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 APPLICATION

(submitted by the competent authority)

Lebensmittelmotten-Falle

Product type 19

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

Case Number in R4BP: BC-CF091203-59

Competent Authority: AT

Date: **24/04/2024 (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
SA-APP	*AT*	BC-CF091203-59	dd.mm.yyyy	*Application for simplified authorisation (SA-APP)[1], taking into account the new active substance concentration of 2.5 mg as per major change described above.*	

[1] There was a preceding simplified authorisation, cf. to asset no. EU-0012382-0000. The SA-APP was case no. BC-SN006622-32, and a SA-MIC (BC-BA054534-64) as well as a SA-MAC (BC-JJ086009-33) were performed. As simplified authorisations have no renewal, the present SA-APP was applied instead. No changes are made compared to the previous authorisation recorded under EU-0012382-0000.

1 Conclusion

Lebensmittelmotten-Falle is an any other liquid biocidal product containing Z,E-9,12-Tetradecadien-1-yl acetate as active substance. The product is used as an attractant by non-professional and professional users for the control of Indian meal moths and Flour moths.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised for the use "Attractant – Indian meal moth, Mediterranean Flour Moth – general public, professionals – RTU trap", use by non-professional and professional users as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended use(s) of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

Following evaluation, the biocidal product does meet the conditions required for simplified authorisation as defined in Article 25 of Regulation (EU) No 528/2012, i.e.:

1. The active substance Z,E-9,12-Tetradecadien-1-yl acetate is listed in Annex I of Regulation (EU) 528/2012 with no restrictions applied
2. The biocidal product does not contain any substance of concern;
3. The biocidal product does not contain any nanomaterials;
4. The biocidal product is sufficiently effective;
5. The handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE).

A classification according to Regulation (EC) No 1272/2008[1] is not necessary.

The biocidal product does not contain any non-active substances (so called "co-formulants") which are considered as substances of concern.

The biocidal product should be considered not to have endocrine-disrupting properties.

The biocidal product contains the active substance Z,E-9,12-Tetradecadien-1-yl acetate, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

More information is available in section 2.7 of the PAR and in the confidential annex.

The biocidal product contains Z,E-9,12-Tetradecadien-1-yl acetate which does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered as a candidate for substitution. Therefore, a comparative assessment of the biocidal product is not required.

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturers of the biocidal product are listed in

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substances in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturer of the active substance is listed in section 1.5 of the SPC.

Conclusions of the assessments for each area

The intended use as applied for by the applicant has been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

A validated analytical method for the determination of the concentration of the active substance is available. More information on the analytical methods for the active substance is available in section 3.4 of the PAR.

A validated analytical method or acceptable justification is provided for monitoring of relevant components of the biocidal product and/or residues in soil, air, water, animal, and human body fluids, and in food and feeding stuff. More information is available in section 3.4 of the PAR.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against *Plodia interpunctella* and *Ephestia kuehniella* for all intended uses. More information is available in section 3.5 of the PAR.

Risk assessment for human health

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Dietary risk assessment

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Risk assessment for animal health

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Risk assessment for the environment

Data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No

528/2012.

Post-authorisation conditions

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Table 1-1 Post-authorisation conditions

Description	Due date
NONE	*Not relevant*

2 Information on the biocidal product

2.1 Product type(s) and type(s) of formulation

Table 2-1 Product type(s) and type(s) of formulation

Product type(s)	PT19
Type(s) of formulation	AL any other liquid

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2-2 Overview of uses of the biocidal product

Use number[1]	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (eCA/ refMS)[8]	Comment (eCA/refMS)[9]
1	*Attractant – Indian meal moth, Mediterranean Flour Moth – general public, professionals – RTU trap*	*PT19*	*Plodia interpunctella Ephestia kuehniella*	*Ready to use trap covered with an adhesive glue to protect stored food or feedstuff*	*The recommended application is 1 trap per cupboard or small room (30 m³), 2 traps for larger rooms. Traps should be inspected at least once a week and replaced after 12 weeks or, if covered with moths.*	*General public*	*[R]*	• *The instruction "2 traps for larger rooms" is removed as it is not sufficiently specific*

[1] Use number (as applied for), as indicated in the SPC
[2] Title of the specific use (as applied for), as indicated in the SPC
[3] Product type(s) of the use(s)
[4] Target organisms, group of organisms
[5] Application method for the specific use
[6] Min-max. application rate of the product for the specific use
[7] User categor(y/ies), e.g. general public, non-professional, professional, industrial
[8] eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

[9] If the use is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and indicate the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

2.3 Identity and composition

The identity and composition of the biocidal product are

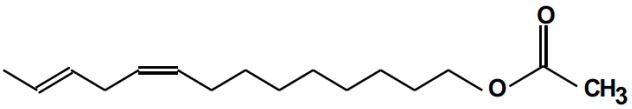
identical ☒
not identical ☐

to the identity and composition of the product(s) evaluated in connection with the inclusion of the active substance in category 6 of Annex I of Regulation (EU) No 528/2012.

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

2.4 Identity of the active substance(s)

Table 2-3 Identity of the active substance(s)

Main constituent(s)	
Common name	*Z,E-9,12-Tetradecadien-1-yl acetate*
Chemical name	*(9Z,12E)-tetradeca-9,12-dien-1-yl acetate*
EC number	*Not allocated*
CAS number	*30507-70-1*
Index number in Annex VI of CLP	*Not allocated*
Minimum purity / content	*977 g/kg*
Structural formula	

2.5 Information on the source(s) of the active substance(s)

Is the source of (Z,E)-Tetradec-9,12-dienyl acetate the same as the one(s) evaluated in connection with the inclusion of the active substance(s) in category 6 of Annex I of Regulation No. 528/2012?

☒ Yes
☐ No

2.6 Candidate(s) for substitution

No candidate(s) for substitution has been identified.

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

The biocidal product does not contain any active substances having endocrine-disrupting properties.

2.8 Classification and labelling

Table 2-4 Classification and labelling of the biocidal product

	Classification	Labelling
Hazard Class and Category code	Not classified	-
Hazard Pictograms	-	-
Signal word(s)	-	-
Hazard statements	-	-
Precautionary statements*	_	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements	-	
Notes		

***P-statements that are excluded based on the risk assessment or the intended use of the product[2], are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

[2] Section 3 of the CA note of Q&A concerning the content of some SPC sections. Document is available at https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b.

2.9 Letter of access

As the applicant is the owner of the data mentioned above, no letter of access is necessary.

2.10 Data submitted in relation to product authorisation

The applicant Aeroxon Insect Control GmbH (Waiblingen, Germany) is the same as for Annex I inclusion of ZE-TDA in product-type 19. Please find the data in the CAR.

Furthermore the applicant submitted new data for the biocidal product (physical and chemical properties, analytical method and efficacy data), which are listed in the reference list in Appendix 4.3 List of studies for the biocidal product.

2.11 Similar conditions of use across the Union

This section is not relevant.

3 Assessment of the biocidal product

3.1 Packaging

Table 3-1 Packaging

Type of packaging[1]	Size/volume of the packaging[2]	Material of the packaging[3]	Type and material of closure(s)	Intended user[4]	Compatibility of the product with the proposed packaging materials (Yes/No)
Carton, two dimensional shape	*2.50 mg packed in:* *Carton* *- 130x90mm*	*Cardboard*	-	*Non professional users /consumers, professionals*	*Yes*
Carton, triangular shape	*2.50 mg packed in:* *Carton* *- 65x341 mm* *- 86x356 mm*	*Cardboard*	-	*Non professional users /consumers, professionals*	*Yes*

[1] Type of packaging e.g. bottle, rolls, can, barrel, tank.
[2] Size for primary packaging (closed packaging that preserves the biocidal product, prevents leakage during storage and is removed or opened before use) and detailed volume in the case of individual packaging intended to be used to prevent human exposure and facilitate the use of the product.
For rolls or individual products such as wipes, the dimension of product / amount of individual products should be reported here: Height*Length*Width for rolls / number and weight of wipes.
[3] For metallic packaging, it should be indicated if there is a varnish layer; in the same way, the nature of plastic packaging should be reported. For sprayer sold with packaging, the nature of the material should be added.
[4] Intended user, e.g. professional, non-professional

The packaging unit consists of 1 – 6 traps.
The first product type is two-dimensional. It consists of the carrier material (cardboard 130x90 mm), the adhesive surface, the pheromone (2.5 mg) and a cover layer. As an option, the activated trap can be inserted into a variant of the packaging, which serves as the housing of the trap during use.
The second type of product (triangle shape) can be folded twice by the user to form a triangle. There are two product versions. The size of the substrate is 65x341 mm for the smaller version of the product and 86x356 mm for the larger one. The "triangular shape" product type also consists of the carrier material, the adhesive surface, the pheromone (2.5 mg) and a cover layer.

3.2 Physical, chemical, and technical properties

An overview of the physico-chemical properties of the active substances can be found in the CAR[3].

ZE-TDA is a colourless liquid with no specific odour. Its melting point is -46.7°C and the boiling point is 318°C. The density is 0.8893 kg/L at 20°C. The vapour pressure of the active substance is 0.18 Pa at 20°C, 0.29 Pa at 25°C and 2.2 Pa at 50°C, and the calculated Henry's law constant is 381.76 Pa x m^3/mol at 20°C. The water solubility is: 0.140 mg/L (pH: 6.10) and 0.115 mg/L (pH: 7.62) at 10°C; 0.143mg/L (pH: 6.22) and 0.119 mg/L (7.58) at 20°C; 0.150 mg/L (pH: 6.18) and 0.121 mg/L (pH: 7.56) at 30°C.
The active substance ZE-TDA hydrolyses in water at acidic and alkaline pH values (DT_{50} is 9h and 13h) but does not form any ions. A reversible dissociation of the active substance is therefore impossible.
A preliminary test is employed to determine the approximate solubility of the test substance. Due to the structure of the test substance, ZE-TDA in n-Heptane, p-Xylene, 1,2-Dichloroethane, Methanol or Propan-2-ol, Acetone and Ethyl acetate could be anticipated to be unlimited soluble.
The active substance does not contain any organic solvent, therefore the stability in organic solvents was not tested. The partition coefficient octanol-water is log P_{ow} >6.5 at pH 6.5 and 20°C. The active substance is not considered surface active because it does not display amphipathic properties.
The active substance displays neither explosive nor oxidizing properties based on its structure. A DSC-measurement on thermal stability showed exothermal decomposition of the active substance at 330 – 450°C. The active substance is not flammable up to 330 – 450°C. The DSC-measurement in a closed glass crucible showed exothermal decomposition in the temperature range of 330 - 450°C with the energy of 374 J/g. ZE-TDA is not considered to be reactive to container material (metal containers).

