

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 SIMPLIFIED AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

ADDENDUM: Major Change



Lebensmittelmotten-Falle

Product type 19

(Z,E)-Tetradeca-9,12-dienyl acetate

Case Number in R4BP: BC-JJ086009-33

Evaluating Competent Authority: AT

Date: 30/01/2024 (Final)

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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
N/A	AT	No case no.	08.08.2013	Registration acc. to RL 98/8/EC	
SA-APP	AT	BC-SN006622-32	01.07.2015	First authorisation acc. to Reg (EU) No. 528/2012	
SA-MIC	AT	BC-BA054534-64	24.03.2021	Change of storage stability	
SA-MAC	AT	BC-JJ086009-33	In progress	Current change, cf. to PAR Addendum	

1 CONCLUSION

The authorisation holder Aeroxon Insect Control GmbH has applied for a major change (SA-MAC) for the authorised product Lebensmittelmotten-Falle.

The change refers to the product composition (increase of active substance), the increase of the packaging size of one product layout, the addition of the target organism *Ephestia kuehniella* (Mediterranean Flour Moth), the increase of the shelf life to 4 years and the increase of time in use to 12 weeks.

The increase of the active substance does not have an influence on the qualitative and quantitative composition since the pure active substance was considered as biocidal product. The previously reached conclusions do not change except for the shelf-life, which is for this part confirmed by the newly submitted efficacy studies. The addition of the target organism *Ephestia kuehniella* is acceptable because all requirements regarding efficacy are fulfilled, just as the increase of the in-use service life from 6 to 12 weeks is sufficiently proven for both, the fresh and the 4 years aged product.

The active substance is listed in Annex I of Reg. (EU) 528/2012 and the biocidal product does not contain any substance of concern or nanomaterial. Thus, any further assessment with regards to exposure and/or risk is not relevant in this case.

It can be concluded that the conditions of Article 19 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 major change (SA-MAC) for the authorised product Lebensmittelmotten-Falle (R4BP Asset no. EU-0012382-0000; R4BP Case no. BC-JJ086009-33)

2.2 Description of changes

The following major change is applied for:

Increase of active substance concentration from 2 mg to 2.5 mg TDA, increase of the dimensions of the packaging material for the triangle shape (from 55x274 mm to 65x341 mm and 86x356 mm), addition of the target organism *Ephestia kuehniella* and capture claim, increase of shelf-life from 2 to 4 years, increase of time in use from 6 to 12 weeks.

In addition, the eCA has performed some redactional changes to the wording of the authorised use in order to reflect the latest SPC guidance (ECHA 2022a).

2.3 Evaluation of changes

2.3.1 Identity and physico-chemical properties

The identity of the biocidal product itself remains unchanged. However, the amount of active substance per trap (article) changes from 2 mg to 2.5 mg TDA.

There is no additional information or studies concerning physico-chemical properties compared to the PAR addendum from 09/04/2020 (MIC, case no.: BC-BA054534-64). The increase of shelf-life is based on the stability study which was already provided and evaluated for the MIC. However, the results are summarised again in the following table.

Table 2.3.1.1 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.1.2.	Storage stability test – long-term storage at ambient temperature	Storage for 48months at 20 ± 2°C	Food moth trap Batch: 2mg N143 Projekt 5002 2.14 mg a.s. (± 100% w/w) Packaging: rectangular carton (165x90mm)	<u>Stability of the packaging material:</u> No change after storage for 48 months was observed: The packaging was tightly sealed and no damage was observed, neither on the test item, nor on the packaging material. <u>Weight change:</u> No significant change in	Anonymous 2017

				<p>weight was observed after storage for 48 months (Δ -0.35%)</p> <p><u>Appearance, colour and odour:</u> No change after storage for 48 months was observed.</p> <p><u>Content of a.s.per unit:</u> Start: 1.85 mg 12 months: 1.07 mg (loss: 42%) 24 months: 0.88 mg (loss: 52%) 36 months: 0.71 mg (loss 62%) 48 months: 0.70 mg (loss: 62%)</p> <p><u>Applicability of the glue trap:</u> The applicability did not change after storage for 48 months.</p> <p><u>Catching ability of the Glue:</u> No changes in the catching ability were observed after storage for 48 months.</p>	
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Table 2.3.1.2 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties

As the pure active substance is considered as biocidal product, the increase of active substance from 2 to 2.5 mg per trap does not have an impact on the qualitative and quantitative composition of the biocidal product. It can be concluded that this change neither has an impact on the chemical and technical properties, nor on the physical hazards and respective characteristics of the biocidal product.

