usage unique en cas d'intervention sur le matériel d'épandage ;
- 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) ;
- EPI partiel (blouse ou tablier à manches longues) 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).

#### ***Pour le travailleur, porter***

- Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m<sup>2</sup>) et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

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

- Non applicable.

### **Respect des limites maximales de résidus (LMR)**

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



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

**Protection de l'eau**

- 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 11 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	Récurrence (mois)
Fournir une méthode analytique validée et son ILV pour la détermination des résidus de métaldéhyde dans les denrées d'origine animales.	11/07/2020	-
Fournir une méthode validée pour la détermination de l'impureté pertinente (acétaldéhyde) dans le produit.	11/07/2020	-
Fournir un suivi des effets aigus sur les populations d'oiseaux et de mammifères granivores.	11/07/2020	-



### **Appendix 3 – Letter(s) of Access**