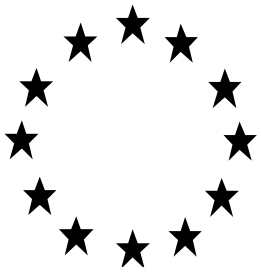
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR SIMPLIFIED AUTHORISATION APPLICATION



Food Moth Monitoring Glue Trap

Product type 19

(9Z,12E)-Tetradeca-9, 12-dien-1-yl acetate (TDA)

Case Number in R4BP: BC-XU079755-85

Competent Authority: FI

Date: 03/11/2023

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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	FI	BC-XU079755-85	3.11.2023	first authorisation	

1 Conclusion

Food Moth Monitoring Glue Trap is a ready to use biocidal product containing (9Z,12E)-Tetradeca-9, 12-dien-1-yl acetate (TDA) as an active substance. The product is used as an attractant by consumers to monitor food moths of the *Pyralidae* family.

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 monitoring of food moths indoors by consumers, 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 substances (9Z,12E)-Tetradeca-9, 12-dien-1-yl acetate (TDA) is listed in Annex I of Regulation (EU) 528/2012 with the following restriction: only for traps containing a maximum of 2 mg of (Z,E)-Tetradeca-9,12-dienyl acetate for indoor use.;
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 (9Z,12E)-Tetradeca-9, 12-dien-1-yl acetate (TDA), 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 (9Z,12E)-Tetradeca-9, 12-dien-1-yl acetate (TDA) 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

[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

biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.3 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance 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 1.4 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 method for the active substance is available in section 3.4 of the PAR.

Efficacy against target organisms

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

Human health

Risk assessment for human health is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012 for simplified authorisations.

No substances of concern regarding human health were identified.

The handling of the product and its intended use do not require personal protective equipment.

Environment

Risk assessment for the environment is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012 for simplified authorisations.

No substances of concern regarding environment were identified.

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
The long-term storage test at ambient temperature is on-going and results after 24 months are expected in March 2024.	30 June 2024

See Table 3.3. conclusion on physical, chemical, and technical properties for justification on setting a post-authorisation condition.

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)	19
Type(s) of formulation	Vapour releasing product (VP)

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	Monitoring of food moths (*Pyralidae*)	19	Food moths *Ephestia kuehniella* *Plodia interpunctella* *Ephestia elutella* *Cadra cautella* *Cadra figulilella*	Placing moth trap in cabinets or areas that contain food	1 trap per area with suspected infestation	Non-professional	A	

[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 X

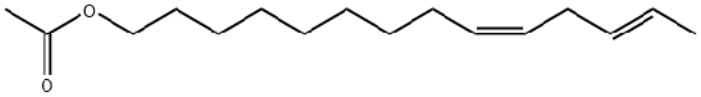
to the identity and composition of the product(s) evaluated in connection with the inclusion of the active substance(s) in category 6 of Annex I of Regulation (EU) No 528/2012.

Condition for SA: Only for traps containing a maximum of 2 mg of (Z,E)-Tetradeca-9,12-dienyl acetate for indoor use.

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	TDA
Chemical name	(9Z,12E)-tetradeca-9,12-dien-1-yl acetate
EC number	not available
CAS number	30507-70-1
Index number in Annex VI of CLP	not available
Minimum purity / content	97.7 % (w/w)
Structural formula	

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

Is the source of (9Z,12E)-tetradeca-9,12-dien-1-yl 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?

X Yes

☐ No

2.6 Candidate(s) for substitution

The active substance is not a candidate for substitution.

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.

The biocidal product contains the active substance (9Z,12E)-tetradeca-9,12-dien-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.

2.8 Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

	Classification	Labelling
Hazard Class and Category code	Not classified	No labelling required.
Hazard Pictograms		
Signal word(s)		
Hazard statements		
Precautionary statements*		
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

A Letter of Access to the product has been submitted.

2.10 Data submitted in relation to product authorisation

No new data on the active substance have been submitted.

