

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: Malathion 10% w/w EC**

**Product name: CYLON**

**Active substance: malathion, 91.7 g/L**

**COUNTRY: FRANCE**

**Interzonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(new application)**

**Applicant: LODI S.A.S.**

**Date: 30/10/2018 (Decision)**

## 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 in accordance with Regulation (EC) No1272/2008</i>	5
2.2.2	<i>Other phrases in compliance with Regulation (EU) No 547/2011</i>	6
2.2.3	<i>Other phrases linked to the preparation</i>	6
2.3	PRODUCT USES	7
<b>3</b>	<b>RISK MANAGEMENT</b>	<b>8</b>
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES	8
3.1.1	<i>Physical and chemical properties</i>	8
3.1.2	<i>Methods of analysis</i>	8
3.1.3	<i>Mammalian Toxicology</i>	8
3.1.4	<i>Residues and Consumer Exposure</i>	10
3.1.5	<i>Environmental fate and behaviour</i>	10
3.1.6	<i>Ecotoxicology</i>	10
3.1.7	<i>Efficacy</i>	10
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT	11
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING	11
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	11
3.4.1	<i>Post-authorisation monitoring</i>	11
3.4.2	<i>Post-authorisation data requirements</i>	11
3.4.3	<i>Label amendments</i>	11
	<b>APPENDIX 1 – COPY OF THE FRENCH DECISION</b>	<b>12</b>
	<b>APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT</b>	<b>16</b>
	<b>APPENDIX 3 – LETTER(S) OF ACCESS</b>	<b>19</b>

## PART A – Risk Management

The company LODI S.A.S. has requested marketing authorisation in France for the product CYLON (product code: Malathion 10% w/w EC), containing 91.7 g/L malathion, for use as an insecticide.

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 CYLON (Malathion 10% w/w EC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of CYLON (Malathion 10% w/w EC) have been made using endpoints agreed in the EU peer review of malathion.

This document describes the specific conditions of use and labelling required for France for the registration of CYLON (Malathion 10% w/w EC).

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 LODI S.A.S.'s application to market CYLON (Malathion 10% w/w EC) in France as an insecticide (product uses described under point 2.3). France acted as an interzonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the European Union.

#### 1.2 Active substance approval

##### Malathion

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<sup>1</sup>.

Specific provisions of Regulation (EU) No 540/2011 were as follows:

##### PART A

Only uses as insecticide may be authorised. Authorisations shall be limited to professional users.

##### 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 malathion, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account.

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

- the operator and worker safety: conditions of use shall prescribe the use of adequate personal protective equipment;
- the protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones;
- the protection of insectivorous birds and honey bees: conditions of authorisation shall include risk mitigation measures, where appropriate. As regards bees, the necessary indications shall be provided on the labelling and

the accompanying instructions as to avoid exposure.

Member States shall ensure that malathion-based formulations are accompanied by the necessary instructions to avoid any risk of formation of isomalathion in excess of the permitted maximum quantities during storage and transport.

Where appropriate, conditions of authorisation shall include further risk mitigation measures.

The Member States concerned shall ensure that the notifier presents to the Commission:

- information confirming the consumer risk assessment and the acute and long-term risk assessment for insectivorous birds;
- information on the quantification of the different potency of malaoxon and malathion.

An EFSA conclusion is available (EFSA Scientific Report (2009) 333, 1-118, EFSA Scientific Report (2016), 1-61).

A Review Report is available (SANCO/10668/2009 final, 14 January 2010).

### 1.3 Regulatory approach

The present application (2016-0112) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)<sup>2</sup> in the context of the zonal procedure for all Member States of the European Union, taking into account the worst-case uses (“risk envelope approach”)<sup>3</sup> – the highest application rates over the European Union. 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 4 May 2017<sup>4</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>5</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>6</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014<sup>7</sup> provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the

<sup>2</sup> French Food Safety Agency, Afssa, before 1 July 2010

<sup>3</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>4</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 <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI1632554A/jo/texte>

<sup>5</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>6</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>7</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI1407093A/jo>

## 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>8</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 mitigation measures.

