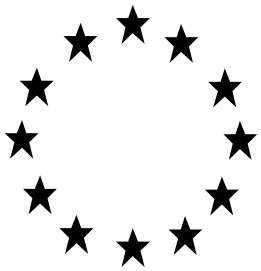
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

# PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

## ADDENDUM: Minor Change



Ameisen-Köderdose

Product type 18

Spinosad as included in the Union list of approved active substances

Case Number in R4BP: BC-XW082383-95

Evaluating Competent Authority: AT

**17/10/2023 (Final)**

# Table of Contents

# CHANGES HISTORY TABLE

| Application type | refMS/eCA | Case number in the refMS | Decision date | Assessment carried out (i.e. first authorisation / amendment / renewal) | Chapter/ page |
|---|---|---|---|---|---|
| NA-APP | AT | No source case number available | 12/03/2014 | First authorisation | |
| NA-MIC | AT | BC-JL017595-31 | 04/08/2016 | Amendment of Comparative Assessment, extension of shelf life to 3 years, change of co-formulant | |
| NA-MIC | AT | BC-RK022393-36 | 04/08/2016 | Amendment of Comparative Assessment, extension of shelf life to 3 years, change of co-formulant | |
| NA-ADC | AT | BC-XF027491-37 | 04/05/2017 | Adaption of labelling text | |
| NA-AAT | AT | BC-NH031263-50 | 27/03/2017 | Correction of the expiry date | |
| NA-MIC | AT | BC-TW032164-13 | 17/07/2018 | Extension of shelf life to 4 years | |
| NA-RNL | AT | BC-SC033783-41 | 13/08/2019 | Renewal of first authorisation | |
| NA-AAT | AT | BC-SA049799-24 | 08/03/2019 | Extension of the validity of the first authorisation | |
| NA-AAT | AT | BC-FH050008-55 | 18/03/2019 | Extension of the validity of the first authorisation | |
| NA-AAT | AT | BC-YY050942-92 | 15/04/2019 | Extension of the validity of the first authorisation | |
| NA-AAT | AT | BC-NC051534-51 | 15/04/2019 | Extension of the validity of the first authorisation | |
| NA-ADC | AT | BC-EM055451-42 | 11/11/2020 | Inclusion of an additional trade name | |
| NA-AAT | AT | BC-VS058888-85 | 04/05/2020 | Addition of documents in the asset | |
| NA-AAT | AT | BC-DR059179-17 | 12/05/2020 | Extension of the validity of the first authorization, Reduction of storage stability for 2 years by decision of the Coordination Group | |
| NA-ADC | AT | BC-YN062334-19 | 02/04/2021 | Inclusion of an additional trade name | |
| NA-ADC | AT | BC-FL063441-44 | 02/04/2021 | Inclusion of an additional trade name | |
| NA-AAT | AT | BC-YT088011-11 | 27/07/2023 | SPC corrigendum | |
| NA-MIC | AT | BC-XW082383-95 | In progress | Current change, cf. to PAR Addendum | |
| NA-RNL | AT | BC-TK084455-18 | In progress | Evaluation on-going | |

# 1 CONCLUSION

The authorisation holder Aeroxon Insect Control GmbH has applied for a minor change in accordance with Regulation (EU) No 354/2013 to the authorised product Ameisen-Köderdose. The application contains a minor change (NA-MIC) related to the product composition.

The change in the composition is a minor change according to Reg.(EU)No. 354/2013, Annex, Title 2, point 2.
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.

It is demonstrated that the proposed changes would not adversely affect the conclusions previously reached on the assessment of the biocidal product Ameisen-Köderdose.

**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.**

# 2 ASSESSMENT

## 2.1 Background

The authorisation holder Aeroxon Insect Control GmbH has applied for a minor change in accordance with Regulation (EU) No 354/2013 to the authorised product Ameisen-Köderdose.

## 2.2 Description of changes

The following minor change is applied for:

The minor change refers to a change in the composition of the biocidal product.

