REGISTRATION REPORT

Part A

Risk Management

Product code: Garland

Product name: GARLAND

Active substance:

garlic extract, 80% w/w

COUNTRY: FRANCE

Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: **OMEX International Ltd**

Date: **2019/04/19**

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PART A – Risk Management

The company OMEX International Ltd has requested marketing authorisation in France for the product GARLAND (product code: Garland), containing 800 g/kg garlic extract, for use as a nematicide.

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 GARLAND/(product code: Garland) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of GARLAND/(product code: Garland) have been made using endpoints agreed in the EU peer review of garlic extract.

This document describes the specific conditions of use and labelling required for France for the registration of GARLAND/(product code: Garland).

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 OMEX International Ltd’s application to market GARLAND/(product code: Garland) in France as a nematicide (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

Garlic extract

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 repellent, insecticide and nematicide 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 garlic extract (SANCO/2612/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
An EFSA conclusion is available (EFSA Journal 2012;10(2):2520). A Review Report is available (SANCO/2612/08 – rev. 1 revised 14 July 2015).

1.3 Regulatory approach

The present application (2014-2290) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) 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")[1] – 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[2] 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[3], 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[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[5] provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] is to supply "minor" crops with registered plant protection products.

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

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

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1 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

2 Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

3 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

4 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

5 http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of GARLAND/(product code: Garland), 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

Not necessary: the active substance garlic extract is an existing substance approved under Directive 91/414/EEC.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	GARLAND (product code: Garland).
Authorisation number	2190200
Function	Nematicide
Applicant	OMEX International Ltd.
Composition	800 g/kg garlic extract.
Formulation type (code)	Suspension concentrate (SC).
Packaging	Polyethylene high density containers (1 L, 5 L)

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	Skin sensitisation, Category 1. Eye irritation, Category 2.	
Environmental hazards	-	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H319	Causes serious eye irritation.
	H317	May cause an allergic skin reaction.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	

Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

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

2.2.2 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).

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment[7]: refer to the Decision in Appendix 1 for the details.
Re-entry period[8]: N/A
Pre-harvest interval[9]: 1 day.
Other mitigation measures: -
The label may include the following recommendations: - The product must be stored at a temperature below 40 °C. The label must reflect the conditions of authorisation.

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

[8] 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]

[9] 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 izRMS. Those uses are then granted in France.

GAP rev. 2019-04-19

PPP (product name/code)	**GARLAND/(product code:**	**Formulation type:**	**Suspension concentrate (SC)**
Garland)		**Conc. of a.s. 1:**	**800 g/kg**
active substance 1	**garlic extract**		
Applicant:	**OMEX International Ltd**	**professional use**	☒
Zone(s):	**EU**	**non-professional use**	☐
Verified by MS:	**yes**		

Crop and/ or situation (a)	**Zone**	**Product code**	**F G or I (b)**	**Pests or Group of pests controlled (c)**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days) (l)**	**Remarks: (m)**
					Type (d-f)	**Conc. of a.s. (i)**	**method kind (f-h)**	**growth stage & season (j)**	**number min max (k)**	**interval between applications (min)**	**kg a.s./hL min max**	**water L/ha min max**	**kg a.s./ha min max**		**RMS Conclusion**
Tomatoes Eggplant	France	GARLAND	G	Root-knot nematodes (*Meloidogyne* spp.)	SC	80 % w/w garlic extract	Soil in-row drip irrigation	BBCH 00 up to 89	5	21 days	5 L/ha at transplant; 1 – 5 L/ha thereafter	5000 – 20 000	4 20	1	Acceptable

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)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(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
(i) g/kg or g/l
(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
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) 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

GARLAND/(product code: Garland) is a suspension concentrate formulation (SC). 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 slightly viscous orange/brown-coloured liquid, with a darker orange layer and an oil-like appearance throughout. It has a strong garlicky odour. It is not explosive and has no oxidising properties. The product is not flammable and has a flash point > 100 °C. It has a self-ignition temperature > 400 °C. In aqueous solution (1 %), it has a pH value of 5.3 at ambient temperature. There is no effect of low and high temperatures on the stability of the formulation, since after 7 days at 0 °C and 8 weeks at 40 °C, neither the active substance 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 PE. Its technical characteristics are acceptable for an SC formulation.

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

The formulation must be stored at a temperature below 40 °C.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methodology for the determination of the active substance in the formulation is available and validated. As the active substance does not contain any relevant impurity, no analytical method is required.

3.1.2.2 Analytical methods for residues

As no MRL is required, no analytical method for the determination of residues of garlic extracts in plants and in food of animal origin is necessary.

Garlic extracts and metabolites occur naturally in plant tissue; analytical methods for their determination of residues in soil, water and air are not necessary.

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

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active substance: garlic extract		
ADI	3 mg/kg bw/d	EU (09/01/2009)
ARfD	Not applicable	
AOEL	Not applicable	
AAOEL	Not applicable	

3.1.3.1 Acute Toxicity

GARLAND/(product code: Garland)containing 891.2 g/L garlic extract has a low acute oral and inhalational toxicity, is not irritating to the rabbit skin but is irritating to the eye and is a skin sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[10]	Equipment Application method	Maximum application rate kg a.s./ha	Minimum volume water (L/ha)
Fruiting vegetables	G	Soil in-row drip irrigation	8.912	5000

The EFSA model is not suitable for calculating a risk assessment for operators on the basis of a non-existent dose-effect relationship.

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

3.1.3.3 Bystander Exposure

Following the reasons given above for not estimating the operator risk, this also applies to bystanders. As regards the application method, bystander exposure is not considered relevant for greenhouse uses.