For details please see the CAR, DOC II-A, section 1.3.

As the biocidal product is identical with the active substance, please see above.

Updated self-life of 4 years is demonstrated via the efficacy trials, conducted with aged product. See following studies in 3.5.3:
- Drago, A. (2023), Q129A-22 and
- Drago, A. (2023), Q129A-22-01.

[3] Competent Authority Report

Table 3-2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20 °C and 101.3 kPa	Visual inspection	Food moth trap. Batch: 1 mg N143 Projekt 5002. 0.93 mg (Z,E)-tetradeca-9,12-dienyl acetate	The food moth trap consists of front protective paper, one odourless glue trap with imprinted moth motives and cardboard backing sheet. A red protective strip on the cardboard backing sheet covers s line of adhesive that fixes the trap to its intended place.	Anonymous 2013a
		Visual inspection	Food moth trap. Batch: 2 mg N143 Projekt 5002. 2.14 mg (Z,E)-tetradeca-9,12-dienyl acetate	The food moth trap consists of front protective paper, one odourless glue trap with imprinted moth motives and cardboard backing sheet. A red protective strip on the cardboard backing sheet covers a line of adhesive that fixes the trap to its intended place.	Anonymous 2013b
3.1.1.	Physical state at 20 °C and 101.3 kPa	Visual inspection	Food moth trap. Batch: 1 mg N143 Projekt 5002. 0.93 mg (Z,E)-tetradeca-9,12-dienyl acetate	The commercial packaging (white side-seamed pouch pack with double closing seam on the back side) contained one rectangular (about 16.5 cm x 9 cm) glue trap. The commercial packaging was found tightly sealed prior to	Anonymous 2013a

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				opening, and no damage neither to the commercial packaging nor to the test item was observed.	
		Visual inspection	Food moth trap. Batch: 2 mg N143 Projekt 5002. 2.14 mg (Z,E)-tetradeca-9,12-dienyl acetate	The commercial packaging (white side-seamed pouch pack with double closing seam on the back side) contained one rectangular (about 16.5 cm x 9 cm) glue trap. The commercial packaging was found tightly sealed prior to opening, and no damage neither to the commercial packaging nor to the test item was observed.	Anonymous 2013b
3.1.2.	Colour at 20 °C and 101.3 kPa	Visual inspection	Food moth trap. Batch: 1 mg N143 Projekt 5002. 0.93 mg (Z,E)-tetradeca-9,12-dienyl acetate	The food moth trap consists of front protective paper, one odourless glue trap with imprinted moth motives and cardboard backing sheet. A red protective strip on the cardboard backing sheet covers s line of adhesive that fixes the trap to its intended place.	Anonymous 2013a
		Visual inspection	Food moth trap. Batch: 2 mg N143	The food moth trap consists of front	Anonymous 2013b

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
			Projekt 5002. 2.14 mg (Z,E)-tetradeca-9,12-dienyl acetate	protective paper, one odourless glue trap with imprinted moth motives and cardboard backing sheet. A red protective strip on the cardboard backing sheet covers a line of adhesive that fixes the trap to its intended place.	
3.1.3.	Odour at 20 °C and 101.3 kPa	Organoleptic inspection	Food moth trap. Batch: 1 mg N143 Projekt 5002. 0.93 mg (Z,E)-tetradeca-9,12-dienyl acetate	The food moth trap consists of front protective paper, one odourless glue trap with imprinted moth motives and cardboard backing sheet. A red protective strip on the cardboard backing sheet covers s line of adhesive that fixes the trap to its intended place.	Anonymous 2013a
		Organoleptic inspection	Food moth trap. Batch: 2 mg N143 Projekt 5002. 2.14 mg (Z,E)-tetradeca-9,12-dienyl acetate	The food moth trap consists of front protective paper, one odourless glue trap with imprinted moth motives and cardboard backing sheet. A red protective strip on the cardboard backing sheet covers a line of adhesive that fixes the trap to its intended place.	Anonymous 2013b

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.2.	Acidity, alkalinity and pH value	This biocidal product is eliglible for the simplified authorisation procedure according to Art. 25 of the BPR. Thus, according to Art. 20 of the BPR this endpoint is not required.			
3.3.	Relative density / bulk density	This biocidal product is eliglible for the simplified authorisation procedure according to Art. 25 of the BPR. Thus, according to Art. 20 of the BPR this endpoint is not required.			
3.4.1.1.	Storage stability test – **accelerated storage**	In-house method	Food moth trap. Batch: M131. 2 mg (Z,E)-tetradeca-9,12-dienyl acetate	After storage for 24 weeks at 35ºC: - there was a production tolerance of 30% in the test item - there was no linear decrease of the pheromone contents between the sampling points - with the aid of a simple linear regression a constant linear decrease of the pheromone content could be demonstrated	Anonymous 2011a
		CIPAC MT 46.3	Food moth trap. Batch: 1 mg N143 Projekt 5002. 0.93 mg (Z,E)-tetradeca-9,12-dienyl acetate	Storage for 12 Weeks at 35°C: 1. Stability of the commercial packaging material (visual): BS (before storage): The commercial packaging (white side-seamed pouch pack with double closing seam on the back side) contained one rectangular (about 16.5 cm × 9 cm) glue trap. The packaging was found tightly sealed prior to opening and no damage neither to the	Anonymous 2013a

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				commercial packaging nor to the test item was observed. AS (after storage): No visible damage or deterioration neither to the commercial packaging nor to the test item was observed after storage. 2: Weight change of the commercial packaging material AS: The change in weight of the entire test item (including packaging) after storage was ≤ 2.72 % of the initial weight. 3. Appearance, colour and odour (visual) BS: The food moth trap consists of front protective paper, one odourless glue trap with imprinted moth motives and cardboard backing sheet. A red protective strip on the cardboard backing sheet covers a line of adhesive that fixes the trap to its intended place. AS: No visual differences or any other changes in appearance,	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				colour and odour were observed after storage compared to initial values. 4. Mean content of active ingredient (GC/FID): BS: 0.95 mg (Z,E)-tetradeca-9,12-dienyl acetate (TDA) per unit. AS: 0.98 mg (Z,E)-tetradeca-9,12-dienyl acetate (TDA) per unit (Δ +3.2 %). 5. Applicability of the glue trap: BS: The glue traps were found to be mechanically stable during the application, but were not easily and residue-free removable from the solid surface. AS: The glue traps were found to be mechanically stable during the application, but were not easily and residue-free removable from the solid surface. 6. Catching ability of the glue: BS: suitable. AS: suitable.	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		CIPAC MT 46.3	Food moth trap. Batch: 2 mg N143 Projekt 5002. 2.14 mg (Z,E)-tetradeca-9,12-dienyl acetate	1. Stability of the commercial packaging material (visual): BS: The commercial packaging (white side-seamed pouch pack with double closing seam on the back side) contained one rectangular (about 16.5 cm × 9 cm) glue trap. The packaging was found tightly sealed prior to opening and no damage neither to the commercial packaging nor to the test item was observed. AS: No visible damage or deterioration neither to the commercial packaging nor to the test item was observed after storage. 2: Weight change of the commercial packaging material AS: The change in weight of the entire test item (including packaging) after storage was ≤ 2.67 % of the initial weight. 3. Appearance, colour and odour (visual) BS: The food moth trap	Anonymous 2013b

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				consists of front protective paper, one odourless glue trap with imprinted moth motives and cardboard backing sheet. A red protective strip on the cardboard backing sheet covers a line of adhesive that fixes the trap to its intended place. AS: No visual differences or any other changes in appearance, colour and odour were observed after storage compared to initial values. 4. Mean content of active ingredient (GC/FID): BS: 1.85 mg (Z,E)-tetradeca-9,12-dienyl acetate (TDA) per unit AS: 1.95 mg (Z,E)-tetradeca-9,12-dienyl acetate (TDA) per unit (Δ –5.4 %). 5. Applicability of the glue trap: BS: The glue traps were found to be mechanically stable during the application but were not easily and residue-free removable	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				from the solid surface. AS: The glue traps were found to be mechanically stable during the application but were not easily and residue-free removable from the solid surface. 5. Catching ability of the glue: BS: suitable. AS: suitable	
		The studies were only conducted at 35°C, thus the following label claim will be included in the SPC: N-372 Store at temperatures not exceeding 35°C.			
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	CIPAC MT 46.3	Food moth trap. Batch: 2 mg N143 Projekt 5002. 2.14 mg (Z,E)-tetradeca-9,12-dienyl acetate	Summary of physico-chemical properties of the "Food Moth Trap" (after 4 years of storage) 1. Stability of the commercial packaging material (visual): BS: The commercial packaging (white side-seamed pouch pack with double closing seam on the back side) contained one rectangular (about 16.5 cm x 9 cm) glue trap. The commercial packaging was found tightly sealed prior to opening, and no damage neither to the	Anonymous 2017a

