Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Thermally treated garlic juice

Product type: 19

ECHA/BPC/375/2023

Adopted

05 June 2023

Opinion of the Biocidal Products Committee

on the application for approval of the active substance thermally treated garlic juice for product type 19

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 19 of the following active substance:

Common name:	**Thermally treated garlic juice**
Chemical name:	**Thermally treated garlic juice (intended new name, formerly named "garlic extract")**
EC No.:	**N/A**
CAS No.:	**N/A**

Existing active substance submitted under Article 7 of the Biocidal Products Regualtion (EU) 528/2012

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of the BPC opinion

Following the submission of an application by Ecospray Limited on 17 September 2019, the evaluating Competent Authority Austria submitted an assessment report and the conclusions of its evaluation to ECHA on 23 September 2022. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-47) and its Working Groups (WG I 2023). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Austria

The BPC opinion on the application for approval of the active substance thermally treated garlic juice in product type 19 was adopted on 5 June 2023.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that thermally treated garlic juice in product type 19 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of thermally treated garlic juice in product type 19. Specifications for the reference source are established.

This active substance is already approved under the Plant Protection Products Regulation (PPPR)[1] with the name "garlic extract" (with CAS No. 8008-99-9 and 8000-78-0) and was also submitted to the BPR as "garlic extract"[2]. During the peer review process under BPR it was agreed to change the name to "thermally treated garlic juice" as it could be concluded from the information provided that the substance cannot be considered as an extract. Under BPR no CAS-number will be associated to this UVCB substance.

Thermally treated garlic juice is a plant juice and UVCB substance. It is derived from garlic juice that is thermally treated and has food grade quality. Four marker compounds, namely Diallyl sulfide (DAS1), Diallyl di- (DAS2), tri- (DAS3) and tetra- (DAS4) sulfide characterise the active substance. Analysis was performed by high performance liquid chromatography using a diode array detector to determine the weight percentage of the polysulfides (DAS1-7) in the batches of thermally treated garlic juice (as DAS3 equivalents).

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

On 22.09.2022 the competent authority Austria submitted a CLH dossier to ECHA.

The proposed classification and labelling for thermally treated garlic juice according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

(Proposed)[Error! Bookmark not defined.] **Classification according to the CLP Regulation**	
Hazard Class and Category Codes	H317: Skin Sens. 1B
Labelling	
Pictogram codes	GHS07
Signal Word	Warning
Hazard Statement Codes	H317
Specific Concentration limits, M-Factors	--

[1] Commission Implementing Regulation (EU) 2021/129.
[2] Entry 1071 in Annex II to Delegated Regulation (EU) No 1062/2014 as amended via Delegated Regulation (EU) 2022/825: Garlic ext. (*Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc. obtained from Allium sativum, Liliaceae*) with CAS No. 8008-99-9 and EC No. 232-371-1.

b) Intended use, target species and effectiveness

The carrier based biocidal product consists of sepiolite granules (a clay mineral composed of magnesium silicate) coated with the active substance. The biocidal product is used in gardens (outdoor). It deters cats of all ages from defecating in treated areas (lawns, flowerbeds). The biocidal product is intended to be used by non-professional users.

Thermally treated garlic juice is an olfactory repellent. The principal biologically active compound produced by garlic is a group of organo-sulfur compounds (sulfanes) with antimicrobial and repellent properties. Various pests including mammals are sensitive to organo-sulfur compounds. This produces a repellent effect.

Based on efficacy report it can be concluded that the representative product will deter cats (*Felis catus*) from defecation but not from entering the treated areas. The field trial was considered as robust due to the number of observed individuals, the exclusion of other vertebrates by camera monitoring and the proven efficacy of >90%. Since there are no requirements for PT19 products against vertebrates in the BPR Efficacy Guidance in force at the time of dossier submission, the test setting (not to treat the food of cats but rather the area which should be protected) and the minimum necessary efficacy of ≥80% was harmonised in the course of an e-consultation in 2019 among the BPC Efficacy Working Group experts. The average number of excrements per m^2 before and during product application was determined. The shown efficacy, which is generated by the reduction in the number of faecal piles in a treated test area compared to a control field, was 94%. In conclusion, sufficient efficacy has thus been demonstrated as the results on the defecation behaviour show that the requirement of minimum 80% efficacy was fulfilled.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

Thermally treated garlic juice is processed from food grade material and is the processed and concentrated juice of the garlic clove. Garlic has been used in the diet for a very long time and garlic preparations are also marketed for health claims.

Non-clinical and clinical data of Garlic (*Allium sativum* L., bulbus) were assessed by the European Medicines Agency in 2017 (EMA, 2020[3]) because of possible beneficial health effects. Clinical studies assessed were insufficient for a well-established indication. However, traditional use for dried powdered garlic, garlic oil or dried aged garlic extract may support mild benefits in the prevention of atherosclerosis or relief of symptoms of common cold.

