Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

ADDENDUM: Minor Change

COM 116 02 I AL

Product type 18

Lambda-cyhalothrin as included in the Union list of approved active substances

Case Number in R4BP: BC-WH082187-22

Evaluating Competent Authority: Austria

04/08/2023 (Final)

PUBLIC

Table of Contents

CHANGES HISTORY TABLE

R4BP Asset in AT: **AT-0002401-0000**

Application type	**refMS/eCA**	**Case number in the refMS**	**Decision date**	**Assessment carried out (i.e. first authorisation / amendment / renewal)**	**Chapter/ page**
NA-APP	Austria	BC-MD000941-57	04/06/2019	Initial assessment	PAR
NA-MAC **NA-ADC**	Austria	BC-UY063371-02 BC-EB072434-59	14/03/2022	Addendum MAC and confidential: Change of product composition; addition of a non-active substance (bittering agent) and of further co-formulants to the a.s. premix; Post authorisation condition: New efficacy field studies, changing the time interval for application (from every 2 to every 4 weeks for silverfishes). ADC: Addition of a further trade name;	2.3. Identity and composition PAR confidential 2.3.3 Authorised use 2.3.4 Efficacy SPC
NA-ADC	Austria	BC-CT074172-29	05/05/2022	Addition of further trade names;	SPC
NA-MIC	Austria	BC-WH082187-22	In progress	Cf. to this addendum: change in product composition, change in naming/wording of target organisms (without addition or deletion) and packaging sizes.	PAR confidential 2.2 Uses 3.1 Packaging
NA-RNL	Austria	BC-KG082210-55	In progress	Renewal of the authorisation	In progress

1 CONCLUSION

The authorisation holder COMPO Austria GmbH has applied for a minor change in accordance with Regulation (EU) No 354/2013 for the authorised biocidal product COM 116 02 I AL. The application contains a minor change (NA-MIC) related to the product composition, change in naming/wording of target organisms (without addition or deletion) and packaging sizes.

The change in the composition is a minor change according to Reg.(EU)No. 354/2013, Annex, Title 2, point 1.
The criteria for the minor change application are fulfilled because no substance of concern is added to the product, the change does not lead to an increase of the active substance or substance of concern, the physical-chemical properties and shelf-life of the product as well as the risk and efficacy profile are expected to remain the same and a new quantitative risk assessment is not expected to be necessary.

The addition of pack sizes is a minor change according to Reg.(EU)No. 354/2013, Annex, Title 2, point 7.
The criteria for the minor change application are fulfilled because the new range is consistent with the dose rate and instructions for use as approved in the SPC, the user category does not change and the same risk-mitigation measures apply.

The rewording of the target organisms is interpreted as a minor change according to Reg.(EU)No. 354/2013, Annex, Title 2, point 3. According to the efficacy guidance[1], it is allowed to state the target organisms as "crawling insects" if certain target species have been tested. Therefore, the change does not affect the exposure adversely.

It is demonstrated that the proposed changes would not adversely affect the conclusions previously reached on the assessment of the biocidal product COM 116 I 02 AL.

It can be concluded that the conditions of Article 19 1)-4) of regulation (EU) no. 528/2012 are fulfilled and that the product may be authorised with the proposed changes.

[1] ECHA 2022, Guidance on the BPR, Vol. II: Efficacy, Part B+C, Assessment and Evaluation, Version 5.0

2 ASSESSMENT

2.1 Background

The authorisation holder COMPO Austria GmbH has applied for a minor change in accordance with Regulation (EU) No 354/2013 for the authorised biocidal product COM 116 02 I AL. The application contains a minor change (NA-MIC) related to the product composition, naming/wording of target organisms (without addition or deletion), and packaging sizes.

2.2 Description of changes

The **product composition** changed with regard to the addition of the bittering agent denatonium benzoate for the safety reason to avoid any potential poisoning by children and pets. The composition of the deterrent changed. For the old formulation of the authorised biocidal product the deterrent is used as a aqueous solution. This is replaced by a solution of denatonium benzoate in ethanol. The composition of the biocidal product is adapted accordingly in the PAR. The content of the deterrent in the biocidal product remains the same.

For the **target organisms in use #1** a general claim is added for crawling insects. Use 1 is reworded from "Insecticide and product to control other arthropods - garden ants, silverfishes, woodlice and cockroaches – non-professionals – spraying – indoor" to: "Use 1 – garden ants, crawling insects (including silverfishes and cockroaches) and woodlice – non-professionals – spraying – indoor".