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				commercial packaging nor to the test item was observed AS: The commercial packaging (white side-seamed pouch pack with double closing seam on the back side) contained one rectangular (about 16.5 cm x 9 cm) glue trap. The commercial packaging was found tightly sealed prior to opening, and no damage neither to the commercial packaging nor to the test item was observed. 2: Weight change of the commercial packaging material AS: No significant change in weight was found after storage. 3. Appearance, colour and odour (visual) BS: The food moth trap consists of front protective paper, one odourless glue trap with imprinted moth motives and cardboard backing sheet. A red protective strip on the cardboard	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				backing sheet covers a line of adhesive that fixes the trap to its intended place. AS: No deviation to the result prior to storage was observed. 4. Mean content of active ingredient (GC/FID): BS: 1.85 mg (Z,E)-tetradeca-9,12-dienyl acetate (TDA) per unit AS: 0.70 mg (Z,E)-tetradeca-9,12-dienyl acetate (TDA) per unit (Δ –62.1 %). 5. Applicability of the glue trap: BS: The glue traps were found to be mechanically stable during the application, but were not easily and residue-free removable from the solid surface. AS: No deviation to the results prior to storage was observed. 5. Catching ability of the glue: BS: Suitable. AS: Suitable. No deviation to the results prior to storage was	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				observed. Efficacy of the stored product is supported by the study Parker, R. (2019). Shelf life: 2 years.	
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	Based on the composition of the biocidal product and that the product is distributed on a glue, phase separation during storage is not considered as possible. Thus, additional testing is not considered as nessecary.			
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	The material of packaging of the biocidal product is cardboard which is opaque. Thus, additional testing is not considered as nessecary.			
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Accelerated storage studies do not show significant changes in any tested parameters and thus confirm the stability at elevated temperatures (cf. Section 3.4.1.1).			
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Long term storage studies do not show any changes in the packaging and thus confirm stability of the packaging (cf. Section 3.4.1.2).			
3.5.1.	Wettability	Not applicable. The formulated product is a trapping system. The product is not a granule or powder and thus, any specific physical-chemical studies are not required.			
3.5.2.	Suspensibility, spontaneity, and dispersion stability	Not applicable. The formulated product is a trapping system. The product is not a granule or powder and thus, any specific physical-chemical studies are not required.			
3.5.3.	Wet sieve analysis and dry sieve test	Not applicable. The formulated product is a trapping system. The product is not a granule or powder and thus, any specific physical-chemical studies are not required.			
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability	Not applicable. The formulated product is a trapping system. The product is not a granule or powder and thus, any specific physical-chemical studies are not required.			
3.5.5.	Disintegration time	Not applicable. The formulated product is a trapping system. The product is not a granule or powder and thus, any specific physical-chemical studies are not required.			

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	Not applicable. The formulated product is a trapping system. The product is not a granule or powder and thus, any specific physical-chemical studies are not required.			
3.5.7.	Persistent foaming	Not applicable. The formulated product is a trapping system. The product is not a granule or powder and thus, any specific physical-chemical studies are not required.			
3.5.8.	Flowability/pourability/dustability	Not applicable. The formulated product is a trapping system. The product is not a granule or powder and thus, any specific physical-chemical studies are not required.			
3.5.9.	Burning rate — smoke generators	Not applicable. The formulated product is a trapping system, but not a smoke generator.			
3.5.10.	Burning completeness — smoke generators	Not applicable. The formulated product is a trapping system, but not a smoke generator.			
3.5.11.	Composition of smoke — smoke generators	Not applicable. The formulated product is a trapping system, but not a smoke generator.			
3.5.12.	Spraying pattern — aerosols / spray	Not applicable. The formulated product is a trapping system. The product is not an aerosol.			
3.6.1.	Physical compatibility	Not applicable. The formulated product is a trapping system. The product is not intended to be used with another biocidal product.			
3.6.2.	Chemical compatibility	Not applicable. The formulated product is a trapping system. The product is not intended to be used with another biocidal product.			
3.7.	Degree of dissolution and dilution stability	Not applicable. The formulated product is a trapping system but neither a tablet or water soluble preparation, nor available in a water soluble bag.			
3.8.	Surface tension	This biocidal product is eligible for the simplified authorisation procedure according to Art. 25 of the BPR. Thus, according to Art. 20 of the BPR this endpoint is not required.			
3.9.	Viscosity	This biocidal product is eligible for the simplified authorisation procedure according to Art. 25 of the BPR. Thus, according to Art. 20 of the BPR this endpoint is not required.			

Table 3-3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
Lebensmittelmotten-Falle is a ready to use trap. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Shelf-life of 4 years is confirmed via efficacy trials conducted with aged product. Implications for labelling: No unacceptable risk arising from physico-chemical properties could be identified and no classification and labelling with regard to physico-chemical properties are required. Studies on accelerated storage stability were only conducted at 35°C, thus the following label claim will be included in the SPC: N-372 Store at temperatures not exceeding 35°C.

3.3 Physical hazards and respective characteristics

Table 3-4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.1.	Explosives	C-C unsaturation was identified as functional group associated with explosive properties in the a.s.. However, in the CAR the a.s. was not classified as explosive based on a DCS scan. Thus, additional testing is not considered as necessary. The biocidal product is not classified as explosive.		
4.2.	Flammable gases	Not relevant to be tested since the biocidal product is not a gas.		
4.3.	Flammable aerosols	Not relevant to be tested since the biocidal product is not an aerosol.		
4.4.	Oxidising gases	Not relevant to be tested since the biocidal product is not a gas.		
4.5.	Gases under pressure	Not relevant to be tested since the biocidal product is not a gas.		
4.6.	Flammable liquids	No data were submitted regarding this physical hazard and respective characteristics of the product. However, the a.s. is included in Annex I of the BPR and therefore does not give rise to concern for high flammability. In addition, the product does not contain any other substance known to be flammable.		
4.7.	Flammable solids	No data were submitted regarding this physical hazard and respective characteristics of the product. The liquid biocidal product is used in an adheasive trap and hence the hazard flammable solid is not applicable.		
4.8.	Self-reactive substances and mixtures	C-C unsaturation was identified as functional group associated with self-reactive properties in the a.s.. However, in the CAR the a.s. was not classified as self-reactive based on a DCS scan. Thus, additional testing is not considered as nessecary. The biocidal product is not classified as self-reactive.		
4.9.	Pyrophoric liquids	The product is known to be stable in contact with air at room temperature for prolonged periods of time (cf. to storage stability studies) and hence the classification procedure does not need to be applied.		
4.10.	Pyrophoric solids	No data were submitted regarding this physical hazard and respective characteristics of the product. The liquid biocidal product is used in an adheasive trap and hence the hazard flammable solid is not applicable.		
4.11.	Self-heating substances and mixtures	The phenomenon of self-heating applies only to solids. The surface of liquids is not considered as large enough for reaction with air and the test method is not applicable to liquids. The liquid biocidal product is used in an adheasive trap and hence the surface area is not considered to be large enough for reaction with air.		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.12.	Substances and mixtures which in contact with water emit flammable gases	Not relevant to be conducted since none of the components present in the formulated biocidal product contain metals or metalloids and hence the classification procedure does not need to be applied.		
4.13.	Oxidising liquids	The biocidal product does contain oxygen, but only bound to carbon or hydrogen. Thus, the classification procedure doesn't need to be applied.		
4.14.	Oxidising solids	No data were submitted regarding this physical hazard and respective characteristics of the product. The liquid biocidal product is used in an adheasive trap and hence the hazard oxidising solid is not applicable.		
4.15.	Organic peroxides	Not relevant to be conducted since none of the components present in the formulated biocidal product fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.		
4.16.	Corrosive to metals	Not relevant to be conducted since based on the chemical evaluation none of the components present in the formulated biocidal product contain chemical groups, which could initiate an irreversible electrochemical reaction with metals leading to significant damage or destruction. Moreover, the biocidal product does not contain acid, base or halogens and the pH in is close to neutral. Thus, there is no need for further testing.		
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	No data were submitted regarding this physical hazard and respective characteristics of the product. However, the a.s. is included in Annex I of the BPR and therefore does not give rise to concern for high flammability (not flammable up to 330–450°C). In addition, the product does not contain any other substance to rise a concern.		
4.17.2.	Relative self-ignition temperature for solids	No data were submitted regarding this physical hazard and respective characteristics of the product. The liquid biocidal product is used in an adheasive trap and hence the hazard flammable solid is not applicable.		
4.17.3.	Dust explosion hazard	Not relevant to be tested since the corresponding study is only applicable to all powders and products containing or able to produce dust that can either ignite or explode when exposed to an ignition source when dispersed in air.		

Table 3-5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product is not classified for physical hazards.

3.4 Methods for detection and identification

Table 3-6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
Principle of the method: The complete unit (glue trap) was cut in pieces of about 4.5 x 1.5 cm by scalpel and scissor. Then 50 mL extraction solvent hexane/n-pentane (50/50); v/v) were added into an appropriate Erlenmeyer flask. The flask was closed with an appropriate plug. Then the front protective paper from the first piece was removed by a pair of tweezers, given in the extraction solvent and mixed by about 5 minutes intensive stirring (about 150 rpm/min) to dissolve the glue from the piece and prevent the pieces sticking during the extraction process. The pieces were given in the same was as described above. Finally, the flask was placed into an ultrasonic bath for two hours. Every 15 minutes the ultrasonic bath was started for two minutes at room temperature. Then about 1 mL of the supernatant of the raw extract (wait for settling down of the cloudiness/turbidness) was transferred into an amber crimp vial and measured by GC/FID.											
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
(Z,E)-tetradeca-9,12-dienyl acetate (TDA)	1.0 mg/L to 100.00 mg/L n=5 r=1.0000 Calibration line: y = 2252.933 ·x – 26.176	Interference not present at >3% of peak sample area. Chromatograms of standard, blank sample and samples at recovery determination.	1 mg/unit	5	0.93-1 mg/unit	0.95 mg/unit	3.2	1 mg/unit	5	n.a.	Anonymous 2013c
			0.40 mg/unit & 4 mg/unit	10	100-110%	105 %	2.7	0.40 mg/unit & 4 mg/unit	10		

Table 3-7 Analytical methods for soil

Analytical methods for soil									
Analyte (type of analyte e.g. active substance) **Analytical method**	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		
Not required according to TNsG on data requirements (Guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC).										