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)
Individual trap: Cardboard carrier	Ca. 4.6 g per trap	Cardboard (covered with siliconized paper)	Not applicable	Non-professional	Yes
Secondary: Tubular bag containing 3 traps	60 mm x 200 mm	Paper and sealable PE	Not applicable	Non-professional	Yes
Secondary: Tubular bag containing 5 traps	60 mm x 200 mm	Paper and sealable PE	Not applicable	Non-professional	Yes
Secondary: Carton box containing 3 traps	60 mm x 200 mm	Carton box	Not applicable	Non-professional	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

3.2 Physical, chemical, and technical properties

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				
3.1.1.	Physical state at 20 °C and 101.3 kPa	OPPTS 830.6302	Batch #10615 0.272 % w/w in the test mixture	Solid Pack containing a ready to use adhesive trap. The trap is constituted by a cardboard covered with a homogeneous mixture of sticky glue; in the middle of each cardboard there is an area covered by glue mixed with the active substance. The adhesive trap is protected by a film.	CH – 0012/2022 TDS (2017)
3.1.2.	Colour at 20 °C and 101.3 kPa	OPPTS 830.6303	Batch #10615 0.272 % w/w in the test mixture	Colourless	CH – 0012/2022
3.1.3.	Odour at 20 °C and 101.3 kPa	OPPTS 830.6304	Batch #10615 0.272 % w/w in the test mixture	Odourless	CH – 0012/2022
3.2.	Acidity, alkalinity and pH value	CIPAC MT 75.3, OECD No. 122	Batch #10615 0.272 % w/w in the test mixture	pH = 5.8 (1% (w/v) aqueous dispersion). Acidity or alkalinity not needed as pH is	CH – 0012/2022

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				within pH range 4-10	
3.3.	Relative density / bulk density	Not determined		Not required for simplified authorisation.	
3.4.1.1.	Storage stability test – accelerated storage	AS content: Internal Analytical Method No. 0013/2022 Weight loss: technical balance OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304 CIPAC MT 75.3, OECD No. 122	Batch #10615 0.272 % w/w in the test mixture	After 8 weeks of storage at 40°C, the active substance content and the physical-chemical properties of the Food Moth Monitoring Glue Trap were comparable to the relevant values obtained in the initial characterisation (t0). Pack containing a ready to use adhesive trap. The trap is constituted by a cardboard covered with a homogeneous mixture of sticky glue; in the middle of each cardboard there is a composed by glue mixed with the active substance. The adhesive trap is protected by a film. The glue with the active substance is colourless and odourless. There was no	CH – 0014/2022

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				significant weight variation and traps did not present any deformation or loss of sample or evident corrosion phenomena. The active substance content at start was 1.70 mg/trap, equivalent to 0.23 % w/w. The active substance content after storage was 1.56 mg/trap, equivalent to 0.21 % w/w. The decrease was – 8.54%. The pH was 5.8 at start and 6.1 after storage. “Store at temperature below 40 °C” is added to the label.	
3.4.1.2.	Storage stability test – long-term storage at ambient temperature	AS content: Internal Analytical Method No. 0013/2022 Weight loss: technical balance OPPTS 830.6302 OPPTS 830.6303	Batch #10615 0.272 % w/w in the test mixture	Results after 24 months of storage at ambient temperatures are expected in March 2024. After 6 and 12 months of storage at ambient	CH – 0015/2022 ongoing; Statement on the results after 6 and 12 months available.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		OPPTS 830.6304 CIPAC MT 75.3, OECD No. 122		temperatures, the active substance content and the physical-chemical properties of the Food Moth Monitoring Glue Trap were comparable to the relevant values obtained in the initial characterisation (t0). Pack containing a ready to use adhesive trap. The trap is constituted by a cardboard covered with a homogeneous mixture of sticky glue; in the middle of each cardboard there is a composed by glue mixed with the active substance. The adhesive trap is protected by a film. The glue with the active substance is colourless and odourless. There was no significant weight variation and traps did not present any	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				deformation or loss of sample or evident corrosion phenomena. The active substance content at start was 1.70 mg/trap, equivalent to 0.23 % w/w. The active substance content after storage was 1.75 mg/trap, equivalent to 0.24 % w/w after 6 months and 1.65 mg/trap, equivalent to 0.22 % w/w after 12 months. The decrease was +3.08 and -2.40%. The pH was 5.8 at start and 5.9 and 5.8 after storage for 6 and 12 months, respectively.	
3.4.1.3.	Storage stability test – low temperature stability test for liquids	Not determined		Data not required for solids. However, it is recommended not to expose the product to temperatures below 0°C and “Protect from frost” is added to the label.	
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal	Not determined		It is recommended to keep the product away from direct	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
	product – light			sunlight. “Keep away from sunlight” is added on the label.	
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity	Not determined		Due to the packaging, the product is not impacted by humidity. The label states that the product should be stored at temperature below 40 °C.	
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	This assessment was performed by internal and external inspection through visual examination of the commercial packaging.	Batch #10615 0.272 % w/w in the test mixture	The trap did not present any deformation or loss of sample or evident corrosion phenomena.	CH – 0014/2022 CH – 0015/2022
3.5.1.	Wettability			Data not required for simplified authorisation.	
3.5.2.	Suspensibility, spontaneity, and dispersion stability				
3.5.3.	Wet sieve analysis and dry sieve test				
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability				
3.5.5.	Disintegration time				
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability				
3.5.7.	Persistent foaming				
3.5.8.	Flowability/pourability/dustability				
3.5.9.	Burning rate — smoke generators				