#### 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CYLON (Malathion 10% w/w EC), 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 of access.

## 2 DETAILS OF THE AUTHORISATION

### 2.1 Product identity

<b>Product name (code)</b>	CYLON (Malathion 10% w/w EC)
<b>Authorisation number</b>	Not applicable (not registered in France)
<b>Function</b>	Insecticide
<b>Applicant</b>	LODI S.A.S.
<b>Composition</b>	91.7 g/L malathion
<b>Formulation type (code)</b>	Emulsifiable concentrate (EC)
<b>Packaging</b>	N/A not registered in France

### 2.2 Classification and labelling

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

<b>Physical hazards</b>	-
<b>Health hazards</b>	Skin sensitisation, category 1B.
<b>Environmental hazards</b>	Hazardous to the aquatic environment, Acute Hazard, Category 1. Hazardous to the aquatic environment, Chronic Hazard, Category 1.
<b>Hazard pictograms</b>	
<b>Signal word</b>	Warning

<sup>8</sup> SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

<b>Hazard statements</b>	H317	May cause an allergic skin reaction.
	H400	Very toxic to aquatic life.
	H410	Very toxic to aquatic life with long-lasting effects.
<b>Precautionary statements –</b>	<i>For the P phrases, refer to the extant legislation</i>	

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

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

N/A: not registered in France.

### **2.2.3 Other phrases linked to the preparation**

N/A: not registered in France.

## 2.3 Product uses

**Please note:**

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

GAP rev. 1, date: 2018-10-30

**PPP (product name/code)** CYLON (Malathion 10% w/w EC)  
**active substance 1** malathion  
**Applicant:** LODI S.A.S.  
**Zone(s):** EU  
**Verified by MS:** yes

**Formulation type:** EC  
**Conc. of as 1:** 91.7 g/L  
**professional use**   
**non-professional use**

Crop and/or situation (a)	F or G or I (b)	Pest or group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI (days)(l)	Remarks: (m)	zRMS conclusion
			Type (d-f)	Conc. of a.s. (i)	Method, kind (f-h)	Growth stage (j)	Number (range) (k)	kg a.s./hL	water L/ha	g a.s./ha			
Stored cereals treatment	I	Stored cereals pests: <i>Tribolium</i> sp. (TRIBSP) <i>Sitotroga</i> sp. (SITTSP) <i>Sitophilus</i> (1SITOG) <i>Oryzaephilus</i> sp. (ORYZSP)	EC	91.7 g/L malathion	Ultra low volume fogging ULVA	Post-harvest	1	n.a. (applied undiluted)	n.a. (applied undiluted)	367 g/100 t	n.a. (post-harvest)	Treatment of stored cereals post-harvest before storage Application rate: 4 L/100 t	<b>Not acceptable (Residues):</b> Conformity with in force MRL cannot be established since no residue trials were submitted)
Storage facilities treatment	I	Various pests (including <i>Tyrophagus</i> sp. (TYROSP), <i>Tribolium</i> sp. (TRIBSP), <i>Stegobium</i> sp. (STEGSP), <i>Sitophilus</i> sp. (1SITOG), <i>Plodia</i> sp. (PLODSP), <i>Blattella</i> sp.(BLTTSP)	EC	91.7 g/L malathion	High-volume spraying /HVA	Post – harvest, before storage	1	0.459	5 L/100 m <sup>2</sup>	22.9 g/100 m <sup>2</sup>	n.a. (post-harvest)	Treatment of surfaces before storage Application rate: 0.250 L product in 5 L water/100 m <sup>2</sup>	<b>Not acceptable (Residues):</b> Conformity with in force MRL cannot be established since no residue trials were submitted)