Table 3-8 Analytical methods for air

Analytical methods for air										
Analyte (type of analyte e.g. active substance) **Analytical method**	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		
(Z,E)-tetradeca-9,12-dienyl acetate (TDA)	0–24.4 mg/L n=6 R^2=0.998	Interference not present at >3% of peak sample area. Chromatograms of standard at lower fortification point	3.39 -196 µg a.s./m³ air 5 concentration levels 5 measurements per level	80.0-107.9	n.s.	4.9-16.1			3.39 µg a.s./m³	Anonymous 2006a

Table 3-9 Analytical methods for water

Analytical methods for water										
Analyte (type of analyte e.g. active substance) **Analytical**	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		

method										
Not required according to TNsG on data requirements (Guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC).										

Table 3-10 Analytical methods for animal and human body fluids and tissues

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance) **Analytical method**	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		
Not required according to TNsG on data requirements.										

Table 3-11 Analytical methods for monitoring of active substances and residues in food and feeding stuff

Analytical methods for monitoring of active substances and residues in food and feeding stuff										
Analyte (type of analyte e.g. active substance) **Analytical method**	**Linearity**	**Specificity**	**Fortification range, level, and number of measurements at each level**	**Recovery rate (%)**			**Precision (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
				Range	Mean	RSD	Concentration tested	Number of replicates		
Not required according to TNsG on data requirements under the condition that the stored food and feedstuff is kept closed.										

Table 3-12 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
An analytical method, Anonymous 2013c, for the determination of (Z,E)-tetradeca-9,12-dienyl acetate (TDA) in the biocidal product is available. Specificity, linearity, accuracy and precision were checked and found acceptable. A method for the detection of (Z,E)-tetradeca-9,12-dienyl acetate (TDA) in air was provided and deemed acceptable at EU level. No other data is required. According to the Guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC1, analytical methods for determination of (Z,E)-tetradeca-9,12-dienyl acetate (TDA) in water, sediment and soil are not necessarily required. As the active substance (Z,E)-tetradeca-9,12-dienyl acetate (TDA) is not classified as toxic or very toxic, an analytical method for the determination of residues in animal and human body fluids and tissues is not required. No analytical method for the determination of (Z,E)-tetradeca-9,12-dienyl acetate (TDA) in food/feedstuffs is presented, because the biocidal product Lebensmittelmotten-Falle is not designed to be used in a manner which may cause contamination of food and feedstuffs.

3.5 Assessment of efficacy against target organisms

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

Male adults of the Indian meal moth *Plodia interpunctella* and the Flour moth *Ephestia kuehniella* are attracted by the pheromone. By confusing the male moths they are prevented from finding the female moths. Thus mating is disrupted, reproduction is inhibited and infestation of dried foodstuff is reduced.
Products intended to be protected are dried food and feedstuffs, e.g. nuts, muesli, cookies, chocolate, flour, rice, dried fruits, fodder, etc. that is stored in closed or re-closed package.

Lebensmittelmotten-Falle is a trap that captures adult males of *Plodia interpunctella* and *Ephestia kuehniella*. The trap is to be used by the general public indoor with the recommended application of 1 trap per cupboard or small room (30 m^3). Traps should be inspected at least once a week and be replaced after 12 weeks or, if covered with moths.

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

Lebensmittelmotten-Falle is a trap that captures a number of moths by physical means with adhesive glue also. It is based on the active substance (Z,E)-Tetradeca-9,12-dienyl acetate, a sex pheromone naturally produced by the females of *Plodia interpunctella* and *Ephestia kuehniella*, to call males for mating. This mechanism of attraction is disturbed by emitting pheromone in the storage facilities which results in confusing the males and finally in mating disruption.

Using the active substance (Z,E)-Tetradeca-9,12-dienyl acetate in a trap results in males being guided to the trap where they are partly caught or mainly disoriented with respect to females. Mating is disrupted because the males cannot find the females and consequently reproduction is inhibited. No time delay of responses of males is expected and an immediate response within one day has been observed in the reported studies.

The pheromone is not active against eggs and larvae that have already infested the foodstuff. The product is targeting in preventing further spoiling of foodstuff.

3.5.3 Efficacy data

Table 3-13 Efficacy data

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
Efficacy data already submitted for Annex I inclusion						
PT19 Use 1	Lebensmittelmotten-Falle Pheromone trap with Z,E-Tetradeca-9,12-dienyl acetate (TDA), Ready to use	Attractant *Plodia interpunctella*, laboratory strain, emerging adult moths from a culture vessel containing pupae and young adults (both sexes)	Simulated use study Room temperature was 20-22 °C, Seasonal photo period 1 replicate, 60 m³ test chamber, 3 traps per test chamber, Exposure time: 6 days. Traps: 1. LeMoFa 1) (batch P 134, test item) 2. Salvo Mottenval (reference) 3. Adhesive paper (control)	No. of trapped male moths (cumulated): 1. LeMoFa: 62 2. Salvo Mottenval: 15 3. Control: 0	Anonymous 2005a	01/ Comparative Testing of two Commercial Pheromone Traps for Phycitid Moths with Plodia interpunctella (HÜBNER 1810 - 1813)
PT19 Use 1	Lebensmittelmotten-Falle Pheromone trap with Z,E-Tetradeca-9,12-dienyl acetate (TDA), Different batches, Ready to use	Attractant *Plodia interpunctella*, laboratory strain, emerging adult moths from a culture vessel containing pupae and young adults (both sexes)	Room temperature was 20-22 °C, Seasonal photo period 2 replicates, 60 m³ test chamber, 5 different traps per test chamber, Exposure time: 6 days Traps (different batches): 1. LeMoFa 1) (Aeroxon P056, test item) 2. LeMoFa (Aeroxon, P051, test item) 3. LeMoFa (Aeroxon, P027, test item)	No. of trapped moths (cumulated): Mean of 2 replicates 1. Aeroxon P056: 18.5 2. Aeroxon, P051: 23.5 3. Aeroxon, P027: 2.5 4. Kapo L4 035: 23 5. Control: 0	Anonymous 2004a	02/Testing of pheromone traps for phycitid moths

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
			4. Kapo L4 035 (batch P02.04, reference) 5. Adhesive paper (control)			
PT19 Use 1	Lebensmittelmotten-Falle Pheromone trap with Z,E-Tetradeca-9,12-dienyl acetate (TDA), Ready to use	Attractant *Plodia interpunctella*, laboratory strain, emerging adult moths from a culture vessel containing pupae and young adults (both sexes)	Room temperature was 20-22 °C, Seasonal photo period 2 replicates, 30 m³ test chamber, 4 different traps per test chamber, Exposure time: 6 days , Traps (in 1 test chamber): 1. LeMoFa (batch Aeroxon Q-012, test item) 2. Celaflor NexaLotte (batch 114A33604C003965, reference) 3. Globol (batch not stated, reference) 4. Adhesive paper (control)	No. of trapped male moths (cumulated): Mean of 2 replicates 1. Aeroxon Q-012: 38.5 2. Celaflor: 34.0 3. Globol: 8 4. Control: 1.5	Anonymous 2005b	03/ Comparative Testing of three Commercial Pheromone Traps for Phycitid Moths with Plodia interpunctella (HÜBNER 1810 - 1813)
PT19 Use 1	Lebensmittelmotten-Falle Pheromone trap with 2 mg Z,E-Tetradeca-9,12-dienyl acetate (TDA) Ready to use	Attractant *Plodia interpunctella*, laboratory strain, 10 male and 10 female moths per relicate (age: 48±24 h)	Temperature: 17.3-30.1°C (test room) and 26.5-34°C (climate chamber), Moisture: 11-56% (test room) and 29-73% (climate chamber), Seasonal photo period 8 replicates, 10 male and 10 female adults, 30 m³ test room (4 x 2.7 m²), 1 trap per room, Egg laying medium: almonds and cereals, Exposure time: 7 days, Incubation of medium: 4	No. of trapped male moths (cumulated): Mean of 8 replicates 1. Test item: 3.5 2. Control: 1.25 Efficacy: 25.7% Hatched larvae in food containers: 1. Test item: 19.9 2. Control: 48.0	Anonymous 2008a	04/ Determination of Efficacy of Lebensmittelmotten-Falle, a Sticky Lure Trap with a Sexual Pheromone, against Indian Meal Moth (Plodia interpunctella)

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
			weeks, Traps: 1. LeMoFa (test item) 2. Adhesive paper (control)	Efficacy: 58.6%		
PT19 Use 1	Lebensmittelmotten-Falle Pheromone trap with Z,E-Tetradeca-9,12-dienyl acetate (TDA), Aged under shelf life conditions, Ready to use	Attractant *Plodia interpunctella*, laboratory strain, emerging adult moths from a culture vessel, both sexes, about 100-125 adult male moths emerged during the test	Room temperature 23 °C, Seasonal photo period 3 replicates, 30 m³ test chamber, 4-5 different traps per test chamber, Exposure time: 7 days Traps: 1. LeMoFa (batch PB of 2004, test item) 2. LeMoFa (batch P287 of 2004, test item) 3. LeMoFa (batch Q283 of 2005, test item) 4. LeMoFa (batch R353 of 2006, test item) 5. LeMoFa (batch S256 of 2007, test item) 6. Adhesive paper (control)	No. of trapped moths (cumulated): Mean of 2-3 replicates 1. PB: 21.0 2. P287: 28.5 3. Q28: 26.0 4. R353: 20.0 4. S256: 22.0 5. Control: 1.3 Each trap caught between 12 and 28% of the estimated number of adult male moths in the test. The total number of 3-4 traps caught on average 70% of the estimated number of available male moths.	Anonymous 2008b	05/ Comparative testing of AEROXON Pheromone traps for phycitid moths after long-term storage
Efficacy data submitted for product authorisation						
PT19 Use 1	Lebensmittelmotten-Falle Pheromone trap with Z,E-Tetradeca-9,12-dienyl acetate (TDA),	Attractant *Plodia interpunctella*, laboratory strain, larvae, pupae and	Room temperature 22 °C, Seasonal photo period 2 replicates, 30 m³ test chamber, 3 different traps per test	No. of trapped moths (cumulated: 1st / 2nd replicate I) 23 / 32 II) 29 / 22	Anonymous 2011b	06/ Has the Usage of a Protective Cardboard Box an Influence on the Trapping Efficacy of the Aeroxon Pheromone Trap for Phycitid Moths?