No additional long-term storage stability studies were performed. In order to support the shelf life of 4 years the already provided study with the initial amount of active substance (2 mg) per unit (Anonymous, 2017) was applied. The stability of the packaging was confirmed for 48 months. However, the amount of active substance is decreasing significantly. After 12 months a loss of more than 10% was observed. Efficacy studies with the aged product (after storage of 4 years) with an amount of 2.5 mg active substance per trap confirmed the efficacy of the product.

Thus, based on the nature and the general low risk of the active substance (Annex I), the shelf-life study performed with the product containing 2 mg of active substance (confirming the stability of the packaging) and the two efficacy studies conducted with the aged product (4 years) containing 2.5 mg of active substance (confirming efficacy), are considered as applicable for confirming a shelf life of 4 years for the biocidal product

containing 2.5 mg of active substance.

This decision is based on the proposed conclusion for simplified authorisations as depicted in the CA-May14-Doc.5.5 – Final (6): "The Commission services consider that data on storage stability, stability and shelf-life as requested in point 3.4 of Annex III to BPR shall also be included in applications for product authorisation submitted through the simplified authorisation procedure, as the conditions of storage, the stability and shelf-life of the product directly affect the efficacy of the product." The conclusion is further supported by (7b) of the CA-document: " (b) Stability data could be waived where the applicant demonstrates that the product is efficacious by the end of the proposed shelf-life (i.e. data from efficacy tests using aged/stored product)."

Implications for labelling: None.

2.3.2 Authorised use and General directions of use

2.3.2.1 Use description

Use # 1 Repellent – Indian meal moth, Mediterranean flour moth (adults, males) – general public – RTU trap incl. attractant - indoor

Product Type	PT19 - Repellents and attractants
Where relevant, an exact description of the authorised use	Attractant
Target organism (including development stage)	<p>Scientific name: <i>Plodia interpunctella</i> Common name: Indian meal moth Development stage: Adults (males)</p> <p>Scientific name: <i>Ephestia kuehniella</i> Common name: Mediterranean Flour Moth Development stage: Adults (males)</p>
Field of use	Indoor Ready-to-use product for indoor use in rooms or cupboards where well packaged ¹ food or feedstuff is stored.
Application method(s)	Stock protection / food protection Use one trap per cupboard or for a small room. Larger rooms should be equipped with 2 traps. The traps should be checked at least once a week and replaced after 12 weeks or when they are covered with moths. The sexual attractant contained in the adhesive surface attracts the male moths and holds them securely in place. In addition, the slowly emitted pheromone confuses males in their search for females, preventing them from reproducing and reducing egg laying by disrupting mating.
Application rate(s) and frequency	1 trap (containing 2.5 mg active substance) per volume up to 30 m ³ (e.g.cupboard or small room)

	<p>Application: Preventive and upon infestation</p> <p>Traps should be inspected at least once a week and replaced after 12 weeks or when they are covered with moths.</p>
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	<p>One packaging unit consist of 1-6 traps².</p> <p>There are 2 variants of traps: Trap type 1: 2 dimensional form; the cardboard is covered with adhesive glue and has a size of 130x90 mm Trap type 2: triangle form; the cardboard is covered with adhesive glue and has a size of 65x341 mm or 86x356 mm</p> <p>Each trap contains 2.5 mg pheromone, which is slowly released.</p>

¹ This insertion is removed, as it is not a condition of the Annex I entry.

² The number of traps in one packaging unit has been changed from 2 to 1-6 upon commenting of the applicant. This has no impact on the assessment, as this affects the outer packaging.

2.3.2.2 Use-specific instructions for use

2.3.2.3 Use-specific risk mitigation measures

2.3.2.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

2.3.2.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

2.3.2.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

2.3.3 General directions of use

2.3.3.1 Instructions for use

Place the ready-to-use trap in rooms or cupboards where ~~well-packaged~~¹ food or feedstuff is stored. Use 1 trap per volume up to 30 m³ (e.g. cupboard or small room).

Remove the silicone paper from the sticky glue on front of the trap for its activation.

Check the traps at least once a week and replace them after 12 weeks or when covered with moths.

~~Food or feed has to be stored in tightly closed containers (glass or plastic).~~¹

Keep out of reach of children.

Avoid contact with the product (adhesive tape).

~~Do not use in spaces where un-packaged food or feed is kept.~~¹

¹This insertion is removed, as it is not a condition of the Annex I entry.

2.3.3.2 Risk mitigation measures

2.3.3.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Due to the application and dosage of the biocidal product (active ingredient on carrier (cardboard)) direct or indirect impact is not expected under foreseeable conditions of use.

After skin contact: Instantly wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

[add phone number of PCN, if nationally required]

Measures to protect the environment: Do not discharge into sewage/surface or groundwater.

2.3.3.4 Instructions for safe disposal of the product and its packaging

Dispose the used trap in residual waste.

2.3.3.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Store in a cool and dry place.

