

REGISTRATION REPORT

Part A

Risk Management

Product code: CLAIL0021

Product name(s): NEMGUARD SC

Chemical active substance(s):

Garlic extract, 100% w/w

Southern zone and Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: CBC (Europe) S.r.l.

Date: 01/08/2024

Table of Contents

1	Details of the application	4
1.1	Application background.....	4
1.2	Letters of Access.....	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorisation decision	5
2.1	Product identity.....	5
2.2	Conclusion	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling.....	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011.....	6
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009).....	6
2.5	Risk management.....	6
2.5.1	Restrictions linked to the PPP.....	7
2.5.2	Specific restrictions linked to the intended uses.....	8
2.6	Intended uses (only NATIONAL GAP)	9
3	Background of authorisation decision and risk management	13
3.1	Physical and chemical properties (Part B, Section 2).....	13
3.2	Efficacy (Part B, Section 3)	13
3.3	Methods of analysis (Part B, Section 5).....	13
3.3.1	Analytical method for the formulation	13
3.3.2	Analytical methods for residues.....	14
3.4	Mammalian toxicology (Part B, Section 6)	14
3.4.1	Acute toxicity.....	14
3.4.2	Operator exposure.....	14
3.4.3	Worker exposure.....	14
3.4.4	Bystander exposure.....	15
3.4.5	Resident exposure	15
3.4.6	Combined exposure	15
3.5	Residues and consumer exposure (Part B, Section 7).....	15
3.6	Environmental fate and behaviour (Part B, Section 8)	16
3.7	Ecotoxicology (Part B, Section 9)	17
3.8	Relevance of metabolites (Part B, Section 10)	17
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	17

5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....	17
5.1.1	Post-authorisation monitoring.....	17
5.1.2	Post-authorisation data requirements.....	17
Appendix 1	Copy of the product authorisation	18
Appendix 2	Copy of the product label.....	25

PART A

RISK MANAGEMENT

1 Details of the application

The company CBC (Europe) S.r.l. has requested a marketing authorisation in France for the product NEMGUARD SC (product code: CLAIL0021), containing 100% garlic extract¹ as a nematicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of CBC (Europe) Srl's application submitted on 30/05/2022 to market NEMGUARD SC (CLAIL0021) in France (product uses described under point 2.3). France acted as a interzonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the European Union.

The present application (2022-2581) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone for field uses and for all MSs of the European Union for uses under protection, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of NEMGUARD SC (CLAIL0021) has been made using endpoints agreed in the EU peer review of garlic extract. It also includes assessment of data and information related to NEMGUARD SC (CLAIL0021) where those data have not been considered in the EU peer review process.

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 risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

¹ Commission Implementing Regulation (EU) 2021/129 of 3 February 2021 renewing the approval of the active substance garlic extract in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

² 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

³ 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](#)

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

CLAIL0021 / NEMGUARD SC
Part A - National Assessment
FRANCE

This document also describes the specific conditions of use and labelling required for France for the registration of NEMGUARD SC (CLAIL0021).

1.2 Letters of Access

The owner of data which support the renewal of approval of the active substance as provided the Letter of Access to the applicant.

1.3 Justification for submission of tests and studies

According to the applicant: « In addition to the submission of studies as listed in each section(s) of the dRR, no exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009. Only new studies that has not been evaluated during the peer review process are submitted. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of NEMGUARD SC (CLAIL0021), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	CLAIL0021
Product name in MS	NEMGUARD SC
Authorisation number	2240384
Kind of use	Professional use
Low risk product (article 47)	No
Function	nematicide
Applicant	CBC (Europe) Srl
Active substance(s) (incl. content)	Garlic extract, 100% w/w
Formulation type	Soluble concentrate [SC]
Packaging	HDPE (1L, 5L)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

CLAIL0021 / NEMGUARD SC
Part A - National Assessment
FRANCE

2.2 Conclusion

The evaluation of the application for NEMGUARD SC (CLAIL0021) resulted in the decision **to grant** the authorisation.