3.1.3.4 Worker Exposure

Garlic extract is not toxic; an unacceptable risk for the worker wearing appropriate protection equipment is not expected.

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

3.1.3.5 Resident Exposure

Following the reasons given above for not estimating the operator risk, this also applies to residents. As regards the application method, residential exposure is not considered relevant for greenhouse uses.

3.1.4 Residues and Consumer Exposure

It was concluded by EFSA (2012[11]) that the proposed application rates would lead to much lower polysulfide levels than the amounts naturally occurring in the field when growing *Allium* crops.

The mode of application of the preparation (to the soil) prevents any contact with edible parts (tomatoes).

There are thus no areas of concern or data gaps identified.

No MRL is required; garlic extract is included in the Annex IV of Commission Regulation (EC) No 396/2005.

3.1.5 Environmental fate and behaviour

The predicted environmental concentration (PEC) of garlic extract in soil has been assessed according to FOCUS guidance documents. The PECsoil value derived for the active substance is used for the ecotoxicological risk assessment.

Considering the intended use for the preparation GARLAND/(product code: Garland) (glasshouse only), exposure of the groundwater compartment to the active substance is considered negligible. Consequently, no risk assessment for groundwater is deemed necessary.

[10] Open field or glasshouse
[11] EFSA Conclusion, *op. cit.*

Considering the intended use (greenhouse) and the application method (via drip irrigation system), it may be considered that exposure to surface water is non-relevant. Consequently, no risk assessment for non-target aquatic organisms is deemed necessary.

3.1.6 Ecotoxicology

The risk was assessed for birds, mammals, aquatic organisms, arthropods, earthworms, other soil non-target macro-organisms and non-target plants, in accordance with ongoing regulatory guidance documents and requirements. There is no unacceptable risk for the requested use.

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its metabolites were used 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.

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms are acceptable for the intended use.

The exposure of aquatic organisms is considered negligible and no risk assessment for non-target aquatic organisms is deemed necessary.

3.1.7 Efficacy

The product complies with the Uniform Principles.

Considering the data submitted:

- the efficacy of GARLAND/(product code: Garland) is considered satisfactory;
- the selectivity of GARLAND/(product code: Garland) is considered satisfactory;
- the risk of negative impact (on yield, quality, succeeding and adjacent crops) is considered acceptable;
- the risk of resistance developing or appearing is considered to be very 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

No further information is required.

3.4.2 Post-authorisation data requirements

None.

3.4.3 Label amendments

The draft label proposed by the applicant in Appendix 2 must 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 must reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

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

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

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

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

de la société *OMEX INTERNATIONAL LTD*

enregistrée sous le *n°2014-2290*

Vu les conclusions de l'évaluation de l'Anses du 1er avril 2019,

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.

GARLAND
AMM n°2190200

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Informations générales sur le produit	
Nom du produit	GARLAND
Type de produit	Produit de référence
Titulaire	OMEX INTERNATIONAL LTD c/o Conyers Dill & Pearman PO Box 391 2 Church Street Clarendon House Hamilton,HM11 Bermudes
Formulation	Suspension concentrée (SC)
Contenant	800 g/kg - extrait d'ail
Numéro d'intrant	9616-2014.01
Numéro d'AMM	2190200
Fonction	Nématicide
Gamme d'usage	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 août 2021.

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, 19 AVR. 2019

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)

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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**
Bouteilles en polyéthylène Haute densité	1 L
Bidons en polyéthylène Haute densité	5 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Sensibilisants cutanés - Catégorie 1	H317 : Peut provoquer une allergie cutanée
Lésions oculaires graves et irritation oculaire - Catégorie 2	H319 : Provoque une sévère irritation des yeux
Pour les phrases P se référer à la règlementation 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.**	

GARLAND
AMM n°2190200

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Liste des usages autorisés
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
16952501 Tomate*Trt Sol*Nématodes	**5 L/ha**	**5/an**	entre les stades BBCH 00 et BBCH 89	1	-	-	-	-
	Uniquement autorisé sous abri. Application uniquement *via* le système d'irrigation en goutte à goutte. Efficacité montrée sur *Meloidogyne spp.* Intervalle minimum entre les applications : 21 jours.							

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Conditions d'emploi du produit

Stockage et manipulation du produit

Ne pas stocker le produit dans un local où la température peut dépasser 40°C.

Protection de l'opérateur et du travailleur

Pour l'opérateur, porter
Dans le cadre d'une application effectuée *via* le système d'irrigation en goutte à goutte

• pendant le mélange/chargement
- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application) ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

• pendant le nettoyage du matériel d'irrigation
- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail 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.

Pour le travailleur, porter
Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant et des gants en nitrile certifiés EN 374-3.

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.

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

Garland
Nematicide

Content: x.x L

Approval number: xXxXxX

Formulation type: Suspension concentrate (SC)
Active substance: Garlic extract
Concentration: 80% w/w

Warning

H319	Causes serious eye irritation
P264	Wash hands thoroughly after handling.
P280	Wear eye / face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.
EUH401	To avoid risks to human health and the environment, comply with the instructions for use.

INSTRUCTIONS FOR USE

Garland is a nematicide for the control of root-knot nematode (*Meloidogyne* spp.) in tomato.
Garland is applied by means of drip irrigation and protects the crop from transplanting on.
Apply a dose rate of 5-10 L/ha at transplanting, followed by 1 L/ha at a 21- to 42-day interval.

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Tupholme
Lincoln
LN3 5TP
United Kingdom
enquire@omex.com

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Appendix 3 – Letter(s) of Access

Not applicable.