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.5.10.	Burning completeness — smoke generators				
3.5.11.	Composition of smoke — smoke generators				
3.5.12.	Spraying pattern — aerosols / spray				
3.6.1.	Physical compatibility			Not relevant, the product is not intended to be used with other products, mixtures or products.	
3.6.2.	Chemical compatibility			Not relevant, the product is not intended to be used with other products, mixtures or products.	
3.7.	Degree of dissolution and dilution stability			Data not required for simplified authorisation.	
3.8.	Surface tension				
3.9.	Viscosity				

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
Food Moth Monitoring Glue Trap is a ready to use adhesive trap with cardboard carrier material and a biocical mixture, covered by siliconized paper. The glue with the active substance is colourless and odourless and pH of 1% (w/v) aqueous dispersion is 5.8. The accelerated storage data at 40 °C for 8 weeks show that the product is stable at temperature below 40 °C. Label phrase “Store at temperature below 40 °C is added on the lable. The long term storage test at ambient temperature is on-going and results after 24 months are expected in March 2024. Results after 6 and 12 months storage at ambient temperature are available. Active substance content decreased 2.4% after 12 months of storage. No changes on color, odour or physical state of the product were observed. Based on the results of accelerated and ambient temperature storage stability studies available, a provisional shelf life of 24 months is granted. Based on the Coordination Group document (CG-53-2022-07 AP 14.1 Shelf-life setting during PA vf) accelerated data can still be used for ongoing product applications. The following was stated in the document on p.10 point 8: "8. This approach shall immediately be applicable to all BP/BPF applications that are submitted after the publication of the updated relevant CG and BPC documents, as well as TAB entry. However, this approach can be applied for ongoing product applications on a voluntary basis if there is in an agreement between the rMS/eCA and the applicant." The application was submitted on 9.9.2022 i.e. before the aforementioned CG meeting (20.-22.9.2022) and the applicant is not complying on a voluntary basis. The shelf life of 24 months must be confirmed with results of 24 months storage at ambient temperature by 30 June 2024. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Implications for labelling: Store at temperature below 40 °C Protect from frost. Keep away from sunlight. Store in a cool, dry place. Shelf life 24 months.

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	Not determined		Active substance is included in Annex I of the BPR and therefore does not give rise to concern for explosivity. In addition, the other components of the biocidal product do not contain relevant functional groups associated with explosive properties and therefore the product can be considered as not explosive. For further information, please refer to confidential annex MSCA only.
4.2.	Flammable gases			Not relevant, the product is not a gas.
4.3.	Flammable aerosols			Not relevant, the product is not an aerosol.
4.4.	Oxidising gases			Not relevant, the product is not a gas.
4.5.	Gases under pressure			Not relevant, the product is not a gas.
4.6.	Flammable liquids			Not relevant, the product is not a liquid.
4.7.	Flammable solids	Not applicable		Active substance is included in Annex I of the BPR and therefore does not give rise to concern for high flammability. Moreover, the main co-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				formulant has high flash point (>200 °C) and therefore the product can be considered as not flammable.
4.8.	Self-reactive substances and mixtures	Not determined		The components of the biocidal product contain low concentration of chemical groups associated with self-reactive properties, but the biocidal product is not considered to be classified as self-reactive. Please see the confPAR MSCA only for further justification.
4.9.	Pyrophoric liquids			Not relevant, the product is not a liquid.
4.10.	Pyrophoric solids	Not applicable		The product is known to be stable in contact with air at room temperature for prolonged periods of time and hence the classification procedure does not need to be applied.
4.11.	Self-heating substances and mixtures	Not applicable		The main co-formulant has a low softening point and therefore it is assumed that the product is completely molten <160 °C. In addition, the biocidal product is ready to use adhesive trap constituted by stickly glue and hence the surface area is not considered to

