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)

ANTI-MITES ALIMENTAIRES-GEA_P04031D

Product type 19

(Z,E)-Tetradec- 9,12-dienylacetate

Case Number in R4BP: BC-JL085811-29

Competent Authority: FR CA

Date: [30 July 2024]

Table of Contents

Changes history table

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
SA-APP	FR CA	BC-VC030923-43	18/04/2014	Initial assessment Simplified national authorisation
SA-MIC	FR CA	BC-UB028563-44	04/07/2017	Minor change - Change of a non-active substance intentionally incorporated - Change in the shelf-life (24 months to 36 months)
SA-MIC	FR CA	BC-WE044062-48	11/06/2019	Minor change - Change of the hot melt adhesive - Extension of the duration of the trap after opening of the packet from the current 2 months to 3 months)
SA-ADC	FR CA	BC-QP05698-99	29/05/2020	Change of authorisation holder's address and the location of manufacturing sites of the product and the active substance
SA-ADC	FR CA	BC- WP082371-15	14/12/2022	Addition of trades names
SA-AAT	FR CA	BC-JR088032-26	NA	Amendment of the PAR only in the frame of DE comment (SN-NOT)
SA-APP	FR CA	BC-JL085811-29	01/08/2024	Second authorisation

1 Conclusion

ANTI-MITES ALIMENTAIRES-GEA_P04031D is a biocidal product containing (9Z,12E)-tetradeca-9,12-dien-1-yl acetate as active substance. The product is used as a PT19 by non-professionals for the control of 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 for the control of food moths by non-professionals, 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 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 **meets the conditions required for simplified authorisation as defined in Article 25** of Regulation (EU) No 528/2012, i.e.:

1. The active substance (9Z,12E)-tetradeca-9,12-dien-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 BPF does not contain any non-active substance (so called "co-formulant(s)") which is considered as a substance of concern.The biocidal product should be considered not to have endocrine-disrupting properties.

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

Based on the available information, there are indications (not significant ones) that some non-active substances may have endocrine-disrupting properties and these will have to be further investigated[2].

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

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 manufacturer of the biocidal product is 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

[2] This sentence should be included only if there are significant indications. Please see the document CA-March21-Doc.4.4 ("Approach on providing information in public documents on non-active substances with indications of endocrine-disrupting properties") available in CIRCABC at https://circabc.europa.eu/w/browse/f28c5951-e162-4571-af1f-d2dc27992455.

section 1.4 of the SPC.

The chemical identity, quantity, 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 1.5 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 substanceis available. More information on the analytical methods for the active substances is available in section 3.4 of the PAR.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against the Mediterranean flour moth (*Ephestia kuehniella*) and the Indian meal moth (*Plodia interpunctella*) for the intended use. More information is available in section 3.5 of the PAR.

Risk assessment for human health

No substances of concern were identified for Human Health.

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

Dietary risk assessment

Considering the use, food, or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substance is considered as negligible, and no dietary risk assessment has been performed.

Risk assessment for the environment

No substance of concern was identified for the environment. The product ANTI-MITES ALIMENTAIRES-GEA_P04031D is not classified for the environment.

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	Ready-to-use adhesive trap

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 method5	Application rate6 (min-max)	User category7	Conclusion (eCA/ refMS)8	Comment (eCA/refMS)9
1	Indoor moth attraction	PT19	Food moths Mediterranean flour moth (*Ephestia kuehniella*) and Indian meal moth (*Plodia interpunctella*) (male adults)	Double adhesive tape in the back of the trap to be used to place the trap in the desired place. Release paper to be peeled off in order to activate the product.	1 trap / 1.5 m^3 if the trap is used inside a cupboard. 1 trap / 20 m^3 volume room if the trap is used outside a cupboard	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.

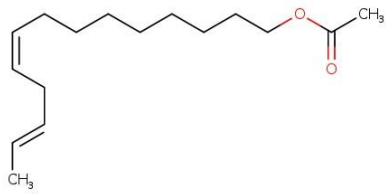
2.3 Identity and composition

The determination whether the identity and composition of the biocidal product are identical or not identical to the identity and composition of the product(s) evaluated in connection with the inclusion of the active substance(s) in Annex I of Regulation (EU) No 528/2012, is not applicable.

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)-Tetradeca-9,12-dienyl acetate
Chemical name	(Z,E)-Tetradeca-9,12-dienyl acetate
EC number	608-490-3
CAS number	30507-70-1
Index number in Annex VI of CLP	-
Minimum purity / content	Minimal: 979 g/kg
Structural formula	

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

The information on the source of the active substance is not applicable.