2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Skin sensitisation, category 1B Not classified for the environment
Hazard pictograms:	 GHS07
Signal word:	Warning
Hazard statement(s):	H317: May cause an allergic skin reaction.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	-

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

2.4.2 Standard phrases under Regulation (EU) No 547/2011

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.
	For other restrictions refer to 2.5

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

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

The French Order of 4 May 2017⁵ provides that:

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

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

Moreover, the French Order of 12 April 2021⁶ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” 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 “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ is to supply “minor” crops with registered plant protection products.

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

Finally, the French Order of 20 November 2021⁸ on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop⁹ when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

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

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.

⁵ 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, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

⁶ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

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

⁸ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

⁹ List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

CLAIL0021 / NEMGUARD SC
 Part A - National Assessment
 FRANCE

Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
	-
Other specific restrictions	
Re-entry period	48 hours.
Storage	-
SPa 1	-
Risk mitigation measures	No risk mitigation measure.
Risk mitigation measures	-
Agricultural recommendations	- The product efficacy level being variable and partial, specify the optimal conditions of use. - Specify the optimal conditions of use to prevent any risk to biological control beneficials when implementing an integrated biological protection program.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

CLAIL0021 / NEMGUARD SC
Part A - National Assessment
FRANCE

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as izRMS. Those uses are then granted in France.

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

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

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

GAP rev. 1, date: 2024-08-01

PPP (product name/code): NEMGUARD SC (CLAIL0021)

Formulation type: Suspension Concentrate (SC) (a,b)

Active substance 1: Garlic extract (purity: 1000 g/kg)

Conc. of as 1: 100% (c)

Applicant: CBC (Europe) S.r.l., Italy

Professional use:

Zone(s): Southern zone/interzonal (d)

Non professional use:

Verified by MS: yes

Field of use: nematocide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha (f) RMS CONCLUSION
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val be- tween ap- plications (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		

CLAIL0021 / NEMGUARD SC

Part A - National Assessment

FRANCE

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	France	Tomato (LYPES), eggplant (SOLME), bell pepper (CPSAN)	F	All free-living stages of plant parasitic nematodes belonging to the genera <i>Meloidogyne</i> (1MELGG), <i>Tylenchus</i> (1TYLNG), <i>Trichodorus</i> (1TRIHG), <i>Longidorus</i> (1LONGG), <i>Pratylenchus</i> (1PRATG), <i>Xiphinema</i> (1XIPHG), <i>Globodera</i> (1GLOBG), <i>Heterodera</i> (1HETG)	Application via any type of drip, handheld, or other irrigation system before, at transplanting/sowing and post-planting/sowing	BBCH 00 – BBCH 89	a) 6 b) 6	10	a) 4.0 L/ha b) 24.0 L/ha	a) 5.40 kg as/ha b) 30.84 kg as/ha	1,000 – 30,000	Not necessary	Product dosage: 2-4 L/ha. Average density: 1.285 kg/L. Acceptable (Efficacy demonstrated on <i>Meloidogyne</i> (1MELGG))
2	France	Cucurbits with edible peel: cucumber (CUMSA), zucchini (CUUPG)	F	All free-living stages of plant parasitic nematodes belonging to the genera <i>Meloidogyne</i> (1MELGG), <i>Tylenchus</i> (1TYLNG), <i>Trichodorus</i> (1TRIHG), <i>Longidorus</i> (1LONGG), <i>Pratylenchus</i> (1PRATG), <i>Xiphinema</i> (1XIPHG), <i>Globodera</i> (1GLOBG), <i>Heterodera</i> (1HETG)	Application via any type of drip, handheld, or other irrigation system before, at transplanting/sowing and post-planting/sowing	BBCH 00 – BBCH 89	a) 6 b) 6	10	a) 4.0 L/ha b) 24.0 L/ha	a) 5.40 kg as/ha b) 30.84 kg as/ha	1,000 – 30,000	Not necessary	Product dosage: 2-4 L/ha. Average density: 1.285 kg/L. Acceptable (Efficacy demonstrated on <i>Meloidogyne</i> (1MELGG))
3	France	Cucurbits with inedible peel: melon (CUMME), watermelon (CITLA), pumpkin (CUUPE)	F	All free-living stages of plant parasitic nematodes belonging to the genera <i>Meloidogyne</i> (1MELGG), <i>Tylenchus</i> (1TYLNG), <i>Trichodorus</i> (1TRIHG), <i>Longidorus</i> (1LONGG), <i>Pratylenchus</i> (1PRATG), <i>Xiphinema</i> (1XIPHG), <i>Globodera</i> (1GLOBG), <i>Heterodera</i> (1HETG)	Application via any type of drip, handheld, or other irrigation system before, at transplanting/sowing and post-planting/sowing	BBCH 00 – BBCH 89	a) 6 b) 6	10	a) 4.0 L/ha b) 24.0 L/ha	a) 5.40 kg as/ha b) 30.84 kg as/ha	1,000 – 30,000	0 days	Product dosage: 2-4 L/ha. Average density: 1.285 kg/L. Acceptable (Efficacy demonstrated on <i>Meloidogyne</i> (1MELGG))