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				be large enough for reaction with air.
4.12.	Substances and mixtures which in contact with water emit flammable gases	Not determined		None of the components are known to emit flammable gases when in contact with water. In addition, the biocidal product does not contain any metals or metalloids and therefore the study does not need to be conducted.
4.13.	Oxidising liquids			Not relevant, the product is not a liquid.
4.14.	Oxidising solids	Not applicable		The product contains constituent with oxygen bound to other elements than carbon or hydrogen. However, the product is not considered to be oxidising. For further information, please refer to confPAR MSCA only.
4.15.	Organic peroxides	Not applicable		Not relevant because the product contains no organic peroxides.
4.16.	Corrosive to metals	Not determined		The product is solid and classification criteria in the UN-MTC excludes solids. Moreover, the product does not contain acid, base, halogens and the pH is close to neutral. Thus, there is no need for further testing.
4.17.1.	Auto-ignition temperatures of products			Not relevant, the product

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
	(liquids and gases)			is not a liquid or gas.
4.17.2.	Relative self-ignition temperature for solids	Not applicable		The main co-formulant has a low softening point and therefore it is assumed that the product is completely molten <160 °C and study does not need to be conducted.
4.17.3.	Dust explosion hazard			Not relevant, the product is not a powder and does not contain dust.

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 *[reference method]*: *The test item is cut, the siliconized paper is removed, the test item is placed into a 100 mL conical flask.* *Internal standard and n-hexane are added. The sample is mixed and placed into an ultrasonic bath and then on the mechanical shaker.* *An aliquot of the test item solution is filtered any analyzed with 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		

Active substance	*r= 0.99975 slope = 0.02721 intercept = -0.02156 rang= 60-140% of the nominal 5 concentrations 1 injection per concentration*	No other peaks present, Interference not >3% of peak sample area. Chromatograms / mass spectra provided (formulation and solvent blanks, fortified samples)	µg/mL 27.48 36.63 45.79 54.95 64.11 (for linearity) 1.10 – 2.56 mg per test item	1 1 1 1 1	110% of nominal concentration min 92.02 % max 97.73 %	94.9 %	4.07	1.70 mg per test item Precision: 0.03 mg per test item 0.23 ± 0.005 % (w/w)	5 RSD = 1.98 RSD_r = 3.35 Horrat value = 0.59	Not applicable	CH – 0013/2022

Analytical methods for monitoring soil, air, water, animal and human body fluids and tissues and for monitoring of active substance and residues in food and feeding stuff are not listed as requirements for biocidal products eligible for simplified authorisation according to Article 25 of the BPR.

Table 3.7 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
An analytical GC-FID method (Report No. CH – 0013/2022) for the determination of (9Z,12E)-Tetradeca-9,12-dienyl in the biocidal product is available. Specificity, linearity, accuracy and precision were determined and found acceptable. Analytical methods for monitoring soil, air, water, animal and human body fluids and tissues and for monitoring of active substance and residues in food and feeding stuff are not listed as requirements for biocidal products eligible for simplified authorisation according to Article 25 of the BPR.

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)

The biocidal product is an attractant trap for monitoring use in indoor areas where moths may be present.

The product releases the active substance into the air, where it attracts male moths. The male insect are attracted by the sexual pheromone and captured by the glue on the trap. The product is to be used when moths' presence is suspected, when months are regularly present, or to determine how infestation develops or to determine if an eradication treatment was successful. If infestation is confirmed, treatment to control infestation should be done with suitable products.

Organisms to be monitored:
Plodia interpunctella (Indian meal moth)
Ephestia kuehniella (Mediterranean flour moth)
Ephestia elutella (Tobacco moth)
Cadra cautella (Almond moth)
Cadra figuliella (Raisin moth)

Objects to be protected:
Food

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

According to the assessment report of the active substance, products containing it are intended to be used in pheromone traps containing max. 2 mg of active substance. Male adults of moths are attracted via the air phase.