**Remarks:**

(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)	(i)	g/kg or g/L
(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(j)	Growth stage at 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
(c)	e.g. biting and suckling insects, soil born insects, foliar fungi, weeds	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
(d)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(l)	PHI - minimum pre-harvest interval
(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989	(m)	Remarks may include: Extent of use/economic importance/restrictions
(f)	All abbreviations used must be explained		
(g)	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench		
(h)	Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated		

### 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

CYLON (Malathion 10% w/w EC, 91.7 g/L) is an emulsifiable concentrate (EC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of a homogeneous transparent yellowish liquid, with a light oily odour. It is not explosive and has no oxidising properties. The product has a flash point of 136 °C and a self-ignition temperature up to 220 °C. In aqueous solution (1 % dilution), it has a pH value around 5.4 at 25 °C. There is no effect of low and high temperature on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in a white HDPE-PA bottle of 1 L volume. Its technical characteristics are acceptable for an EC formulation.

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

##### 3.1.2 Methods of analysis

###### 3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of the active substance and the relevant impurities in the formulation are available and validated.

###### 3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and validated for the determination of residues of malathion in plants (dry content) and air.

Considering the intended uses (cereals), analytical methods for the determination of residues of malathion in soil and water (surface and drinking) are not necessary.

##### 3.1.3 Mammalian Toxicology

###### Endpoints used in risk assessment

Active Substance: <b>malathion</b>			
ADI	0.03 mg kg bw/d	EU (2010)	
ARfD	0.3 mg/kg bw		
AOEL	0.03 mg/kg bw/d		
Dermal absorption	Based on average dermal absorption of malathion in the study ranging from 5.5% to 15%, depending on the formulation. (worst case assumption, EFSA, 2009) :		
		Concentrate (used in formulation) 91.7 g/L	Spray dilution (used in formulation) 4.59 g/L (food storage facilities)
	<b>Dermal absorption endpoints %</b>	<b>5 %</b>	<b>15 %</b>

### 3.1.3.1 Acute Toxicity

CYLON (Malathion 10% w/w EC), containing 91.7 g/L malathion, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye but is a skin sensitiser.

The classification according to Regulation (EC) No 1272/2008 is shown in Section 2.2.2.

### 3.1.3.2 Operator Exposure

Considering the proposed uses, operator systemic exposure was estimated using the EFSA parameters for the mixing/loading phase from the EFSA model and the spraying model 1 from the TNsG User guidance (2002) dedicated to the assessment of biocidal products for low-pressure spray application of insecticides<sup>9</sup> :

Crop	Phases and equipments	PPE and/or working coverall	% AOEL malathion
Stored cereals	Mixing/loading	Gloves during mixing and loading	38.6
Food storage facilities treatment	Storage cell cleaning: Hand-held sprayer	Working coverall and gloves during and RPE (type P3) mixing/loading and application	77.4

According to the model calculations, it may be concluded that the risk for the operator using CYLON (Malathion 10% w/w EC) is acceptable with a working coverall (90 % protection factor), RPE type P3 and gloves during mixing/loading and application.

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

### 3.1.3.3 Bystander and Resident Exposure

Bystander and resident exposure is not expected when CYLON (Malathion 10% w/w EC) is applied according to the requested uses (specific enclosed spaces).

### 3.1.3.4 Worker Exposure

Workers are exposed when removing the remaining grain from the storage cell during emptying.

Workers can be in contact with contaminated dust during truck loading or when cleaning storage cells and their surroundings. They can also be in contact with the contaminated surfaces of the storage cells which have been treated (surface or volume). Inhalation exposure was compared with the minimum explosive concentration (MEC) for wheat of 65 g/m<sup>3</sup> (INRS, 2006<sup>10</sup>) and the eight-hour mean dust limit concentration in air of 10 mg/m<sup>3</sup> set for dust<sup>11</sup>. It may be concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers not wearing PPE when re-entering crops storage areas treated with CYLON (Malathion 10% w/w EC). However, the good practice in grain storage facilities is to use at least a simple dust mask during specific high-dust-exposure tasks, to prevent serious delayed allergic reactions.