CLAIL0021 / NEMGUARD SC
Part A - National Assessment
FRANCE

Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
4	France	Tomato (LYPES), eggplant (SOLME), bell pepper (CPSAN)	G	All free-living stages of plant parasitic nematodes belonging to the genera <i>Meloidogyne</i> (1MELGG), <i>Tylenchus</i> (1TYLNG), <i>Trichodorus</i> (1TRIHG), <i>Longidorus</i> (1LONGG), <i>Pratylenchus</i> (1PRATG), <i>Xiphinema</i> (1XIPHG), <i>Globodera</i> (1GLOBG), <i>Heterodera</i> (1HETG)	Application via any type of drip, handheld, or other irrigation system before, at transplanting/sowing and post-planting/sowing	BBCH 00 – BBCH 89	a) 6 b) 6	10	a) 4.0 L/ha b) 24.0 L/ha	a) 5.40 kg as/ha b) 30.84 kg as/ha	1,000 – 30,000	Not necessary	Product dosage: 2-4 L/ha. Average density: 1.285 kg/L. Acceptable (Efficacy demonstrated on <i>Meloidogyne</i> (1MELGG))
5	France	Cucurbits with edible peel: cucumber (CUMSA), zucchini (CUUPG)	G	All free-living stages of plant parasitic nematodes belonging to the genera <i>Meloidogyne</i> (1MELGG), <i>Tylenchus</i> (1TYLNG), <i>Trichodorus</i> (1TRIHG), <i>Longidorus</i> (1LONGG), <i>Pratylenchus</i> (1PRATG), <i>Xiphinema</i> (1XIPHG), <i>Globodera</i> (1GLOBG), <i>Heterodera</i> (1HETG)	Application via any type of drip, handheld, or other irrigation system before, at transplanting/sowing and post-planting/sowing	BBCH 00 – BBCH 89	a) 6 b) 6	10	a) 4.0 L/ha b) 24.0 L/ha	a) 5.40 kg as/ha b) 30.84 kg as/ha	1,000 – 30,000	Not necessary	Product dosage: 2-4 L/ha. Average density: 1.285 kg/L. Acceptable (Efficacy demonstrated on <i>Meloidogyne</i> (1MELGG))
6	France	Cucurbits with inedible peel: melon (CUMME), watermelon (CITLA), pumpkin (CUUPE)	G	All free-living stages of plant parasitic nematodes belonging to the genera <i>Meloidogyne</i> (1MELGG), <i>Tylenchus</i> (1TYLNG), <i>Trichodorus</i> (1TRIHG), <i>Longidorus</i> (1LONGG), <i>Pratylenchus</i> (1PRATG), <i>Xiphinema</i> (1XIPHG), <i>Globodera</i> (1GLOBG), <i>Heterodera</i> (1HETG)	Application via any type of drip, handheld, or other irrigation system before, at transplanting/sowing and post-planting/sowing	BBCH 00 – BBCH 89	a) 6 b) 6	10	a) 4.0 L/ha b) 24.0 L/ha	a) 5.40 kg as/ha b) 30.84 kg as/ha	1,000 – 30,000	Not necessary	Product dosage: 2-4 L/ha. Average density: 1.285 kg/L. Acceptable (Efficacy demonstrated on <i>Meloidogyne</i> (1MELGG))

* As some standards may have undergone changes, it is the responsibility of the applicant to update the references.