3.5.3 Efficacy data

Table 3.8 Efficacy data

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects *[address here results related to efficacy of the test product and validity of the test]*	Reference	Number in IUCLID section 6.7 / Test report title
PT19 Use 1: Monitoring of food moths	Food Moth Monitoring Glue Trap 2 mg of AS per trap Control: double-sided adhesive tape	Attractant Objects to be protected: Food Species (Ephestia kuehniella) Development Stages: adults Sex: male:female = 20:5 Number tested: 20 Number of replicates: 2	Laboratory/Simulated use test, indoor For each type of method, test system: - Location: Laboratory - Temperature: Room temperature - Humidity: Not recorded - Doses tested: 1 trap per box - Light cycle: Normal daylight - Number of replication per modality: 2 Method of application: A glue trap was positioned inside a 0.77 m³ cardboard box, near to the ceiling of the box and on one of the narrow sidewalls. Test days were 1 and 3 days after insect exposure into the box. Fresh and aged glue traps were used (6 and 12 weeks). Method for recording / scoring effects: Counting of cought male moths.	Effects observed: male moths were attracted, efficacy ranged between 63 and 78%. Fresh product: 73-75% (control: 5%) 6 weeks aged product: 63-78% (control: 3%) 12 weeks aged product: 65-78% (control: 0%) Conclusion: The product has been demonstrated to be efficacious for up to 12 weeks.	Luepkes KH 2014 study N° Mo4912	Efficacy data to support these claims.001

3.5.4 Efficacy assessment

The product is intended to indicate an existing infestation with food moths (*Pyralidae*). The application is carried out in case of suspicion based on feeding traces or empirical data (e.g. seasonal infestations). For this reason, the use of the product is aimed in particular at moths in the immediate vicinity of the infested objects. After an infestation has been reliably detected by the traps, appropriate measures can then be taken.

The biocidal product is intended explicitly as a monitoring trap and not to control or reduce pest populations. One simulated-use-study was provided in support of the product's efficacy. The claimed target organisms are adult male food moths (*Pyralidae).* The product is tested in 0.77 m^3 cardboard boxes with one trap and 25 *Ephestia kuehniella* moths placed inside. Cought male moths were counted after 1 or 3 days. The boxes are empty and contain no food, water or hiding places for the moths. However as the trap contains a sex pheromone attracting males moths, the presence of female moths in the box is considered adequate to test if the male moths enter the trap even in the presence of live female moths. Regular double-sided tape is used as a negative control.

In the intended use scenario, the pests are already in the "test box" (drawers, cupboards, etc.). The trap should only inform the user whether there is an infestation in the suspected area. Moths outside the infested area are not considered pests in this sense. It is explicitly not desired to attract additional pests towards the product. On one hand, these would increase the infestation and, on the other hand, falsify the monitoring result. Taking into account the intended use and claims, the test design simulates the real use adequatly.

For monitoring merely the presence or absence of moths, attracting only a small portion of the male moths present would suffice. According to the TNsG monitoring traps are not in the scope of the guidance and hence there is no guidance or set limits for acceptable levels of efficacy for monitoring traps. The trap trapped 63-78% of male moths present in the box compared to the control that trapped 0-5%. The product is clearly more efficacious than the control and efficacious enough to monitor the presence of male moths. The product has thus shown acceptable efficacy for up to 12 weeks.

For attractants without PT18 active substances the TNsG states that due to the diverse nature (biology, ecology, habitat, diet, behaviour, etc.) of the organisms included in the group of stored-goods attacking insects and mites, and due to the specificity of active substances such as pheromones, efficacy can only be claimed against the species for which efficacy was demonstrated in efficacy studies. However, general claims for smaller groups which consist of specific organisms and a specific type of stored good to be protected could be authorised. For example, when different moth species may produce the same pheromone components for the attraction of sex mates.

The main pheromone components and chemical structures of the sexual and aggregation pheromones of all relevant storage and material pests have been elucidated to this day. Pheromones consist of one or more components, that can be further identified as main and secondary components. In some cases identical main components are present in different species and thus a wider range of pests can be caught in pheromone traps. This is the case for pyralides also. A distinction is made between sex pheromones, which are released by one sex, usually the females, in order to attract the sexual partner, and aggregation pheromones, which are predominantly produced by the males and have an attractive effect on both sexes. Especially male attracting sex pheromones, e.g. for the stored-product pyralids, function well in pest monitoring. The active ingredient (Z,E)-9,12-tetradecadienyl (TDA) is a female-produced sex pheromone. According to scientific literature (Plarre 2013, Ryne et al 2007) TDA has been demonstrated to be the main component of the sex

pheromone for *Plodia interpunctella*, *Ephestia kuehniella, Ephestia elutella, Cadra cautella (Ephestia cautella)* and *Cadra figulilella (Ephestia figuliella)* of the *Pyralidae* family. Hence the product can be considered efficacious for all the claimed species based on the provided study.