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
	Trap inside cardboard box Ready to use	emerging adults from a culture vessel , both sexes	chamber: I) LeMoFa 1) in cardboard box II) LeMoFa III) Control trap Distance between traps: >2m, Traps in height of 1.8-2.0m, Change of trap position after 1st replicate, 7 days exposure time	III) 0 / 1 No difference between the original trap and the trap covered by a cardboard box.		
PT19 Use 1	Lebensmittelmotten-Falle Pheromone trap with 1 mg Z,E-Tetradeca-9,12-dienyl acetate (TDA) Aged for 5 weeks under in-use conditions	Attractant *Plodia interpunctella*, laboratory strain, 10 male and 10 female moths per replicate, newly emerged, unmated	I) Aging of traps: 18.4 - 21.4°C, dark II) Test chamber: Temperature: 22.4 - 28.0°C, Humidity: 16.4% and 23.6%, Lighting: diffuse, even lighting; 12:12 light : dark photoperiod III) Incubation of Petri dishes: 26 - 33°C 4 replicates, 10 male and 10 female adult moths, 15 m³ test chamber, 1 trap per test chamber, Petri dishes with egg laying medium, Exposure period: 5 days (for mating, trapping, egg laying), Incubation of medium: 17 days	No. of trapped moths (cumulated (mean, n=4): 1. Test item: 3.0 2. Control: 3.5 Hatched larvae in the petri dishes (mean, n=4): 1. Test item: 6.0 2. Control: 129.3 Efficacy: 95.4%	Anonymous 2013d	07/ Simulated use trial to determine the efficacy of Lebensmittelmottenfalle (pheromone moth trap) against Plodia interpunctella
PT19 Use 1	Lebensmittelmotten-Falle, Pheromone trap with 1 mg Z,E-Tetradeca-9,12-dienyl acetate	Attractant *Ephestia kuehniella*, laboratory strain, 10 male	I) Aging of traps: 18.4 - 21.4°C, dark II) Test chamber: Temperature: 23.6 - 28.2°C, Humidity: 14.2% and 21.5%,	No. of trapped moths (cumulated, Ø, n=4): 1. Test item: 3.5	Anonymous 2013e	08/ Simulated use trial to determine the efficacy of Lebensmittelmottenfalle (pheromone moth trap) against ephestia

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
	(TDA), Aged for 5 weeks under in-use conditions Ready to use	and 10 female moths per replicate, newly emerged, unmated	Lighting: diffuse, even lighting; 12:12 light : dark photoperiod III) Incubation of Petri dishes: 26 - 33°C 4 replicates, 10 male and 10 female adult moths, 15 m³ test chamber, 1 trap per test chamber, Petri dishes with egg laying medium, Exposure period: 5 days (for mating, trapping, egg laying), Incubation of medium: 27 days	2. Control: 2.8 Hatched larvae (Ø, n=4): 1. Test item: 1.8 2. Control: 5.3 Efficacy: 66.7%		kuehniella
PT19 Use 1	Lebensmittelmotten-Falle, Pheromone trap with 1 mg Z,E-Tetradeca-9,12-dienyl acetate (TDA), Aged for 5 weeks under in-use conditions Ready to use	Attractant *Ephestia cautella*, laboratory strain, 10 male and 10 female moths per replicate, newly emerged, unmated	I) Aging of traps: 18.4 - 21.4°C, dark II) Test chamber: Temperature: 23.6 - 28.0°C, Humidity: 17.1% and 26.8%, Lighting: diffuse, even lighting; 12:12 light : dark photoperiod III) Incubation of Petri dishes: 26 - 33°C 4 replicates, 10 male and 10 female adult moths, 15 m³ test chamber, 1 trap per test chamber, Petri dishes with egg laying medium, Exposure period: 5 days (for mating, trapping, egg laying), Incubation of medium: up to 24 days	No. of trapped moths (cumulated, Ø, n=4): 1. Test item: 3.0 2. Control: 1.0 Hatched larvae (mean, n=4): 1. Test item: 2.5 2. Control: 8.8 Efficacy: 71.4%	Anonymous 2013f	09/ Simulated use trial to determine the efficacy of Lebensmittelmottenfalle (pheromone moth trap) against Ephestia cautella
PT19	Lebensmittelmotten-	Attractant	I) Aging of traps: 18.4 -	No. of trapped moths (cumulated, Ø,	Anonymous 2013g	10/ Simulated use trial to determine the efficacy of

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
Use 1	Falle, Pheromone trap with 1 mg Z,E-Tetradeca-9,12-dienyl acetate (TDA), Aged for 5 weeks under in-use conditions Ready to use	*Ephestia elutella*, laboratory strain, 10 male and 10 female moths per replicate, newly emerged, unmated	21.4°C, dark II) Test chamber: Temperature: 22.3 - 28.3°C, Humidity: 14.2% and 34.8%, Lighting: diffuse, even lighting; 12:12 light : dark photoperiod III) Incubation of Petri dishes: 26 - 33°C 4 replicates, 10 male and 10 female adult moths, 15 m³ test chamber, 1 trap per test chamber, Petri dishes with egg laying medium, Exposure period: 5 days (for mating, trapping, egg laying), Incubation of medium: up to 23 days	n=4): 1. Test item: 1.5 2. Control: 0.5 Hatched larvae (Ø, n=4): 1. Test item: 1.5 2. Control: 4.8 Efficacy: 68.4%		Lebensmittelmottenfalle (pheromone moth trap) against Ephestia elutella
PT19 Use 1	Lebensmittelmotten-Falle Pheromone trap with either 0.5 mg, 0.7mg or 0.88 mg Z,E-Tetradeca-9,12-dienyl acetate (TDA) Aged for 5 weeks	Attractant *Plodia interpunctella*, laboratory strain, 10 male and 10 female moths per replicate, 1-7 days old, unmated	Simulated use trial 4 replicates, 10 male and 10 female adult moths, 15 m³ test chamber I) Test chamber: Temperature: 22.1 - 30.1°C, Humidity: 18% to 57% II) The rearing medium was removed from the test chamber and incubated for an additional 4 week period 3 different traps: I) N177 0.5 mg trap	No. of trapped moths (cumulated): Mean percentage of 4 replicates 1. N177: 37.5 male, 22.5 female 2. Q224: 22.5 male, 12.5 female 3. R267: 22.5 male, 22.5 female 4. Control: 20.0 male, 7.5 female Hatched larvae (Median, n=4, after	Anonymous 2019a	11/ Simulated use trial to determine the efficacy of a pheromone moth trap product against Indian meal moth, *Plodia interpunctella*

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
			II) Q224 0.7 mg trap III) R267 0.88 mg trap IV) Control trap Traps suspended 30 cm from chamber floor 1 trap per test chamber Plastic tank with egg laying medium Exposure period: 5 days (for mating, trapping, egg laying) Incubation of plastic tanks with egg laying medium: 4 weeks, larvae counted after 7, 14, 21 and 28 days	28 days): 1. N177: 69 (58.7% efficacy) 2. Q224: 62.5 (62.6% efficacy) 3. R267: 19.5 (88.3% efficacy) 4. Control: 167		
Efficacy data to support claim against *Ephestia kuehniella* and capture of moths						
PT19 Use 1	Food moth trap 2.5% pheromone/trap Batches C069 (fresh product), U236 (4-yr-old product)	Attractant *Ephestia kuehniella, Plodia interpunctella*	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 m2 and a volume of 30 m3 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	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 trapped food moth trap/untreated	Anonymous 2022a	12/Efficacy data.012/ Attractant efficacy evaluation of a sticky trap against Ephestia kuehniella and Plodia interpunctella (room test)

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
			product was activated and stored for 11 weeks Replicates: 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.	control: *Ephestia kuehniella* 1) 121/10 2) 77/10 3) 111/8 *Plodia interpunctella* 1) 36/0 2) 34/3 3) 24/2		
PT19 Use 1	Food moth trap 2.5% pheromone/trap Batches C255 (fresh product) and U236 (4-yr-old product)	Attractant *Plodia interpunctella, Ephestia kuehniella*	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 m2 and a volume of 30 m3 2 test product variants: 1) VP_0027A - T0y-0w: fresh product 2) T4y-3m: after storage of 4 years Replicates: 7 Test individuals from laboratory breeding; unknown number of adults, pupae, and	1) 4:1 ratio was reached within a maximum of 2 days 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: *Plodia interpunctella* 1) 92.5%	Anonymous 2022b	13/Efficacy data.013/ Attractant efficacy evaluation of a sticky trap against Ephestia kuehniella and Plodia interpunctella (room test)

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
			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.	2) 97.1% *Ephestia kuehniella* 1) 93.1% 2) 94.7%		

3.5.4 Efficacy assessment

To assess the efficacy of "Lebensmittelmotten-Falle" under close to application test conditions, a study was performed where 10 male and 10 female moths per replicate were introduced into a room with either a test product trap or a control trap attached above a shelf with containers of flaked almonds and breakfast cereals. Moths were allowed to stay in the test room for mating and egg deposition for 7 days. During this period trapped moths were counted. The containers with stored goods were then transferred into a climate chamber for incubation. After 4 weeks the developed offspring was counted. This test was replicated 8 times. The efficacy in trapping male moths was 26% on average. In terms of reduced food infestation with moth larvae, the application of the pheromone-baited traps led to a reduction of food infestation by 58%.

The different degrees of efficacy and the time course of male catches over the experimental period indicate a combined mechanism. Some of the males were caught on the traps while the remaining males were most probably impaired in their mate finding capabilities.
Further experiments were carried out to compare the efficacy of "Lebensmittelmotten-Falle" to other products on the market and to assess the efficacy of the product after up to four years of storage. The results indicate, that the efficacy of "Lebensmittelmotten-Falle" is comparable to the efficacy of other products on the market, and that the efficacy of the product is therefore maintained for up to four years of storage.

The relevant trials conducted with formulations equal to "Lebensmittelmotten-Falle" is summarised in Table 3-13 above.

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* larvae.