2.6 Candidate(s) for substitution

The active substance (Z,E)-Tetradeca-9,12-dienyl acetate contained in the biocidal product ANTI-MITES ALIMENTAIRES-GEA_P04031D does not meet any substitution criteria listed in Article 10 of Regulation (EU) No.528/2012.

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.

Based on the available information, there are indications (not significant ones) that some non-active substances may have endocrine-disrupting properties and these will have to be

further investigated[3]. However, at this stage, it is not possible to conclude before the expiration of the legal deadline in the BPR (Articles 30(2), 34(4) and 44(1)) whether the non-active substance(s) should be considered to have endocrine-disrupting properties. More detailed information is available in the confidential annex of the PAR.

[3] This sentence should be included only if there are significant indications. Please see the document CA-March21-Doc.4.4 ("Approach on providing information in public documents on non-active substances with indications of endocrine-disrupting properties") available in CIRCABC at https://circabc.europa.eu/w/browse/f28c5951-e162-4571-af1f-d2dc27992455.

2.8 Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

	Classification	Labelling
Hazard Class and Category code	-	-
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[4], are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

[4] 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

No letter of Access has been submitted.

2.10 Data submitted in relation to product authorisation

Please see Appendice 4.3.

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)
Flow-pack	180*85 mm	flow pack PET/Alu/PE	-	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	FR evaluation
3.1.	Appearance at 20 °C and 101.3 kPa	EPA OPPTS 830.6303 and 830.6304	Food-Moth trap-GEA P-04086D 1.69mg of ZE-TDA		[redacted] (2013b) – CH-687/2012	Read-across acceptable as the mix glue+pheromone is the same
3.1.1.	Physical state at 20 °C and 101.3 kPa			solid		
3.1.2.	Colour at 20 °C and 101.3 kPa			transparent		
3.1.3.	Odour at 20 °C and 101.3 kPa			odourless		
3.2.	Acidity, alkalinity and pH value					Not relevant as the product is ready-to-use adhesive trap
3.3.	Relative density / bulk density					Not relevant as the product is ready-to-use adhesive trap
3.4.1.1.	Storage stability test – **accelerated storage**	*CIPAC MT 46*	Food-Moth trap-GEA P-04086D 1.69mg of ZE-TDA Packaging: flow-pack with 3 layers PET/Alu/PE (12/7/35µm)	Stable when stored for 8 weeks at 40 °C No change in appearance and weight of the packaging was noted **At t0** / **At+8w**: pH=8.8 / pH=7.9; AS: 1.69mg / AS: 1.66mg	[redacted] *(2013b) – CH-687/2012*	Acceptable. AS content variation: -1.8% < 5% acceptable The product is stable 8 weeks at 40 °C and is compatible with the flow-pack with 3 layers PET/Alu/PE → precautionary statement:

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	FR evaluation
						Do not store at temperatures higher than 40°C Read-across acceptable: Same composition and quantity of the mix glue+pheromone but the size of the carton is higher in the tested product.
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	GIFAP Monograph N°17 Analytical method validated in the first authorization	Food-Moth trap-GEA P-04086D 1.69mg of ZE-TDA (old composition) Packaging: cardboard box containing an aluminium bag (PET / Alu / PE)	After 6, 12, 24 and 36 months: the appearance of the trap is same as the beginning: solid, transparent and odourless. Regarding the packaging: The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena after 6 12, 24 and 36 months. Weight variation is between 0.08% and 0.71%. **Results**	[redacted] (2013b) – CH-688/2012	The product is stable after 36 months.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	FR evaluation
				T0 AS: 1.69 mg pH=8.8 **T6m** AS: 1.67 mg (-1.2%) pH=9.3 **T12m** AS: 1.82 mg (+7.8%) pH=9.2 **T24m** AS: 1.63 mg (-3.5%) pH=9.0 **T36m** AS: 1.68 mg (-0.6%) pH=9.0		
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**					Not relevant as the product is ready-to-use adhesive trap
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	No available data.				Not required as the packaging is a flow pack with aluminium.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	FR evaluation
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-		-		Data on temperature have been provided in the accelerated storage stability
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Refer to the sections on the storage stability tests.				Acceptable
3.5.1.	Wettability	-		-		Not relevant as the product is ready-to-use adhesive trap
3.5.2.	Suspensibility, spontaneity, and dispersion stability	-		-		Not relevant as the product is ready-to-use adhesive trap
3.5.3.	Wet sieve analysis and dry sieve test	-		-		Not relevant as the product is ready-to-use adhesive trap
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability	-		-		Not relevant as the product is ready-to-use adhesive trap
3.5.5.	Disintegration time	-		-		Not relevant as the product is ready-to-use adhesive trap