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

<sup>9</sup> [https://echa.europa.eu/documents/10162/16960215/bpd\\_guid\\_tnsg+human+exposure+2002\\_en.pdf](https://echa.europa.eu/documents/10162/16960215/bpd_guid_tnsg+human+exposure+2002_en.pdf)

<sup>10</sup> J.M. Petit (2006) Les mélanges explosifs – 2. Poussières combustibles Institut National de Recherche et de Sécurité (INRS)- ED 944 - <http://www.inrs.fr/accueil/produits/mediatheque/doc/publications.html?refINRS=ED%20944>

<sup>11</sup> Code du travail, Article R. 4222-10, <https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072050&idArticle=LEGIARTI000018488888&dateTexte=&categorieLien=cid>

### 3.1.4 Residues and Consumer Exposure

**The data available are considered insufficient for risk assessment. Conformity with the MRL cannot be done since no residue trials were submitted.**

In addition, confirmatory data were requested on relevant metabolites when malathion was approved and EFSA considers that the submitted confirmatory data (2016<sup>12</sup>) do not address the requirements. The RMS and EFSA agree that the consumer risk assessment can only be finalised after definite agreement on the residue definition for risk assessment and on appropriate toxicological potency factors to consider the metabolites in the residue definition. For this purpose an expert consultation is deemed necessary to appropriately discuss and agree on the different issues identified during the confirmatory data review process.

A revised risk assessment would be needed once the residue definition has been concluded on.

### 3.1.5 Environmental fate and behaviour

Considering the intended uses for the formulation CYLON (Malathion 10% w/w EC), exposure of environmental compartments to the active substance is considered negligible. Consequently, no risk assessment for the environment and non-target organisms is deemed necessary.

### 3.1.6 Ecotoxicology

See 3.1.5

### 3.1.7 Efficacy

The data package provided for the evaluation of CYLON (Malathion 10% w/w EC) **efficacy is considered insufficient**. A conclusion cannot therefore be finalised, for all the requested uses.

The risks of negative impact on grain quality, propagation and transformation processes (bread-making and brewing) are considered negligible.

The risk of resistance developing or appearing to malathion does not require monitoring, for all the requested uses.

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<sup>12</sup> EFSA Scientific Report (2016),1-61, outcome of the consultation with member states, the applicant and EFSA on the pesticide risk assessment for malathion in light of confirmatory data.

### **3.2 Conclusions arising from French assessment**

Taking into account the above assessment, **an authorisation cannot be granted, due to insufficient residue and data**. A copy of the Decision issued can be found in Appendix 1 – Copy of the product Decision.

### **3.3 Substances of concern for national monitoring**

No information stated.

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

#### **3.4.1 Post-authorisation monitoring**

N/A.

#### **3.4.2 Post-authorisation data requirements**

N/A.

#### **3.4.3 Label amendments**

N/A

## Appendix 1 – Copy of the French Decision



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

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

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

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **CYLON***

*de la société LODI*

*enregistrée sous le n°2016-0112*

*Vu les conclusions de l'évaluation de l'Anses du 16 octobre 2018,*

*Considérant qu'aucun essai résidu n'ayant été fourni, le respect des limites maximales de résidus en vigueur pour le malathion, ainsi que l'absence de risque pour le consommateur n'ont pu être vérifiés,*

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

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



Informations générales sur le produit	
Nom du produit	CYLON
Type de produit	Produit de référence
Titulaire	LODI PARC D'ACTIVITES des 4 ROUTES 35390 GRAND FOUGERAY France
Formulation	Concentré émulsionnable (EC)
Contenant	91,7 g/L - malathion
Numéro d'intrant	068-2016.01
Numéro d'AMM	-
Fonction	Insecticide
Gamme d'usage	Professionnel