Two new efficacy trials are submitted to support the use of "Lebensmittelmotten-Falle" against *P. interpunctella* and *E. kuehniella*. The test product was applied as fresh product and in an aged variant after 4-year storage. The required catch ratio of 4:1 was reached within 2 to 4 days for both target species.

3.5.5 Conclusion on efficacy

The label claim according to the experimental data: Lebensmittelmotten-Falle reduces infestation of dried food stuff by *P. interpunctella* and *E. kuehniella* by mating disruption. 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. Traps should be exchanged after 12 weeks.

3.5.6 Occurrence of resistance and resistance management

No reduced efficacy or resistance has been reported for *P. interpunctella* and *Ephestia kuehniella* up to now. However, under specific conditions resistance to pheromone treatments has been reported in the literature. Risk factors are long-term application on isolated populations and use of a single pheromone compound out of the species-specific pheromone blend. Under these conditions males are selected to discriminate the full natural pheromone blend against the synthetic one-component lure. Most probably some of these factors will not apply to *P. interpunctella* and *E. kuehniella.*

3.5.7 Known limitations

Experimental methods were reliable and overall well documented. The capacity to catch male

P. interpunctella and *E. kuehniella* has been demonstrated. Based on the presented data the product is therefore suitable to monitor and to control *P. interpunctella* and *E. kuehniella*.

3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products

The biocidal product Lebensmittelmotten-Falle is not intended to be authorised for use in combination with other biocidal products.

3.6 Risk assessment for human health

3.6.1 Assessment of effects on human health

Toxicology of the active substance
No new studies on human health have been submitted. The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR.

Toxicology of the biocidal product
As the biocidal product is identical with the active ingredient, please see above.

The biocidal product contains the active substance Z,E-9,12-Tetradecadien-1-yl acetate (min. purity: 977 g/kg) at an amount of 2.5 mg per trap.

3.6.1.1 Skin corrosion and irritation

Table 3-14 Conclusion used in Risk Assessment – Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Lebensmittelmotten-Falle is not corrosive or irritant to the skin
Justification for the value/conclusion	The biocidal product is identical to the active substance, which is non-irritant to the skin.
Classification of the product according to CLP	No classification necessary according to Reg. (EU) 1272/2008.

Table 3-15 Data waiving

Data waiving	
Information requirement	Skin corrosion and irritation
Justification	Extrapolation from the composition of the formulation according to Regulation (EC) No 1272/2008.

3.6.1.2 Eye irritation

Table 3-16 Conclusion used in Risk Assessment – Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Lebensmittelmotten-Falle is not corrosive or irritant to the eye
Justification for the value/conclusion	The biocidal product is identical to the active substance, which is non-irritant to the eyes.
Classification of the product according to CLP	No classification necessary according to Reg. (EU) 1272/2008.

Table 3-17 Data waiving

Data waiving	
Information requirement	Eye irritation
Justification	Extrapolation from the composition of the formulation according to Regulation (EC) No 1272/2008.

3.6.1.3 Respiratory tract irritation

Table 3-18 Data waiving

Data waiving	
Information requirement	Respiratory tract irritation
Justification	No data required

3.6.1.4 Skin sensitization

Table 3-19 Conclusion used in Risk Assessment – Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Lebensmittelmotten-Falle is not sensitising to the skin.
Justification for the value/conclusion	The biocidal product is identical to the active substance, which is non-sensitising to the skin.
Classification of the product according to CLP	No classification necessary according to Reg. (EU) 1272/2008.

Table 3-20 Data waiving

Data waiving	
Information requirement	Skin sensitisation
Justification	Extrapolation from the composition of the formulation according to Regulation (EC) No 1272/2008.

3.6.1.5 Respiratory sensitization

Table 3-21 Conclusion used in Risk Assessment – Respiratory sensitisation

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Lebensmittelmotten-Falle is not sensitising to the respiratory tract.
Justification for the value/conclusion	The biocidal product is identical to the active substance, which is not sensitising to the respiratory tract.
Classification of the product according to CLP	No classification necessary according to Reg. (EU) 1272/2008.

Table 3-22 Data waiving

Data waiving	
Information requirement	Respiratory sensitisation
Justification	Extrapolation from the composition of the formulation according to Regulation (EC) No 1272/2008.

3.6.1.6 Acute oral toxicity

Table 3-23 Value used in the Risk Assessment – Acute oral toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} > 5000 mg/kg bw
Justification for the selected value	Value for active substance. The biocidal product is identical to the active substance.
Classification of the product according to CLP	No classification for acute oral toxicity necessary according to Reg. (EU) 1272/2008.

Table 3-24 Data waiving

Data waiving	
Information requirement	Acute oral toxicity
Justification	Extrapolation from the composition of the formulation according to Regulation (EC) No 1272/2008.

3.6.1.7 Acute inhalation toxicity

Table 3-25 Value used in the Risk Assessment – Acute inhalation toxicity

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC_{50} > 5.2 mg/L, not classified
Justification for the selected value	Value for active substance. The biocidal product is identical to the active substance.
Classification of the product according to CLP	No classification for acute inhalation toxicity necessary according to Reg. (EU) 1272/2008.

Table 3-26 Data waiving

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	Extrapolation from the composition of the formulation according to Regulation (EC) No 1272/2008.

3.6.1.8 Acute dermal toxicity

Table 3-27 Value used in the Risk Assessment – Acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Assumed to be very low
Justification for the selected value	Value for active substance. The biocidal product is identical to the active substance.
Classification of the product according to CLP	No classification for acute dermal toxicity necessary according to Reg. (EU) 1272/2008.

Table 3-28 Data waiving

Data waiving	
Information requirement	Acute dermal toxicity
Justification	Extrapolation from the composition of the formulation according to Regulation (EC) No 1272/2008.

3.6.2 Information on dermal absorption

Table 3-29 Value(s) used in the Risk Assessment – Dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	(Z,E)-Tetradeca-9,12-dienyl acetate
Value(s)	100%
Justification for the selected value(s)	Assumption, because of no data

3.6.3 Available toxicological data relating to substance(s) of concern

The biocidal product does not contain a substance of concern in the definition of Regulation (EU) No 528/2012.

3.6.4 Other

No relevant food and feed stuff exposure is to be expected since "Lebensmittelmotten-Falle" contains only 2.5 mg of ZE-TDA shall not be used in spaces where un-packaged food or feed is kept.
For details of the exposure for the ZE-TDA please see Doc II-C of the CAR.

3.6.5 Available toxicological data relating to endocrine disruption

The product is identical to the active substance. The results of this toxicological assessment can be found in the CAR.

3.6.6 Exposure assessment and risk characterisation for human health

3.6.6.1 Introductory remarks

The assessment of human exposure follows the recommendations of "Technical Notes for Guidance on Human Exposure to Biocidal Products" (European Commission, 2002a) and "Human Exposure to Biocidal Products User guidance version 1" (European Commission, 2002b).

Human exposure towards the active substance/the biocidal product can take place via different "routes of exposure", i.e. via inhalation, dermal contact and/or ingestion. Exposure estimates indicate that exposure towards the active ingredient/the biocidal product Lebensmittelmotten-Falle will be negligible.

3.6.6.2 Identification of the main paths of human exposure towards active substance(s) and substance(s) of concern from use in the biocidal product

Table 3-30 Main paths of human exposure to ZE-TDA

Summary table: main paths of human exposure				
Exposure path	**Production of Lebensmittelmotten-Falle**	**Primary (direct) exposure, during use of the b.p.**		**Secondary (indirect) exposure**
	b.p.	**Industrial use / Professional use**	**General public**	**Incidental contact after application (General public)[2]**
Inhalation	Negligible	Negligible	Negligible	Negligible
Dermal	Yes	Negligible	Negligible	Negligible
Oral	Not relevant	Not relevant	Not relevant	Negligible

[1] As ZE-TDA is produced outside the European Union, no data on exposure to the active substance during its production are required.
[2] Accidental ingestion and skin contact by infants/children were identified as the only relevant exposure routes.

Formulation of Lebensmittelmotten-Falle takes place in a closed system. ZE-TDA is applied as droplets with a commercially available ink jet on a card board with polyethylene layer. The droplets of active substance are immediately covered with a layer of glue and wrapped in silicon paper covers. The only step in production where human exposure (dermal and/or inhalative) may occur is filling of the pheromone reservoir of the automated production device.

Exposure during or after application is considered to be negligible. As worst case assumption immediate uptake of the total amount of the active substance (2 mg) within a single trap is calculated for adults, children and infants. Inhalation exposure is calculated for exposure to 20 traps for adults, children and infants.

In the new biocidal product the active substance concentration is increased from 2 mg ZE-TDA/trap to 2.5 mg ZE-TDA/trap. The exposure estimates for 2 mg ZE-TDA have shown that exposure during or after application is considered to be negligible. Due to this as well as the fact that the increase of active substance is minor, it is assumed that no new exposure estimates are required for exposure during or after application.

For details of the results of the exposure calculations for ZE-TDA please see Doc II-B of the CAR.

3.6.6.3 Reference values to be used in risk characterisation

Threshold Limits and other Values for Human Health Risk Assessment

Table 3-31 Reference values to be used in risk characterisation

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
AELshort-term	-	-	-	-	-
AELmedium-term	Sub-chronic study with structurally related substance: isomeric mixture of acetates with C10 to C14 alkyl groups	100 mg/kg bw/day	100	-	1 mg/kg bw/day
AELlong-term					

Inhalative absorption	100% (assumption, because of no data)
Oral absorption	100% (assumption, because of no data)
Dermal absorption	100% (assumption, because of no data)

3.6.6.4 Specific reference value for groundwater

Not relevant.

3.6.6.5 Risk for Professional users at Production of Lebensmittel-Falle

Based on the risk assessment of the active substance, a risk for professional users resulting from the intended use is unlikely. Regarding occupational safety, there are no objections against the intended use.

Risk from exposure during the production of the product (filling, sampling, maintenance, cleaning of the active substance reservoir, see table 2.7.3.1-1) is acceptable.