3.5.5 Conclusion on efficacy

The efficacy data supports the claim “Monitoring of food moths (*Pyralidae*)”.

3.5.6 Occurrence of resistance and resistance management

Not applicable.

3.5.7 Known limitations

There are no known limitations.

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

Not relevant.

3.6 Risk assessment for human health

No human health risk assessment is considered necessary.

The handling of the biocidal product and its intended use do not require personal protective equipment. The biocidal product complies with Art 25(e) BPR.

3.7 Risk assessment for animal health

No animal health risk assessment is considered necessary.

3.8 Risk assessment for the environment

No environmental risk assessment is considered necessary.

3.9 Assessment of a combination of biocidal products

The biocidal product is not intended to be authorised for the use with other biocidal products.

3.10 Comparative assessment

The active substance is not a candidate for substitution.

4 Appendices

4.1 Calculations for exposure assessment

Not relevant

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

No new information on the active substance is available.

There are no substances of concern in the biocidal product.

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)
Luepkes KH	2014	7.6	Efficacy data to support these claims.001	Efficacy of Rogino food moth monitoring glue trap against Food moth Ephestia kuehniella (males), tested in 0.077 m* cardboard boxes. Study No. Mo4912	Experimental report	Rogino Products GmbH	No	Yes
Nichetti S	2022	3.1 3.2 3.3 3.4.1 3.4.2	Appearance (at 20°C and 101.3 kPa).001 Acidity, alkalinity.001 Relative density (liquids) and bulk, tap density (solids).001 Storage stability tests.001 Storage stability	FOOD MOTH MONITORING GLUE TRAP: Determination of the Colour, Odour and Physical State, pH value and Acidity or Alkalinity	Experimental report	ARIES® Umweltprodukte GmbH & Co. KG	No	Yes

			tests.002	Study No. CH – 0012/2022				
Anonymous	2017	3.1	Appearance	Confidential Technical Data Sheet.	Technical Data Sheet	Henkel AG & Co. KG, Germany	No	No
Nichetti S	2022	5	Methods of detection and identification.001	FOOD MOTH MONITORING GLUE TRAP: Validation of the Analytical Method for the Determination of Active Substance Content Study No. CH – 0013/2022	Experimental report	ARIES® Umweltprodukte GmbH & Co. KG	No	Yes
Nichetti S	2022	3.4.1	Storage stability tests.001	FOOD MOTH MONITORING GLUE TRAP: Determination of the Accelerated Storage Stability Study No. CH – 0014/2022	Experimental report	ARIES® Umweltprodukte GmbH & Co. KG	No	Yes
Nichetti S	2023	3.4.2	Storage stability tests.002	FOOD MOTH MONITORING GLUE TRAP: Two Years Storage	Statement on the results after 6 and 12 months of	ARIES® Umweltprodukte GmbH & Co. KG	No	Yes

				Stability Study No. CH – 0015/2022	storage			
Nichetti S	2024	3.4.2	Storage stability tests.002	FOOD MOTH MONITORING GLUE TRAP: Two Years Storage Stability Study No. CH – 0015/2022	Experimental report Study ongoing	ARIES® Umweltprodukte GmbH & Co. KG	No	Yes

4.4 References

4.4.1 References other than list of studies for the biocidal product

- Anonymous. Assessment Report (Z,E)-Tetradeca-9,12-dienyl acetate, Product-type 19 (Attractant), Date of SCB vote: 24th September 2010, Annex I and IA – RMS Austria.
- Ryne, C. *et al*. Evaluation of long-term mating disruption of Ephestia kuehniella and Plodia interpunctella (Lepidoptera: Pyralidae) in indoor storage facilities by pheromone traps and monitoring of relative aerial concentrations of pheromone. J Econ Entomol. 2007 Jun;100(3):1017-25. DOI: 10.1603/0022-0493(2007)100[1017:eolmdo]2.0.co;2.
- Plarre R. Pheromone im Vorrats- und Materialschutz – Erfahrungen aus 35 Jahren praktischem Einsatz. JOURNAL FÜR KULTURPFLANZEN, 65 (5). S. 173–179, 2013. DOI: 10.5073/JFK.2013.05.01

4.4.2 Guidance documents

– Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C Version 2.1 March 2022
– Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C)

4.4.3 Legal texts

- COMMISSION DIRECTIVE 2011/11/EU of 8 February 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include (Z,E)-tetradeca-9,12-dienyl acetate as an active substance in Annexes I and IA thereto

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

4.5 Confidential information

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