Moreover, **additional packaging sizes** for the PET trigger bottle are applied for: 50 mL and 100 mL.

2.3 Evaluation of changes

2.3.1 Product composition and formulation

2.3.1.1 Qualitative and quantitative information on the composition of the biocidal product

COM 116 02 I AL COMPO Ameisen-Stop COMPO Ungeziefer-Stop COMPO Ungeziefer-Spray COMPO Ameisen-Spray Ameisen-Spray Ungeziefer-Spray Demand Spray DFNT Ant Spray DFNT Cockroach Spray DFNT Silverfish Spray DFNT Multi Insect Spray					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content [%(w/w)]**
Lambda-cyhalothrin	Reaction mass of (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate (1:1)	Active substance	91465-08-6	415-130-7	0.05

Please cf. to confidential annex for full composition. (Composition has changed).

2.3.1.2 Information on the substance(s) of concern

The biocidal product contains no substances of concern. Please see the confidential annex for further details.

2.3.2 Hazard and precautionary statements

The proposed classification and labelling of the product remains unchanged.

2.3.3 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Trigger bottle	**50 mL;** **100 mL;** 200 mL; 250 mL; 300 mL; 400 mL; 500 mL; 750 mL; 900 mL; 1000 mL	PET	Trigger is made of PP	non-professional	Yes

The packaging sizes 50 ml and 100 ml are added to the already authorised packaging sizes for the trigger bottle. The biocidal product was authorised for trigger bottles having the sizes 200 ml to 1000 ml. The trigger sprayer on the new smaller sized packaging (50ml, 100ml) is identical to the previously tested trigger heads. It can be concluded that the added packaging sizes 50 ml and 100 ml do not have any impact on the chemical and technical properties or on the risk of the biocidal product. No impact on the conclusions previously reached is expected.

2.3.4 Authorised use and General directions of use

The chapter remains unchanged except for the additional pack sizes and the additional wording for the target organisms in Use 1, cf. to chapter 2.3.3. and 2.3.5. Also the wording for the application rate in Use 1 is updated.

Use 1 – garden ants, crawling insects (including silverfishes and cockroaches) and woodlice – non-professionals – spraying – indoor

Target organism (including development stage)	Scientific name: crawling insects Common name: crawling insects (shown on *lepismatidae, blattodea)* Development stage: larvae and adults
Pack sizes and packaging material	Please see the relevant section.
Application rate:	Ants: 10 strokes for 1 m route correspond to 10 g product (44.5 g/m2); crawling insects (incl. silverfishes, cockroaches), and woodlice: Treat surfaces from a distance of ca. 30 cm with the trigger sprayer applying spotwise 5 to 6 strokes (100 g/m^2). Apply only where insects are expected running over.

Note: Use #2 remains unchanged.
For harmonisation with Use#1, only the name of Use #2 is changed from
"Use 2: Insecticide - garden ants - non-professionals - spraying – outdoor" to:
"Use 2: garden ants - non-professionals - spraying – outdoor"

2.3.5 Efficacy

The proposed changes have no effect on the efficacy assessment previously reached. The application rate, and application methods do not change. The rewording of the target organisms is based on already available efficacy studies. The efficacy profile is expected to remain the same. According to the efficacy guidance[2], the general claim "crawling insects" is sufficiently supported by the available data that have already been available for the authorised product.
Also the change of the composition has no effect on the efficacy, as it involves compounds that did not contribute to efficacy in the previous composition due to their function and the low concentration included.

2.3.6 Human Health

The conclusions as previously reached on the human and animal health assessment of the biocidal product are not adversely affected by the proposed changes because the intended

[2] ECHA 2022, Guidance on the BPR, Vol. II: Efficacy, Part B+C, Assessment and Evaluation, Version 5.0

uses, instructions for use, application methods, and risk-mitigation measures do not change. For more information please refer to the confidential annex.

2.3.7 Environment

The conclusions as previously reached on the environmental risk assessment of the biocidal product are not adversely affected by the proposed changes because the intended uses, instructions for use, application methods, and risk-mitigation measures do not change. For more information please refer to the confidential annex.

2.3.8 Endocrine disrupting properties

The proposed changes have no effect on the potential endocrine properties of the product. For more information please refer to the confidential annex.

3 ANNEX

3.1 List of studies

Not applicable because no new studies are submitted.

3.2 List of references

Not applicable because no new references are submitted.

3.3 Confidential annex

Please refer to separate document.