Table 3-32 Production of the biocidal product, risk characterisation

Exposure Scenario: Task: Charging a reservoir with active substance		Estimated Internal Exposure [mg/kg bw/day]				Relevant NOAEL [mg/kg b.w/day] & Reference Value	AF MOE_{ref}	MOE	Exposure / AEL
		Estim. oral uptake	Estim. inhal. uptake	Estim. dermal uptake	Estim. total uptake (combined exposure)				
Tier 1	Exposure estimation via Model 3 for mixing and loading[1] (parameters: 2000ml a.s. /event, 60kg bw (adult, default))	n.r.	1.48E-04	0.5929	**0.59**	NOAEL: 100 AEL systemic: 1	100	169	0.593

[1] from „Technical Notes for Guidance on Human Exposure to Biocidal Products" (European Commission, 2002a)

3.6.6.6 Risk for professionals, non-professional users and the general public using Lebensmittelmotten-Falle

Risk from exposure from use of "Lebensmittelmotten-Falle" (activating trap and secondary exposure including children and infants, see table 2.7.3.1-2) is acceptable.

Table 3-33 Indirect exposure as a result of use, risk characterisation

Exposure Scenarios: see below		Estimated Internal Exposure [mg/kg bw/day]				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value	AF MOE_{ref}	MOE	Exposure / AEL
		Estim. oral uptake	Estim. inhal. uptake	Estim. dermal uptake	Estim. total uptake (combined exposure)				
Tier 1	Maximum possible uptake (dermal, oral, and/or inhalative; the whole amount of a.s. contained in one trap is taken up) by an adult (60 kg bw)	0.03			**0.03**	NOAEL: 100 AEL system.: 1	100	3000	0.033
Tier 1	Maximum possible uptake (dermal, oral,	0.13			**0.13**	NOAEL: 100 AEL system.:	100	750	0.133

	and/or inhalative; the whole amount of a.s. contained in one trap is taken up) by a child (15 kg bw)				1			
Tier 1	Maximum possible uptake (dermal, oral, and/or inhalative; the whole amount of a.s. contained in one trap is taken up) by an infant (10 kg bw)	0.20		**0.20**	NOAEL: 100 AEL system.: 1	100	500	0.200
Tier 2	Inhalation exposure, linear release of 2 mg a.s., the whole daily release is inhaled by an adult (60 kg; default) or an infant (10 kg; default) (1 trap; 20 traps)		0.005[1] 0.029[2] 0.1[3] 0.58[4]		NOAEL: 100 AEL system.: 1	100	20000[1] 3448[2] 1000[3] 172[4]	0.005[1] 0.029[2] 0.100[3] 0.580[4]

[1] adult, 1 trap;
[2] infant, 1 trap;
[3] adult, 20 traps;
[4] infant, 20 traps

3.6.7 Dietary risk assessment

No relevant food and feed stuff exposure is to be expected since the "Lebensmittelmotten-Falle" contains only 2 mg of ZE-TDA and should only be applied where food and feed-stuff is stored in closed or re-closed package. Furthermore in analogy to literature data for the structurally related very long chain (C24 to C34) esters (waxes) it is expected that ZE-TDA (C16) is easily catabolised by hydrolysis to the free alcohol, dehydrogenation to the acid and further ß-oxidation or glucuronide conjugation and excreted via the kidneys. It is also known that higher alcohols occur either free or bound in plant and animal tissues. C14 to C24 fatty acids are – bound as esters within phoshpholipids and glycolipids - the major component of cell membranes and a relevant part of our natural diet. Natural intake of the structurally related very long chain (C24 to C34) alcohols, aldehydes, acids and esters (waxes) thereof is

estimated to be about 2 g/day as part of our natural diet including cereal grains, bran, germ, leaves, seeds, nuts and unrefined oils.

Furthermore on the basis of an AEL of 1 mg/kg bw day derived from a sub-chronic rat study (with a structurally related mixture of acetates with C10 to C14 alykyl groups) even the risk for immediate uptake of the total amount of the active substance (2 mg) within a single trap is acceptable, also for infants. The acceptable daily uptake of 10 mg for infants (body weight 10kg) corresponds to the active substance content of 5 traps (=10mg).

Thus the risk from residues from ZE-TDA on food/feeding stuff is considered to be negligible.

3.6.7.1 Information of non-biocidal use of the active substance and residue definitions

The active substance is approved under Regulation (EC) No 1107/2009 within the group of Straight Chain Lepidopteran Pheromones (SCLP). A residue definition was considered not necessary. SCLP fulfil the criteria of Annex VI Reg. 2229/2004. Therefore, no toxicological reference values nor MRLs are set.

Table 3-34 Summary table of other (non-biocidal) uses

Summary table of other (non-biocidal) uses					
	Sector of use	**Residue definition**	**Sample matrix**	**Reference regulation**	**Reference**
1.	Plant protection	Not necessary	-	Reg (EU) 2022/1251	https://eur-lex.europa.eu/eli/reg_impl/2022/1251/oj

3.6.7.2 Estimating livestock exposure to active substances used in biocidal products and Worst Case Consumer Exposure (WCCE)

No livestock exposure expected. Therefore, no estimation necessary.

3.6.7.3 Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s) and consumer exposure

No contact with food or feed intended and also expected.

3.6.7.4 Estimating transfer of biocidal active substances into foods as a result of non-professional use and consumer exposure

No contact with food or feed intended and also expected.

3.6.7.5 Maximum residue limits or equivalent

Not relevant.

3.6.8 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not required as only one active substance and no substance of concern contained in biocidal

product.

3.7 Risk assessment for animal health

3.7.1 Risk for companion animals

Not relevant as not expected.

3.7.2 Risk for livestock animals

Not relevant as not expected.

3.8 Risk assessment for the environment

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.1.1 Endpoints for the active substance, metabolites and transformation products

No new studies have been submitted and the product applied for authorisation is identical to the active ingredient discussed in the CAR. The intended use and the exposure to the environment is the same as discussed in the CAR. So please see the CAR for further information.

No PNECs are available for sediment, soil and aquatic compartments.

3.8.1.2 Endpoints for the product

There are no new additional data available for the product. The exposure assessment and classification and labelling are based on information for the active substance.

3.8.1.3 Substance(s) of concern

No substances of concern regarding the environment were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)). Consequently, only the active substance was addressed in the environmental risk assessment.

3.8.1.4 Screening for endocrine disruption relating to non-target organisms

ZE-TDA is not in discussion to be an endocrine disruptor and there is no substance property or information indicating concern.

3.8.2 Emission estimation

3.8.2.1 General information

No new studies have been submitted and the product applied for authorisation is identical to the active ingredient discussed in the CAR. The intended use and the exposure to the environment is the same as discussed in the CAR. So please see the CAR for further information.

ZE-TDA will dissipate in environmental compartments due to volatilisation and biodegradation. ZE-TDA is readily biodegradable not fulfilling the 10-d window. ZE-TDA is hydrolysed at pH 4 and 9 with DT_{50} values of 9 and 13 hours.

As the exposure of the aquatic and terrestrial compartment during manufacture of Lebensmittelmotten-Falle and indoor usage is negligible for these compartments a risk characterisation is not performed.

No potencial for release in the environment exists.

3.8.2.2 Emission estimation for the scenario(s)

No emission estimations were performed.

3.8.3 Exposure calculation and risk characterisation

No new exposure studies have been submitted.

ZE-TDA will dissipate in environmental compartments due to volatilisation and biodegradation. ZE-TDA is readily biodegradable not fulfilling the 10-d window. ZE-TDA is hydrolysed at pH 4 and 9 with DT_{50} values of 9 and 13 hours.

As the exposure of the aquatic and terrestrial compartment during manufacture of Lebensmittelmotten-Falle and indoor usage is negligible for these compartments, a risk characterisation is not performed. Also no predictable risk for the air compartment could be identified based on the exposure and physico-chemical properties. These are also reasons why no unacceptable effects on surface and groundwater as such and for the abstraction of drinking water are likely.

No exposure calculations were performed.

Atmosphere

Conclusion: There are no indications that the active substance contributes to depletion of the ozone layer as the compound is not listed as 'controlled substances' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament.

Sewage treatment plant (STP)

Conclusion: no exposure to sewage treatment plants is expected.

Aquatic compartment

Conclusion: no exposure to the aquatic compartment is expected.

Terrestrial compartment

Conclusion: no exposure to the terrestrial compartment is expected.

Groundwater

Conclusion: the active substance is not expected to be present in groundwater.

3.8.4 Primary and secondary poisoning

3.8.4.1 Primary poisoning

The product is a ready to use trap indoors. Considering that non-target organisms will not have access to the trap, primary poisoning is unlikely. The risks related to primary poisoning are therefore acceptable.

3.8.4.2 Secondary poisoning

ZE-TDA has a log BCF_{fish} ≥2.8. However, based on the chemical similarities between wax esters and ZE-TDA it is reasonable to assume that its metabolism and conversion will follow

the same pattern. As wax esters are an important energy (storage) source/substrate for aquatic marine organisms and an important component of the marine food chain it is unlikely that ZE-TDA will bioaccumulate.

Conclusion: no secondary poisoning is expected.

3.8.5 Mixture toxicity

Lebensmittelmotten-Falle is not a mixture, therefore a mixture toxicity assessment is not relevant.

3.8.5.1 Screening step

Not relevant.

3.8.5.2 Tiered approach

Not relevant.

3.8.6 Aggregated exposure (combined for relevant emission sources)

Not relevant.

3.8.7 Overall conclusion on the risk assessment for the environment

Table 3-35 Overall conclusion on the risk assessment for the environment

Overall conclusion on the risk assessment for the environment			
Use number[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]**
1	ready to use trap consisting of a cardboard carrying the pheromone Z,E-9,12-Tetradecadien-1-yl acetate and is partly covered with an adhesive glue. The aim of use is to protect stored food or feedstuff which should be well closed against the Indian meal moth via mating disruption.	ZE-TDA is not toxic or harmful to the environment.	-

[1] Use numbers in accordance with the list of all uses indicated under section 2.2.
[2] Title of the specific use, as indicated in the SPC
[3] The conclusion and set RMMs should be in alignment with the overall conclusion under section 2.2.

3.9 Assessment of a combination of biocidal products

Not relevant.