** Possible application during the flowering period according to the order of 20 November 2021 on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products

Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d) Select relevant
	(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c) g/kg or g/l	(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

CLAIL0021 / NEMGUARD SC

Part A - National Assessment

FRANCE

Remarks	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
columns:	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench 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 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

The plant protection product NEMGUARD SC (CLAIL0021) is identical to the active substance Garlic Extract (code: CLAIL0021). The appearance of the product is free-flowing viscous brown liquid with a strong garlic odour. It is not explosive, has no oxidising properties. The product has no flashpoint (boils at 100.3 °C). It has no self-ignition temperature observed up to 388 °C. In aqueous solution, it has a pH value around 5-6 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The active substance has a log Pow value of -1.49 (20 °C). The surface tension of the active substance is 41.5 mN/m (20 °C). The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in the original containers (HDPE bottles). Its technical characteristics are acceptable for a SC formulation.

Given the formulation type (SC), sedimentation of the product cannot be excluded for packaging having a volume greater than or equal to 20L, a risk management action is proposed :

Packaging having a volume greater than or equal to must be equipped of a system allowing the product to homogenize.

3.2 Efficacy (Part B, Section 3)

- NEMGUARD SC (CLAIL0021) effectiveness level is considered variable and partial for the claimed uses. However, it is considered acceptable for this type of product based on a natural active ingredient.

- NEMGUARD SC (CLAIL0021) phytotoxicity level is considered negligible for the claimed uses.

- The risks of adverse effects on yield, quality, propagation, succeeding and adjacent crops are considered negligible.

- The risk resistance appearance or development of resistance to garlic extracts is considered very low.

3.3 Methods of analysis (Part B, Section 5)

Analytical methods for the determination of the active substance is applicable as method for post-authorisation control and monitoring purpose.

3.3.1 Analytical method for the formulation

Not applicable. None was required or considered necessary for this food grade product of natural origin. No MRL is established for the active substance Garlic extract. In fact, this active substance is included into Annex IV of Commission Regulation (EC) No. 396/2005.

A fully validated method for analysis of polysulfides in water using diallyl trisulfide (DAS3) as a key marker was developed and validated

3.3.2 Analytical methods for residues

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints	
Active substance	Garlic extract
AOEL systemic	Not required
AAOEL	Not required
Oral absorption	Not required
Vapour pressure	Not required
Reference	EFSA Journal 2020;18(6):6116
Dermal absorption	Not required

3.4.1 Acute toxicity

NEMGUARD SC (CLAIL0021) containing 1000 g/kg garlic extract has a low toxicity in respect to acute oral, inhalation and dermal toxicity. It is not irritating to the rabbit skin or eye and it is a skin sensitizer.

3.4.2 Operator exposure

In the EU renewal review of the active substance Garlic extract, toxicological reference values used were not required. Moreover, the EFSA Peer review (2012) mentioned that “Considering the food grade quality of the product, all toxicological data requirements were waived; reference values were not allocated and no quantitative risk assessment for operator, worker and bystander exposure was considered necessary”.

Therefore, it can be concluded that the risk for the operator using NEMguard is acceptable with a working coverall and gloves during mixing/loading and application.

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

3.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for crop reaching, picking activities.

In the EU renewal review of the active substance Garlic extract, toxicological reference values used were not required. Moreover, the EFSA Peer review (2012) mentioned that “Considering the food grade quality of the product, all toxicological data requirements were waived; reference values were not allocated and no quantitative risk assessment for operator, worker and bystander exposure was considered necessary”.

Therefore, it can be concluded that there is no unacceptable risk anticipated for the worker reentering into treated crops.