Shelf life: 4 years.

2.3.4 Other information

2.3.5 Packaging of the biocidal product

Table 2.3.5-1 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)
<i>Carton, two dimensional shape</i>	<i>- 130x90mm</i>	<i>Cardboard</i>	<i>-</i>	<i>Non professional users /consumers, professionals</i>	<i>Yes</i>
<i>Carton, triangular shape</i>	<i>- 65x341 mm - 86x356 mm</i>	<i>Cardboard</i>	<i>-</i>	<i>Non professional users /consumers, professionals</i>	<i>Yes</i>

One packaging unit consists out of 1 – 6 traps.

The packaging material remains unchanged, only the dimensions for the carton in triangular shape were increased. Additionally, instead of one size two sizes are now available:

Old size of triangular packaging	New size of triangular packaging
<i>- 55x274 mm</i>	<i>- 65x341 mm - 86x356 mm</i>

Storage stability studies showed (conducted with 2 mg of active substance in a rectangular glue trap 165x90mm) that there is no interaction with the packaging material (i.e. appearance and weight of the packaging remained unchanged throughout 48 months, cf. to Section 2.3.1). Thus, the change in the size of the packaging material is not considered to have an impact on the properties of the biocidal product.

2.3.6 Efficacy

2.3.6.1 Efficacy data

In the following table the new efficacy studies relevant for the SA-MAC are mentioned to support the claim against *Ephestia kuehniella* and to support the prolonged shelf-life and the increase of the time in use.

Table 2.3.6.1-1 Efficacy data

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects [address here results related to efficacy of the test product and validity of the test]	Reference	Number in IUCLID section 6.7/Test report title
PT19 Use 1	Food moth trap 2.5 mg pheromone/trap Batches C069 (fresh product), U236 (4-yr-old product)	Attractant <i>Ephestia kuehniella</i> , <i>Plodia interpunctella</i>	Simulated use test in a rectangular-shaped room, measuring 3.15 x 3.15 x 3.03(h) m corresponding to a surface of 9.92 m ² and a volume of 30 m ³ 3 test product variants: 1) VP_0027A - T0y-0w: fresh product 2) VP_0027A - T4y-0w: after storage of 4 years 3) VP_0027A - T4y-11w: after storage of 4 years the product was activated and stored for 11 weeks Replicates per test product and control: 5 Test individuals from laboratory breeding; unknown number of adults, pupae, and larvae 1 trap with 2.5 mg pheromone and 1 control trap per room and per replicate Exposure: >24 h ≤ 7 days The traps were replaced when at least a ratio of 4:1 of test individuals trapped in the trap with pheromone compared to the control trap was reached by each target species.	1) 4:1 ratio was reached in a maximum of 3 days. 2) 4:1 ratio was reached in a maximum of 4 days. 3) 4:1 ratio was reached in a maximum of 2 days. Total numbers (sum of each 5 repl.) trapped food moth trap/untreated control: <i>Ephestia kuehniella</i> 1) 121/10 2) 77/10 3) 111/8 <i>Plodia interpunctella</i> 1) 36/0 2) 34/3 3) 24/2	Anonymous 2023a	12/Efficacy data.012/ Attractant efficacy evaluation of a sticky trap against <i>Ephestia kuehniella</i> and <i>Plodia interpunctella</i> (room test)
PT19 Use 1	Food moth trap 2.5 mg	Attractant <i>Plodia interpunctella</i> ,	Simulated use test in a rectangular-shaped room, measuring 3.15 x 3.15 x 3.03(h) m corresponding to a surface of 9.92 m ² and a	1) 4:1 ratio was reached within a maximum of 2 days	Anonymous 2023b	13/Efficacy data.013/ Attractant efficacy

	<p>pheromone/trap Batches C255 (fresh product) and U236 (4-yr- old product)</p>	<p><i>Ephestia kuehniella</i></p>	<p>volume of 30 m³ 2 test product variants: 1) VP_0027A - T0y-0w: fresh product 2) T4y-3m: after storage of 4 years the product was activated and stored for 3 months Replicates per test product and control: 7 Test individuals from laboratory breeding; unknown number of adults, pupae, and larvae 1 trap with 2.5 mg pheromone and 1 control trap per room and per replicate Exposure: >24 h ≤ 7 days The traps were replaced when at least a ratio of 4:1 of test individuals trapped in the trap with pheromone compared to the control trap was reached by each target species.</p>	<p>2) 4:1 ratio was reached within a maximum of 4 days Percentage males trapped on the total of trapped moths in the traps with pheromone: <i>Plodia interpunctella</i> 1) 92.5% 2) 97.1% <i>Ephestia kuehniella</i> 1) 93.1% 2) 94.7% Total numbers (sum of each 7 repl.) trapped food moth trap/untreated control (adult males): <i>Plodia interpunctella</i> 1) 49/2 2) 67/4 <i>Ephestia kuehniella</i> 1) 67/5 2) 71/4</p>		<p>evaluation of a sticky trap against <i>Ephestia kuehniella</i> and <i>Plodia interpunctella</i> (room test)</p>
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2.3.6.2 Efficacy assessment

The newly submitted efficacy studies in the extent of the SA-MAC were performed according to the requirements of the BPR Guidance on Efficacy (ECHA 2022b).