3.10 Comparative assessment

Comparative assessment is not required since the active substance Z,E-9,12-Tetradecadien-1-yl acetate is not a candidate for substitution according to article 10 of Regulation (EU) 528/2012.

3.10.1 Screening phase

Not relevant.

3.10.2 Tier IA

Not relevant.

3.10.3 Tier IB

Not relevant.

3.10.4 Tier II

Not relevant.

3.10.5 Overall conclusion

Not relevant.

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Safety for professional operators

Lebensmittelmotten-Falle

Date: April 2013

Exposure assessment

Exposure scenarios for intended uses (Annex IIIB, point 6.6)

Primary exposure during production of Lebensmittelmotten-Falle

Component	CAS	Potential Dermal Total [mg/day]	Potential Dermal Total [mg/kg/d]	Actual Dermal Total [mg/day]	Actual Dermal Total [mg/kg/d]	Inhalation Exposure [mg/kg/d]	Model
(Z,E)-Tetradeca-9,12-dienyl acetate	30507-70-1				0.593	$1.48x10^{-4}$	Model 3 for mixing and loading (EUROPOEM, TNsG on Human Exposure (2002a), part 2)

Risk assessment

Component	CAS	AEL [mg/kg/d]	Absorption		Inhal ext [mg/kg/d]			Derm ext [mg/kg/d]			RCR ges
			inh	derm	Act. Expo	RW	RCR	Act. Expo	RW	RCR	
(Z,E)-Tetradeca-9,12-dienyl acetate	**30507-70-1**	**1**	**100**	**100**	**1.48×10^{-4}**			**0.593**			**0.593**

The risk assessment for the substance(s) of concern has to be carried out in almost the same manner.
The product does not contain substances of concern.

Safety for non-professional operators and the general public

Lebensmittelmotten-Falle

Date: April 2013

General information	
Formulation Type	Liquid on solid carrier
Active substance(s) (incl. content)	(Z,E)-Tetradeca-9,12-dienyl acetate, 2 mg/trap
Category	non-professional users / consumers, professionals
Authorisation number	AT/2013/R/0000/xxx/19

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

Data base for exposure estimation	
according to	Appendix: Toxicology and metabolism – active substance/CAR

Exposure scenarios for intended uses (Annex IIIB, point 6.6)	
Primary exposure	See Annex 2.7 to PAR
Secondary exposure, acute	See Annex 2.7 to PAR
Secondary exposure, chronic	See Annex 2.7 to PAR

Conclusion:
Exposure of professionals, non-professionals and the consumers to the biocidal product containing 2 mg as active substance per trap is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

Details for the exposure estimates: See Annex 2.7 to PAR

4.1.2 Dietary assessment

Not relevant

4.1.3 Environment

Not relevant.

4.2 New information on the active substance(s) and substance(s) of concern

No new information on the active substance(s) is available.

There are no substances of concern.

4.3 List of studies for the biocidal product

Table 4-1 List of studies for the biocidal product

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
Anonymous 2011a	2011	3.4.1.1	-	ACCELERATED STORAGE STABILITY STUDY: CONTENT OF TDA IN FOOD MOTH TRAPS DURING STORAGE FOR 24 WEEKS AT 35°C Aeroxon Insect Control Report-no. n/a GLP/GEP: no Published: no	Study report	AER	No	Yes
Anonymous 2017a	2017	3.4.1.2.	-	Physico-chemical Properties of the Food Moth Trap ”2mg N143 Projekt 5002” over 4 Years Storage at 20 °C Aeroxon Insect Control Report-no. n/a GLP/GEP: no Published: no	Study report	AER	No	Yes
Anonymous 2013a	2013	3.1	-	Physico-chemical Properties of the Food Moth Trap "1mg N143 Projekt 5002" before and after Accelerated Storage at 35 °C for 12 Weeks- starting date report- Eurofins Agroscience Services EcoChem GmbH Aeroxon Insect Control	Study report	AER	Yes	Yes

				Report-no. S12-04232 GLP: yes, GEP: yes Published: no				
Anonymous 2013b	2013	3.1.1	-	Physico-chemical Properties of the Food Moth Trap "2mg N143 Projekt 5002" before and after Accelerated Storage at 35 °C for 12 Weeks-starting date report Eurofins Agroscience Services EcoChem GmbH Aeroxon Insect Control Report-no. S12-04234 GLP: yes Published: no	Study report	AER	Yes	Yes
Anonymous 2013c	2013	5.1	-	METHOD SET UP AND VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF THE CONTENT OF ACTIVE INGREDIENT (Z,E)-TETRADECA-9,12-DIENYL ACETATE (TDA) IN FOOD MOTH TRAPS Eurofins Agroscience Services EcoChem GmbH Aeroxon Insect Control Report-no. S12-04228 GLP: yes Published: no	Study report	AER	Yes	Yes
Anonymous 2006a	2006	5.1	-	VALIDATION OF THE DETERMINATION OF Z,E-9,12-TETRADECADIEN-1-YL ACETATE (TDA) IN PRODUCTS	Study report	AER	No	Yes

				Aeroxon Insect Control Report-no. 408-11-13/06 GLP/GEP: no Published: no				
Anonymous 2011b	2011	6.7	-	HAS THE USAGE OF A PROTECTIVE CARDBOARD BOX AN INFLUENCE ON THE TRAPPING EFFICACY OF THE AEROXON PHEROMONE TRAP FOR PHYCITID MOTHS? Aeroxon Insect Control Report-no. Ingelheim_110518 GLP/GEP: no Published: no	Study report	AER	No	Yes
Anonymous 2013d	2013	6.7	-	SIMULATED USE TRIAL TO DETERMINE THE EFFICACY OF LEBENSMITTELMOTTENFALLE (PHEROMONE MOTH TRAP) AGAINST PLODIA INTERPUNCTELLA i2L Research Ltd., Cardiff UK Aeroxon Insect Control Report-no. 12/158A GLP/GEP: no Published: no	Study report	AER	No	Yes
Anonymous 2013e	2013	6.7	-	SIMULATED USE TRIAL TO DETERMINE THE EFFICACY OF LEBENSMITTELMOTTENFALLE (PHEROMONE MOTH TRAP) AGAINST EPHESTIA KUEHNIELLA i2L Research Ltd., Cardiff UK Aeroxon Insect Control Report-no. 12/158B	Study report	AER	No	Yes

				GLP/GEP: no Published: no				
Anonymous 2013f	2013	6.7	-	SIMULATED USE TRIAL TO DETERMINE THE EFFICACY OF LEBENSMITTELMOTTENFALLE (PHEROMONE MOTH TRAP) AGAINST EPHESTIA CAUTELLA i2L Research Ltd., Cardiff UK Aeroxon Insect Control Report-no. 12/158C GLP/GEP: no Published: no	Study report	AER	No	Yes
Anonymous 2013g	2013	6.7	-	SIMULATED USE TRIAL TO DETERMINE THE EFFICACY OF LEBENSMITTELMOTTENFALLE (PHEROMONE MOTH TRAP) AGAINST EPHESTIA ELUTELLA i2L Research Ltd., Cardiff UK Aeroxon Insect Control Report-no. 12/158D GLP/GEP: no Published: no	Study report	AER	No	Yes
Anonymous 2022a	2022	6.7	-	ATTRACTANT EFFICACY EVALUATION OF A STICKY TRAP AGAINST Ephestia kuehniella AND Plodia interpunctella (ROOM TEST) Aeroxon Insect Control Report-no. Q129A-22 GLP/GEP: no Published: no	Study report	AER	No	Yes

Anonymous 2022b	2022	6.7	-	ATTRACTANT EFFICACY EVALUATION OF A STICKY TRAP AGAINST Ephestia kuehniella AND Plodia interpunctella (ROOM TEST) Aeroxon Insect Control Report-no. Q129A-22-01 GLP/GEP: no Published: no	Study report	AER	No	Yes
Anonymous 2005a	2005	6.7	-	Comparative Testing of two Commercial Pheromone Traps for Phycitid Moths with Plodia interpunctella Ingelheim_050202 GLP/GEP: no Published: no	Study report	AER	No	Yes
Anonymous 2005b	2005	6.7	-	Comparative Testing of three Commercial Pheromone Traps for Phycitid Moths with Plodia interpunctella Ingelheim_050504 GLP/GEP: no Published: no	Study report	AER	No	Yes
Anonymous 2004a	2004	6.7	-	Testing of Pheromone Traps for Phycitid Moths, Aeroxon internal report Ingelheim_040324 GLP/GEP: no Published: no	Study report	AER	No	Yes
Anonymous 2008a	2008	6.7	-	DETERMINATION OF EFFICACY OF LEBENSMITTELMOTTEN-FALLE, A STICKY LURE TRAP WITH A SEXUAL PHEROMONE, AGAINST INDIAN MEAL MOTH (PLODIA INTERPUNCTELLA)	Study report	AER	No	Yes

				20072002/01-ELPI GLP/GEP: no Published: no				
Anonymous 2008b	2008	6.7	-	COMPARATIVE TESTING OF AEROXON PHEROMONE TRAPS FOR PHYCITID MOTHS AFTER LONG-TERM STORAGE, Ingelheim_080317 GLP/GEP: no Published: no	Study report	AER	No	Yes
Anonymous 2019a	2019	6.7	-	Simulated use trial to determine the efficacy of a pheromone moth trap product against Indian meal moth, Plodia interpunctella 18/395	Study report	AER	No	Yes

4.4 References

4.4.1 References other than list of studies for the biocidal product

Please refere to the IUCLID dossier.

4.4.2 Guidance documents

- Guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC
- Technical Notes for Guidance on Human Exposure to Biocidal Products" (European Commission, 2002a)
- "Human Exposure to Biocidal Products User guidance version 1" (European Commission, 2002b)
- Guidance on the BPR: Volume IV Environment (Parts B+C)), ECHA 2017

4.4.3 Legal texts

- Regulation (EU) No 528/2012 of the European Parliament and of the Council of of 22 May 2012 concerning the making available on the market and use of biocidal products.

4.5 Confidential information

Please refer to the separate document Confidential Annex of the PAR.