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	FR evaluation
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	-		-		Not relevant as the product is ready-to-use adhesive trap
3.5.7.	Persistent foaming	-		-		Not relevant as the product is ready-to-use adhesive trap
3.5.8.	Flowability/pourability/dustability	-		-		Not relevant as the product is ready-to-use adhesive trap
3.5.9.	Burning rate — smoke generators	-		-		Not relevant as the product is ready-to-use adhesive trap
3.5.10.	Burning completeness — smoke generators	-		-		Not relevant as the product is ready-to-use adhesive trap
3.5.11.	Composition of smoke — smoke generators	-		-		Not relevant as the product is ready-to-use adhesive trap
3.5.12.	Spraying pattern — aerosols / spray	-		-		Not relevant as the product is ready-to-use adhesive trap
3.6.1.	Physical compatibility	Waiving statement		Not relevant since the product is not intended to be used with other products or biocidal products	IUCLID	Acceptable
3.6.2.	Chemical compatibility	Waiving statement		Not relevant since the product is not intended to be used with other products or biocidal products	IUCLID	Acceptable
3.7.	Degree of dissolution and dilution stability					Not relevant as the product is ready-to-use

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	FR evaluation
						adhesive trap
3.8.	Surface tension	statement		The study does not need to be conducted because the substance is a solid	IUCLID	Acceptable
3.9.	Viscosity	statement		The study does not need to be conducted because the substance is a solid	IUCLID	Acceptable

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
The product ANTI-MITES ALIMENTAIRES-GEA_P04031D is a ready-to-use adhesive trap. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The biocidal product is a solid, made of cardboard on which a mixture of glue mixed with pheromone is spreaded. The mixture is solid and transparent, with no odour. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C; neither the active ingredient content nor the technical properties were changed. The product should not be stored above 40°C. The data on stability of the product Food-Moth trap-GEA P-04086D indicates that the product ANTI-MITES ALIMENTAIRES-GEA_P04031D is expected to be stable 3 years at ambient temperature. **Implications for labelling:** Do not store above 40°C. Shelf life: 3 years