The data provided demonstrate that the active substance (Z,E)-tetradeca-9,12-dienyl acetate used in a pheromone trap may significantly reduce infestation of food stuff with *P. interpunctella* and *E. kuehniella*. The emitted pheromone confuses males on their search for females and thereby prevents them from reproducing. If males are found on the traps this indicates potential infestation of the premises.

The requirements for a PT19 repellent against stored-goods attacking insects intended to be used by the general public are fulfilled (for consumer products, simulated-use tests are required).

Two new efficacy trials (simulated-use tests) are submitted to support the use of "Lebensmittelmotten-Falle" against *P. interpunctella* and *E. kuehniella*. Tests were conducted with the fresh product, the 4y aged product as well as the 4y aged and subsequently stored product (see also the test methods in Tab. 2.3.6.1-1).

The required catch ratio of 4:1 compared to an untreated control was reached within 2 to 4 days for both target species. To simulate the in-use time, the traps were activated by removing the protection sheet and were partly stored at about 25°C for 11-12 weeks. Furthermore, Anonymous 2023b showed in addition that more than 90% of the overall trapped moths were males.

In conclusion, the shelf life of 4 years was proven just as the increase of the time in use up to 12 weeks. Traps should be exchanged after 12 weeks, which is proven by efficacy studies against both target species (adults, males).

2.3.6.3 Conclusion on efficacy

The proposed changes in the extent of the SA-MAC were considered acceptable due to the two submitted efficacy studies. The studies fulfil the requirements for the addition of the target organism *E. kuehniella* and show the efficacy of the product of 12 weeks after activation. The shelf life of 4 years is sufficiently proven. Thus the label claim according to the experimental data: The biocidal product reduces infestation of dried food stuff by *P. interpunctella* and *E. kuehniella* by mating disruption is substantiated.

2.3.7 Human Health

Not relevant. The active substance is included in Annex I of Reg. (EU) 528/2012. The biocidal product does not contain any substance of concern or nanomaterial; the handling of the biocidal product and its intended use do not require personal protective equipment.

2.3.8 Environment

Not relevant. The active substance is included in Annex I of Reg. (EU) 528/2012. The biocidal product does not contain any substance of concern or nanomaterial.

3 ANNEX

3.1 List of studies

Section No. in IUCLID	Reference (Author, year)	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
3.4.1.2	Anonymous 2017	Physico-chemical Properties of the Food Moth Trap "2 mg N143 Projekt 5002" over 4 Years Storage at 20°C	Eurofins Agrosience Services EcoChem GmbH / Eurofins Aprosience Services Ecotox GmbH	S12-04233	yes	yes	Aeraxon
6.7.12	Anonymous 2023a	ATTRACTANT EFFICACY EVALUATION OF A STICKY TRAP AGAINST Ephestia kuehniella AND Plodia interpunctella (ROOM TEST)	Entostudio S.r.I., Viale del Lavoro 66, 35020 Ponte San Nicolo PD (Italy)	Q129A-22	no	n.a.	Aeraxon

Section No. in IUCLID	Reference (Author, year)	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
6.7.13	Anonymous 2023b	ATTRACTANT EFFICACY EVALUATION OF A STICKY TRAP AGAINST Ephestia kuehniella AND Plodia interpunctella (ROOM TEST)	Entostudio S.r.I., Viale del Lavoro 66, 35020 Ponte San Nicolo PD (Italy)	Q129A-22-01	No	n.a.	Aerixon

3.2 List of references

ECHA 2022a: Recommendations on preparing a Summary of Product Characteristics (SPC) for single biocidal products and biocidal product families, April 2022; available at: https://echa.europa.eu/documents/10162/17242/recommendation_preparing_spc_format_en.pdf/c4a70e46-200a-3217-0631-fd08883521cc?t=1649819282247

ECHA 2022b: Guidance on the Biocidal Products Regulation, Vol. II Efficacy – Assessment and Evaluation (Parts B+C), Version 4.1, Feb. 2022

LEGAL NORMS

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products; available at: <http://data.europa.eu/eli/reg/2012/528/oj>

Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council; available at: http://data.europa.eu/eli/reg_impl/2013/354/oj

3.3 Confidential information

None.

3.4 Confidential information restricted to authorities

None.