A Maisons-Alfort le, **3 0 OCT. 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)



### ANNEXE I : Conditions de mise sur le marché demandé

Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
<b>15104901</b> Céréales*Trt Prod. Réc. *Conserv. Grains	4 L/100 t	1/an	-
<b>Motivation du refus :</b> L'usage est refusé au motif que, en l'absence de données résidus, le respect des limites maximales de résidus en vigueur pour le malathion, ainsi que l'absence de risque inacceptable pour le consommateur n'ont pu être vérifiés.			
<b>15104108</b> Céréales*Trt Prod. Réc.*Ravagateurs des denrées stockées	4 L/100 t	1/an	-
<b>Motivation du refus :</b> L'usage est refusé au motif que, en l'absence de données résidus, le respect des limites maximales de résidus en vigueur pour le malathion, ainsi que l'absence de risque inacceptable pour le consommateur n'ont pu être vérifiés.			

CYLON  
AMM n°.

Page 3 sur 4



Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
11016102 Traitements généraux* Désinsectisation* L ocx Struct. Matér. (POV)	0,25 L/100 m <sup>2</sup>	1/an	-
<b>Motivation du refus :</b> L'usage est refusé au motif que, en l'absence de données résidus, le respect des limites maximales de résidus en vigueur pour le malathion, ainsi que l'absence de risque inacceptable pour le consommateur n'ont pu être vérifiés.			

CYLON  
AMM n°.

Page 4 sur 4

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

# CYLON

Substance active : Malathion 91.7 g/L (10.0% m/m)

Formulation : EC (concentré émulsionnable)

A.M.M. N°XXXXXXX

Détenteur de l'A.M.M. : LODI S.A.S., Parc d'Activités des quatre routes, 35390 Grand Fougeray

Usages et doses autorisés :

Usage	Principaux organismes nuisibles	Dose homologuée	Nombre maximal d'application par an
Céréales * Traitement des produits récoltés * Ravageurs des denrées stockées	Ver de farine ( <i>Tribolium</i> ), Capucins, Charançons, Teigne (Alucite), Sylvains...	4 L/100 t de grain	1
Céréales * Traitement des produits récoltés * Conservation des grains		4 L/100 t de grain	1
Traitements généraux* Désinsectisation* Locx Struct. Matér. (POV)	Acariens, Blattes, Charançons, Teigne ( <i>Plodia</i> ), Ver de farine ( <i>Tribolium</i> ), Vrillette...	0.25 L dans 5 L d'eau pour 100 m <sup>2</sup>	1

POV : Produits d'Origine Végétale

Réservé strictement aux utilisateurs professionnels.

### Limites maximales de résidus :

Les LMR sont consultables à l'adresse suivante : [http://ec.europa.eu/sanco\\_pesticides/public/index.cfm](http://ec.europa.eu/sanco_pesticides/public/index.cfm)

### Mode d'emploi :

Cylon est un insecticide liquide à appliquer pur ou dans de faibles volumes d'eau (5 L d'eau pour 100 m<sup>2</sup>). Agiter avant l'emploi.

Effet choc : le malathion entraîne la mort des insectes traités très rapidement.

Rémanence sur grains traités : peut avoir une rémanence de 3 mois sur certaines populations d'insectes (observé sur *Sitophilus oryzae* suite à une exposition de 7 à 90 jours débutée jusqu'à 90 jours après traitement).

Rémanence sur surfaces traitées : les insectes, même exposés jusqu'à 13 semaines après le traitement, sont suffisamment contrôlés, et jusqu'à 26 semaines sur certaines espèces.

### Précautions d'emploi :

Traitement direct des grains stockés :

#### Pour protéger l'opérateur :

Pendant le chargement (lors de la connexion du bidon à l'appareil de traitement et lors de la déconnexion de l'appareil), porter :

- Gants en nitrile certifiés pour la protection chimique EN 374-3,
- Combinaison de travail en polyester 65% / coton 35% avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant,
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.
- Bottes de protection conformes à la réglementation et selon la norme EN 13 832-3.