Based on arguments that the active substance is made of certified food grade material and exposure via food is considered much higher than via the use of thermally treated garlic juice as a biocidal product, most toxicological endpoints have not been addressed by experimental data.

The composition of garlic is complex and characterised by organosulfur compounds formed from aliin and allicin as well as flavonoids, flavonoid glycosides, coumarins, sapogenins and saponins, proteins and enzyme amongst others (EMA, 2020[3]). Dietary uptake of garlic compounds via food depends also on the processing methods having a distinct impact on the formed compounds (cf. chapter A.3. and B.3. of the CAR). The dietary intake values of the European population to garlic were taken from EFSA PRIMoV3.1 (2018)[4]. The largest chronic

[3] European Medicines Agency (EMA) 2020. Assessment report on *Allium sativum* L., bulbus, EMA/HMPC/7686/2013, Committee on Herbal Medicinal Products, European Medicines Agency, 18. July 2017
[4] European Food Safety Authority (EFSA) PRIMo rev3.1, 2018. Pesticide Residue Intake Model. Available at: https://www.efsa.europa.eu/en/applications/pesticides/tools

consumption of garlic is 0.0833 g/kg bw/d (for Romania general, equal to an intake of 4.9 g/day). The 97.5th percentile consumption was 0.64 g/kg bw/d, corresponding to an intake of 42.7 g/day (for an UK vegetarian) representing largest acute consumption.

With respect to humans the active substance was not identified as endocrine disrupter in line with EFSA (2020) based on waiving arguments according to the ECHA and EFSA guidance (2018)[5], which stipulates that there may be cases in which an ED assessment does not appear scientifically necessary.

A number of studies were submitted on skin and eye irritation and skin sensitisation. Thermally treated garlic juice is a skin sensitiser and is classified as skin sensitiser category 1B according to Regulation (EC) No. 1272/2008.

Therefore, systemic (qualitative) and local risks were assessed for primary or secondary exposure.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure[6] and description of scenario**	**Exposed group**	**Conclusion**
Outdoor application of the product	Primary exposure: An adult user applies the product "Katzenschreck" by pouring from the container.	Non-professional	acceptable
Exposure to the product from re-entry into treated areas	Secondary exposure: An adult and/or child re-enters an area treated with "Katzenschreck" following the application of the product.	Bystanders (general public)	acceptable

No data for the derivation of quantitative reference values are available and no AELs have been defined for the active substance. For skin sensitisation, no local reference values were derived based on that for this hazard category no quantitative local risk assessment is normally performed (ECHA, 2017[7]).

A qualitative and quantitative exposure assessment has been prepared and describes the exposure potential to humans via use of this biocidal product.

In summary dietary exposure is expected to exceed the secondary systemic exposure of the biocidal product as demonstrated by a comparison of a reasonable worst-case exposure calculation and dietary intake data for primary and secondary exposure situations.

The local risk assessments also indicate an acceptable risk for the scenarios and population. Primary exposure is further minimized amongst others by the use instruction "Pour directly from the container and wash hands after use". Exposure of toddlers and children is further

[5] ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson N, Arena M, Auteri D,Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J,Terron A and Van der Linden S, 2018. Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311,135 pp. https://doi.org/10.2903/j.efsa.2018.5311.

[6] See document: Terminology primary and secondary exposure (available from https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/80f71044-fce2-43b3-a73c-e156effc9fcb/Terminology%20primary%20and%20secondary%20exposure.pdf)

[7] ECHA 2017. Guidance on the BPR: Volume III Human Health - Assessment & Evaluation , Part B+C, , Version 4.0, October 2017

prevented by the pattern of use and by the risk mitigation measure "Keep out of reach of children".

A qualitative assessment was performed for domestic animals that resulted in acceptable risks for the intended use.

Environment

Quantitative environmental risk assessment was not considered necessary. The environmental background concentrations of polysulfides released into the environment due to agricultural activity is compared with the emissions of polysulfides reaching soil based on the proposed application rate.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
--	Quantitative environmental risk assessment was not considered necessary. A semi-quantitative environmental risk assessment based on a study (Anonymous 2021h) submitted by the applicant was conducted.	acceptable

Available information on the active substance indicates that the substance is not classified as an acute or chronic environmental hazard under the CLP criteria, is not bioaccumulative and is expected to be rapidly degradable in the environment.

The applicant submitted a study ("*Natural concentrations of polysulfides released from allium crops*": please refer to Anonymous 2021h in the CAR[8]) showing the effective concentrations released into the environment through agricultural activity and compare the emissions due to the maximum approved application levels proposed by application of the biocidal product. The approach taken in this study is estimating the concentration of sulfoxides (as Polysulfide Alliin Equivalents), which would arise in soil if garlic (*Allium sativum*) and onion (*Allium cepa*) crops were tilled back into the field (e.g. tillage of non-marketable crop).