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

3.4.4 Bystander exposure

In the EU renewal review of the active substance Garlic extract, toxicological reference values used were not required. Moreover, the EFSA Peer review (2012) mentioned that “Considering the food grade quality of the product, all toxicological data requirements were waived; reference values were not allocated and no quantitative risk assessment for operator, worker and bystander exposure was considered necessary”.

Therefore, it can be concluded that an acceptable risk was considered for bystander (adult and/or child).

3.4.5 Resident exposure

In the EU renewal review of the active substance Garlic extract, toxicological reference values used were not required. Moreover, the EFSA Peer review (2012) mentioned that “Considering the food grade quality of the product, all toxicological data requirements were waived; reference values were not allocated and no quantitative risk assessment for operator, worker and bystander exposure was considered necessary”.

Therefore, it can be concluded that an acceptable risk was considered for resident (adult and/or child).

3.4.6 Combined exposure

Not relevant. The product contains only one active substance.

3.5 Residues and consumer exposure (Part B, Section 7)

The data available are considered sufficient for risk assessment. No current MRL for garlic extract is laid down in Reg. (EU) 396/2005. Indeed this active substance is included into Annex IV of Commission Regulation (EC) No. 396/2005, according to Regulation Commission Regulation (EC) No 839/2008. The chronic and the short-term intakes of garlic extract residues are unlikely to present a public health concern. As far as consumer health protection is concerned, France, as a zRMS agrees with the authorization of the intended uses.

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

Data gaps

No areas of concern or data gaps were identified (EFSA Journal 2020;18(6):6116).

CLAIL0021 / NEMGUARD SC
Part A - National Assessment
FRANCE

Summary for NEMGUARD SC (CLAIL0021)

Crop	PHI* for NEMGUARD SC proposed by applicant	PHI	PHI for NEMGUARD SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Garlic extract		
Tomato (LYPES), eggplant (SOLME), bell pepper (CPSAN)	NR	NR	NR	
Cucurbits with edible peel: cucumber (CUMSA), zucchini (CUUPG)	NR	NR	NR	
Cucurbits with inedible peel: melon (CUMME), watermelon (CITLA), pumpkin (CUUPE)	NR	NR	NR	

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

Waiting periods before planting succeeding crops

Not relevant.

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009.

Considering the intended methods of application and considering that the amount of polysulfides from the application of NEMGUARD SC (CLAIL0021) is lower than background levels released into the environment through agriculture, estimation of concentrations of active substance in soil, ground-water and surface water are not deemed necessary for NEMGUARD SC (CLAIL0021).

Consequently, no unacceptable risk of groundwater contamination is expected for all intended uses.

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

3.7 Ecotoxicology (Part B, Section 9)

Considering the intended methods of application and considering that the amount of polysulfides from the application of NEMGUARD SC (CLAIL0021) is lower than background levels released into the environment through agriculture, a risk assessment for non-target organisms is not deemed necessary.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

None.

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

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation

Docusign Envelope ID: CFC677AA-7A24-4746-92F8-AC0E77EFA588



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 **NEMGUARD SC***

*de la société **CBC EUROPE S.R.L.***

enregistrée sous le n° 2022-2581

Vu les conclusions de l'évaluation de l'Anses du 30 mai 2024,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et son annexe.

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.

DocuSign Envelope ID: CFC677AA-7A24-4746-92F8-AC0E77EFA588



Informations générales sur le produit	
Nom du produit	NEMGUARD SC
Type de produit	Produit de référence
Titulaire	CBC EUROPE S.R.L. DIVISION BIOGARD Via Zanica 25 24050 GRASSOBBIO (BG) Italie
Formulation	Suspension concentrée (SC)
Contenant	1000 g/kg - extrait d'ail
Numéro d'intrant	829-2022.01
Numéro d'AMM	2240384
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 28 février 2037.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) n° 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 01/08/2024

DocuSigned by:

Charlotte Grastilleur

AE281A955A42454...

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 : 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 1B	H317 : Peut provoquer une allergie cutanée
Pour les phrases P se référer à la réglementation en vigueur.	
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.	