According to Reg. (EU) No 354/2013, Annex, TITLE 2, this is a minor change in composition and corresponds to the following table entry:

*"2. Increase, reduction, addition or deletion, or replacement of a non-active substance intentionally incorporated in a biocidal product family outside the authorised range, where:*

- *The added or increased non-active substance is not a substance of concern.*
- *The deletion or reduction of the non-active substance does not lead to an increase of an active substance or a substance of concern.*
- *The physical-chemical properties and the shelf-life of the products of the biocidal product family remain the same.*
- *The risk and efficacy profile are expected to remain the same.*
- *A new quantitative risk assessment is not expected to be necessary."*

## 2.3 Evaluation of changes

### 2.3.1 Identity and physico-chemical properties

#### 2.3.1.1 Comparison of qualitative and quantitative composition

The change on the qualitative and quantitative composition of the biocidal product is proposed to be as follows: The co-formulant used as preservative is changed from Kathon CG to Preventol D7. The content of the preservative and rest of the formulation remains unchanged.

| Old composition | | | | | | New composition | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** | **Common name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| Spinosad | Spinosad as a mixture of 50-95% Spinosyn A and 5-50% Spinosyn D. | Active substance | 168316-95-8 | 434-300-1 | 0.08 | Spinosad | Spinosad as a mixture of 50-95% Spinosyn A and 5-50% Spinosyn D. | Active substance | 168316-95-8 | 434-300-1 | 0.08 |
| **Kathon CG** | -- | Preservative | -- | -- | 0.072 | **Preventol D7** | -- | Preservative | -- | -- | 0.072 |
| *Substance of concern* | | | | | | *Substance of concern* | | | | | |
| Isopropanol, Propan-2-ol | 2-propanol | Solvent | 67-63-0 | 200-661-7 | 1.50 | Isopropanol, Propan-2-ol | 2-propanol | Solvent | 67-63-0 | 200-661-7 | 1.50 |

The full composition of the biocidal product is presented in the confidential annex and the full composition of the preservatives is presented in the confidential annex which is restricted to authorities only.

It can be concluded that the change in compostion, i.e. the change from Kathon CG to Preventol D7 neither has any impact on the chemical and technical properties, nor on the physical hazards and respective characteristics of the biocidal product. Thus, the proposed changes have no impact on previously reached conclusions for this endpoint.

### 2.3.2 Authorised use and General directions of use

The proposed changes have no impact on previously reached conclusions for this endpoint.

### 2.3.3 Efficacy

The composition change concerns the replacement of the preservative agent, whereupon the content of preservative in the biocidal product remains the same. The detailed formulation of the preservative is given in the confidential annex. The individual substances of the preservative agent do certainly not contribute to efficacy due to their low concentration and their function. Furthermore, the proposed change has no effect on the previous efficacy assessment because the intended uses, instructions for use, target organisms and application methods do not change.
Thus, the proposed changes have no impact on previously reached conclusions for this endpoint.

### 2.3.4 Human Health

The proposed changes have no impact on previously reached conclusions for this endpoint.

### 2.3.5 Environment

The proposed changes have no impact on previously reached conclusions for this endpoint.

### 2.3.6 ED assessment

The assessment of endocrine disrupting properties for the two new co-formulants according to the application of the MIC contained the new preservative Preventol D7 of the biocidal product was performed with respect to "CA-March21-Doc.4.3" and in line with "CG-50-2022-05". Thus it covers the methodology as outlined in "CG-49-2021-15 AP 16.7 ED assessment of co-formulants by applicants".

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the two new co-formulants of the preservative Preventol D7 contained in the biocidal product.

For the detailed ED assessment refer to the "PAR_ addendum_MIC_MS only".

# 3 ANNEX

## 3.1 List of studies

None.

## 3.2 List of references

ECHA 2017, Guidance on the Biocidal Products Regulation, Vol IV: Environment – Assessment and Evaluation Part B+C, Version 4.0

ECHA 2022, Technical Agreements for Biocides Environment (ENV), Release date: 14. October 2022

OECD 2008, Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses. OECD series on Emission scenario documents, number 18; ENV/JM/MONO(2008)14; 17-Jul-2008

## 3.3 Confidential information

Please cf. to separate document.