The study states that the values calculated from average garlic yield and minimum and maximum alliin equivalents are considered for emission estimates. The average estimated concentration of sulfoxides (as Polysulfide Alliin Equivalents (PAE)) range between 3.2 kg/ha and 64.7 kg/ha.

The emission calculation regarding the application of the biocidal product in this study is based on an estimated maximum amount of polysulfide contents in the active substance [redacted].

Comparing emissions of the biocidal product application with the minimum and maximum residue values, agricultural activity leads to 44 and 899 times higher emissions.

Based on this semi-quantitative approach environmental risk is considered to be negligible compared to agricultural activity and therefore no quantitative risk assessments is considered.

With respect to non-target organisms the active substance was not identified as endocrine disrupter in line with EFSA (2020) based on waiving arguments according to the ECHA and

[8] Anonymous 2021h: Natural concentrations of polysulfides released from allium crops. Ecospray Ltd. CAR chapter B.4.1.

EFSA guidance (2018), which stipulates that there may be cases in which an ED assessment does not appear scientifically necessary.

Overall conclusion

Referring to the envisaged use of the biocidal product, the estimated exposure levels to the active substance thermally treated garlic juice are low. The calculated exposure levels are external levels and represent worst case estimates for systemic exposure levels.

Based on the similarity of the manufacturing process of thermally treated garlic juice and garlic food processes, it is reasonable to anticipate that dietary uptake of industrially manufactured and kitchen prepared garlic food products cover exposure to the allyl polysulfides and other compounds of thermally treated garlic juice. Exposure to the same compounds and lower exposure levels than via diet are assumed for the use of the biocidal product. Therefore, acceptable risk regarding systemic exposure is assumed.

The local risk assessments for non-professional users and the general public indicated acceptable risks due to low exposure, outdoor use and adequate labelling, safety and use instructions.

Based on a semi-quantitative assessment comparing the application of the biocidal product to agricultural activity risks to the environment are considered acceptable.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

<table>
<tr><th colspan="2">Property</th><th colspan="2">Conclusions</th></tr>
<tr><td rowspan="3">CMR properties</td><td>Carcinogenicity (C)</td><td rowspan="3">Thermally treated garlic juice is not expected to exhibit carcinogenic, mutagenic or reprotoxic properties.</td><td rowspan="3">Thermally treated garlic juice does not fulfil criterion (a), (b) and (c) of Article 5(1).</td></tr>
<tr><td>Mutagenicity (M)</td></tr>
<tr><td>Toxic for reproduction (R)</td></tr>
<tr><td rowspan="3">PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td>Not P and not vP</td><td rowspan="3">Thermally treated garlic juice does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1).</td></tr>
<tr><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td><td>Not B and not vB</td></tr>
<tr><td>Toxic (T)</td><td>Not T</td></tr>
<tr><td>Endocrine disrupting properties</td><td>Section A of Regulation (EU) 2017/2100: ED properties with</td><td>Not identified as endocrine disruptor.</td><td>Thermally treated garlic juice does neither fulfil</td></tr>
</table>

Property		Conclusions	
	respect to humans		criterion (d) of Article 5(1)(d) nor criterion (e) of Article 10(1).
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	Not identified as endocrine disruptor.	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s)	No	
Respiratory sensitisation properties	No classification required. Thermally treated garlic juice does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	Thermally treated garlic juice does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Thermally treated garlic juice does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Thermally treated garlic juice does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Thermally treated garlic juice does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012 and is therefore not considered as a candidate for substitution.

The exclusion and substitution criteria were assessed in line with the "*Note on the principles for taking decisions on the approval of active substances under the BPR*"[9], "*Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR*"[10] and "*Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment*[11]" agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based

[9] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc).
[10] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc).
[11] See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (available from https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec-3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx).

on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.2.2. POP criteria

Thermally treated garlic juice is not considered a POP.

2.3. BPC opinion on the application for approval of the active substance thermally treated garlic juice in product type 19

In view of the conclusions of the evaluation, it is proposed that thermally treated garlic juice shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: Thermally treated garlic juice is a UVCB substance. The purity is 100% (w/w). It is derived from garlic juice that is thermally treated and has food grade quality. In addition, thermally treated garlic juice is characterised by four marker compounds: diallyl sulfide (DAS1), diallyl disulfide (DAS2), diallyl trisulfide (DAS3) and diallyl tetrasulfide (DAS4). [redacted]

2. The authorisations of biocidal products are subject to the following condition(s):

    a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012, because it will meet the criteria of Article 28(2)(a) as it is proposed to be classified as H317 (Skin Sens. 1B).

2.4. Elements to be taken into account when authorising products

None were identified.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of thermally treated garlic juice.

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