CLAIL0021 / NEMGUARD SC
Part A - National Assessment
FRANCE

DocuSign Envelope ID: CFC677AA-7A24-4746-92F8-AC0E77EFA588



Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.

En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
16322502 Cucurbitacées à peau comestible*Trt Irrigation loc.*Nématodes	4 L/ha	6/an	jusqu'au stade BBCH 89	1	-	-	-	Non concerné
Également autorisé sous abri. Efficacité montrée sur nématodes à galles (<i>Meloidogyne sp.</i>). Intervalle minimum entre les applications : 10 jours.								
16752502 Cucurbitacées à peau non comestible*Trt Irrigation loc.*Nématodes	4 L/ha	6/an	jusqu'au stade BBCH 89	1	-	-	-	Non concerné
Également autorisé sous abri. Efficacité montrée sur nématodes à galles (<i>Meloidogyne sp.</i>). Intervalle minimum entre les applications : 10 jours.								
16862502 Poivron*Trt Irrigation loc.*Nématodes	4 L/ha	6/an	jusqu'au stade BBCH 89	1	-	-	-	Non concerné
Également autorisé sous abri. Efficacité montrée sur nématodes à galles (<i>Meloidogyne sp.</i>). Intervalle minimum entre les applications : 10 jours.								
16952502 Tomate - Aubergine*Trt Irrigation loc.*Nématodes	4 L/ha	6/an	jusqu'au stade BBCH 89	1	-	-	-	Non concerné
Également autorisé sous abri. Efficacité montrée sur nématodes à galles (<i>Meloidogyne sp.</i>). Intervalle minimum entre les applications : 10 jours.								

CLAIL0021 / NEMGUARD SC
Part A - National Assessment
FRANCE

DocuSign Envelope ID: CFC677AA-7A24-4746-92F8-AC0E77EFA588



Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
16322501 Cucurbitacées à peau comestible*Trt Sol*Nématodes	4 L/ha	6/an	-
Motivation du refus : L'usage est refusé car il est transformé en l'usage 16322502 Cucurbitacées à peau comestible*Trt Irrigation loc.*Nématodes mieux adapté à la revendication.			
16752501 Cucurbitacées à peau non comestible*Trt Sol*Nématodes	4 L/ha	6/an	-
Motivation du refus : L'usage est refusé car il est transformé en l'usage 16752502 Cucurbitacées à peau non comestible*Trt Irrigation loc.*Nématodes mieux adapté à la revendication.			
16862501 Poivron*Trt Sol*Nématodes	4 L/ha	6/an	-
Motivation du refus : L'usage est refusé car il est transformé en l'usage 16862502 Poivron*Trt Irrigation loc.*Nématodes mieux adapté à la revendication.			
16952501 Tomate - Aubergine*Trt Sol*Nématodes	4 L/ha	6/an	-
Motivation du refus : L'usage est refusé car il est transformé en l'usage 16952502 Tomate - Aubergine*Trt Irrigation loc.*Nématodes mieux adapté à la revendication.			



Conditions d'emploi du produit

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 applicateur manuel

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection de catégorie III type 4 ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN 143) ou A2P3 (EN 14387) ;

• pendant l'application

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection de catégorie III type 4 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN 143) ou A2P3 (EN 14387) ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection de catégorie III type 4 ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN 143) ou A2P3 (EN 14387).

Dans le cadre d'une application goutte à goutte

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection de catégorie III type 4 ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN 143) ou A2P3 (EN 14387).

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 et, en cas de contact avec la culture traitée, des gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).

Docusign Envelope ID: CFC677AA-7A24-4746-92F8-AC0E77EFA588



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

- 48 heures.

Respect des limites maximales de résidus (LMR)

Le délai avant récolte est fixé à 1 jour en fonction des pratiques agricoles sur les cultures et afin de limiter l'exposition potentielle des consommateurs.

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.

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- L'efficacité du produit étant variable et partielle, préciser les conditions optimales d'utilisation.
- Préciser les conditions optimales d'utilisation afin de prévenir tout risque éventuel pour les auxiliaires de lutte biologique dans le cadre de la mise en place d'un programme de protection biologique intégrée.