*Traitement des locaux de stockage :*

Pour protéger l'opérateur :

Pendant le mélange/chargement, l'application et le nettoyage du matériel de pulvérisation, porter :

- Gants en nitrile certifiés pour la protection chimique EN 374-3,
- Combinaison de travail en polyester 65% / coton 35% avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant,
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée,
- Bottes de protection conformes à la réglementation et selon la norme EN 13 832-3.

*Protection du travailleur :*

Dans le cas où le travailleur serait amené à intervenir sur les zones de stockage traitées, porter :

- Gants en nitrile certifiés pour la protection chimique EN 374-3,
- Combinaison de travail en polyester 65% / coton 35% avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant,
- Bottes de protection conformes à la réglementation et selon la norme EN 13 832-3,
- Masque anti-poussière conforme à la réglementation et selon les normes EN 143 et EN 149, soit au minimum certifié FFP1 ou P1.

Dans tous les cas, nettoyer le matériel après chaque utilisation. Se laver les mains après chaque manipulation.

**Premiers secours :**

En cas de contact avec la peau :

Enlever immédiatement les vêtements et les chaussures contaminés. Rincer la peau avec beaucoup d'eau. Laver à l'eau et au savon. Consulter un médecin si des symptômes se développent.

En cas de contact avec les yeux :

En cas de contact avec les yeux, laver immédiatement et abondamment à l'eau et consulter un spécialiste.

Retirer les lentilles de contact. Consulter un médecin si l'irritation persiste.

En cas d'ingestion :

Laisser la personne exposée se rincer la bouche, mais ne faire vomir en aucun cas. En cas de vomissement, rincer la bouche. Ne jamais rien faire avaler à une personne inconsciente.  
CONSULTER IMMÉDIATEMENT UN MÉDECIN.

En cas d'inhalation :

Transporter la victime à l'extérieur et la maintenir au chaud et au repos.

Consulter immédiatement un médecin si des symptômes apparaissent.

Conserver dans le récipient d'origine et ne pas réutiliser l'emballage.

L'emballage et le produit doivent être éliminés en tant que déchets dangereux sous l'entière responsabilité du détenteur de ce déchet.

Résistance :

Il existe un risque général d'apparition d'insectes résistant aux insecticides. Afin de limiter ce risque, il convient de respecter les préconisations d'emploi de cette étiquette (dose, conditions d'application...) et, à chaque fois que c'est possible, de varier les substances chimiques et d'alterner avec des produits à mode d'action différent.

 Attention	<b>Cylon</b> Composants : Malathion (CAS n°121-75-5) : 91.7 g/L
	H317 Peut provoquer une allergie cutanée. H410 Très toxique pour les organismes aquatiques, entraîne des effets à long terme EUH401 Respecter les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement. P261 Éviter de respirer les brouillards. P273 Éviter le rejet dans l'environnement. P280 Porter des gants de protection et des vêtements de protection. P302 + P352 En cas de contact avec la peau : laver abondamment à l'eau et au savon. P333 + P313 En cas d'irritation ou d'éruption cutanée : consulter un médecin. P501 Éliminer le contenu/réceptacle suivant les exigences locales, régionales, nationales ou internationales. SP1 Ne pas polluer l'eau avec le produit ou son emballage. Délai de rentrée dans les locaux traités : 48 heures après traitement
	
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En cas d'urgence, appelez le 15 ou le centre anti-poison puis signalez vos symptômes au réseau Phyt'attitude, N° vert 0 800 887 887 (appel gratuit depuis un poste fixe).  
Fiche de Données de Sécurité disponible sur demande.

N° de lot : voir emballage

Date de péremption : voir emballage

Quantité nette de produit : 1 L – 5 L – 10 L – 25 L – 200 L – 1000 L

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

Provided upon request.