CLAIL0021 / NEMGUARD SC

Part A - National Assessment

FRANCE

- EPI vestimentaire conforme à la norme NF EN ISO 27065-A. Combinaison de protection de catégorie III type 4 ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387).

Pour le travailleur, amené à intervenir sur le système d'irrigation et en cas de contact avec la culture traitée, porter un EPI vestimentaire conforme à la norme NF EN ISO 27065-A et des gants en nitrile certifiés EN 374-A1 and NF EN 16523-1+A1 Type A.

MODE D'ACTION - PROPRIETES :

NEMguard® SC est un nématicide contenant de l'extrait d'ail actif contre les nématodes des genres *Meloidogyne*, *Tylenchus*, *Trichodorus*, *Longidorus*, *Pratylenchus*, *Xiphinema*, *Globodera* et *Heterodera*.

DOSES ET RECOMMANDATIONS D'UTILISATION :

NEMguard® SC s'applique à la dose de 2 à 4 L/ha dans le sol en utilisant un système d'irrigation approprié. Utilisez un volume d'eau entre 1000 et 30.000 l/ha par cycle d'irrigation. Les meilleures conditions d'utilisation pour NEMguard SC sont atteintes lorsque le sol est assez humide. Pour cela il est recommandé d'ajouter le produit en fin de cycle d'irrigation.

Usages autorisés

- **Tomate - Aubergine* Trt Sol* Nématodes (tomate, aubergine)**
2 à 4 L/ha.
Sous abri et en plein champ.
Application : après transplantation/plantation et jusqu'à la récolte.
Intervalle entre deux traitements : 10 à 14 jours.
Nombre maximum d'applications : 6 par rotation culturale.
- **Poivron* Trt Sol* Nématodes (poivron, piment)**
2 à 4 L/ha.
Sous abri et en plein champ.
Application : après transplantation/plantation et jusqu'à la récolte.
Intervalle entre deux traitements : 10 à 14 jours.
Nombre maximum d'applications : 6 par rotation culturale.
- **Cucurbitacées à peau comestible* Trt Sol* Nématodes (concombre, courgette, cornichon)**
2 à 4 L/ha.
Sous abri et en plein champ.
Application : après transplantation/plantation et jusqu'à la récolte.
Intervalle entre deux traitements : 10 à 14 jours.
Nombre maximum d'applications : 6 par rotation culturale.
- **Cucurbitacées à peau non comestible* Trt Sol* Nématodes (melon, pastèque, potiron)**
2 à 4 L/ha.
Sous abri et en plein champ.
Application : après transplantation/plantation et jusqu'à la récolte.
Intervalle entre deux traitements : 10 à 14 jours.
Nombre maximum d'applications : 6 par rotation culturale.

COMPATIBILITE : Ne pas appliquer le produit en mélange avec d'autres produits phytosanitaires.

DELAI AVANT RECOLTE (JOURS) : 0 jours.

ÉLIMINATION DU PRODUIT ET DES EMBALLAGES VIDES :

Réemploi de l'emballage interdit. Bien vider l'emballage et l'éliminer via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR.

Pour l'élimination des produits non utilisables, rapporter le produit dans son emballage d'origine à votre distributeur partenaire d'ADIVALOR ou faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

AVERTISSEMENT : Utilisation agricole uniquement. Ce produit est dangereux pour d'autres utilisations. - L'utilisateur final est entièrement responsable de la bonne utilisation du produit. Toutes les directives d'utilisation doivent être prises en compte pour assurer une bonne mise en œuvre du produit, y compris les recommandations sécuritaires et sanitaires de la culture traitée et de la protection des personnes et de l'environnement. - Ne pas appliquer par voie aérienne. - Ne pas appliquer par vent contraire. - Pour utilisation finale uniquement. - Les emballages vides sont collectés conformément à la législation en vigueur. - Ne pas réutiliser les emballages.

Nématicide à usage professionnel. Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'étiquette. Lire attentivement l'étiquette avant toute utilisation.