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	Reference	FR evaluation
4.1.	Explosives	Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, Appendix 6, Section 3 DSC screening in the temperature range 25-500°C (heating rate: 5 K/min)	Pheromone adhesive mixture (adhesive mixture + TDDA) (S-04031D) Batch no. 23248041 0.2138 % w/w of ZE-TDA (1.5 mg of ZE-TDA)	**Not explosive** Stainless steel crucible hermetically sealed with a press (inert High Pressure -HP DSC 15 MPa as recommended by ASTM E537) Conditions: 5 K/min up to 500°C under nitrogen flow) Results: • No exothermic peak • No mass loss Total heat of decomposition: 0 J/g. Since the total heat of decomposition is <500 J/g, no further testing is needed. The product does not require classification in the hazard class 'explosives'.	[redacted] 2024, CH–0092-2024	Acceptable
4.2.	Flammable gases	Not required for a solid formulation. Indeed the biocidal product (pheromone adhesive mixture) is solid at room temperature			-	Acceptable
4.3.	Flammable aerosols	Not required for a solid formulation. Indeed the biocidal product (pheromone adhesive mixture) is solid at room temperature			-	Acceptable
4.4.	Oxidising gases	Not required for a solid formulation. Indeed the biocidal product (pheromone adhesive mixture) is solid at room temperature			-	Acceptable
4.5.	Gases under pressure	Not required for a solid formulation. Indeed the biocidal product (pheromone adhesive mixture) is solid at room temperature			-	Acceptable
4.6.	Flammable liquids	Not required for a solid formulation. Indeed the biocidal product (pheromone adhesive mixture) is solid at room temperature			-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	FR evaluation
4.7.	Flammable solids	UN Test N.1	Anti-Mites Alimentaires-GEA_P04031D (old formula) Batch no. 23248041 0.2138 % w/w of ZE-TDA (1.5 mg of ZE-TDA)	The test has been performed to the finished product (cardboard with the pheromone adhesive mixture), which is considered the worst case. The test item burns when the bunsen burner flame came close, but the combustion did not propagate. Since test item did not propagate combustion, no further testing was required.	[redacted] 2024, CH–0092-2024	Acceptable
4.8.	Self-reactive substances and mixtures	Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, Appendix 6, Section 3 DSC screening in the temperature range 25-500°C *(heating rate: 5 K/min)*	Pheromone adhesive mixture (adhesive mixture + TDDA) (S-04031D) Batch no. 23248041 0.2138 % w/w of ZE-TDA (1.5 mg of ZE-TDA)	Stainless steel crucible hermetically sealed with a press (inert High Pressure -HP DSC 15 MPa as recommended by ASTM E537) Conditions: 5 K/min up to 500°C under nitrogen flow) Results: • No exothermic peak • No mass loss Total heat of decomposition: 0 J/g. Since the total heat of decomposition is <300 J/g, no further testing is needed. The product does not require classification in the hazard class 'explosives'.	[redacted] 2024, CH–0092-2024	Acceptable
4.9.	Pyrophoric liquids	Not required for a solid formulation. Indeed the biocidal product (pheromone adhesive mixture) is solid at room temperature			-	Acceptable
4.10.	Pyrophoric solids	Based on the available information and experience in handling and use, Anti-mites Alimentaires-GEA_P04031D does not ignite spontaneously on coming into contact with air at normal temperatures.			-	Acceptable
4.11.	Self-heating substances and mixtures	Test waived according to Guidance on the Application of the CLP Criteria Version 6.0 – Jan 2024 "Substances or mixtures with a low melting point (< 160 °C) should not be considered for classification in this class since the melting process is endothermic and the substance-air surface is			-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	FR evaluation
		drastically reduced. However, this criterion is only applicable if the substance or mixture is completely molten up to this temperature.”				
4.12.	Substances and mixtures which in contact with water emit flammable gases	Based on the available information and experience in handling and use, Anti-mites Alimentaires-GEA_P04031D does not emit flammable gases when it is in contact with water. Moreover the b.p. is ready-to-use and should not be diluted in water.			-	Acceptable
4.13.	Oxidising liquids	Not required for a solid formulation. Indeed the biocidal product (pheromone adhesive mixture) is solid at room temperature			-	Acceptable
4.14.	Oxidising solids	According to the UN Recommendations of the Transport of Dangerous Goods, Manual of Tests and Criteria, Section 34.4.1, UN Test O.1, Appendix 6, test is not required if substances does not contain oxygen, fluorine or chlorine, or if these elements are present but bonded only to carbon or hydrogen. Based on the structural formula, none of the components does not contain fluorine or chlorine and the oxygen is bonded only to carbon or hydrogen. Thus test is not required and the b.p. should not be considered as oxidizer. Since the composition of the glue is considered confidential information form the supplier a statement has been provided by the supplier in order to confirm the above justification.			General statement	Acceptable
4.15.	Organic peroxides	The study does not need to be conducted, since neither the a.s. nor any co-formulant fall under the definition of organic peroxides according to CLP			-	Acceptable
4.16.	Corrosive to metals	Not required for a solid formulation. Indeed the biocidal product (pheromone adhesive mixture) is solid at room temperature			-	Acceptable
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Not required for a solid formulation. Indeed the biocidal product (pheromone adhesive mixture) is solid at room temperature			-	Acceptable
4.17.2.	Relative self-ignition temperature	The pheromone adhesive mixture is solid at room temperature but melts and becomes liquid at temperature lower than 160°C. Thus the test is not applicable.			-	Acceptable

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference	FR evaluation
	for solids					
4.17.3.	Dust explosion hazard	Not required since the product does not contain dust.			-	Acceptable

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product assessed is neither flammable nor auto-flammable. It has no explosive and no oxidizing properties. The product is not classified with regard to physical and chemical properties.

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 *:GC-FID, sample:* Food-Moth trap-GEA P-04086D											
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		
ZE-TDA	5 concentrations between	No interference has been observed	3 levels: 75, 100 and 125% of the nominal concentration	2 measurements at each	-	99.6% at 75% 97.5 at 100%	-		6 determinations RSD=0.53%	-	[redacted] (2013b) – CH-

	35.22 and 82.18 µg/mL R^2>0.99	at the retention time of ZE-TDA		level		and 98.2% at 125%					686/2012

The analytical method is validated based on SANCO guidance 3030/99. The read across is acceptable as the composition of glue+pheromone is the same between the tested product and the reference product and the weight added in the two products is the same. It is concluded that the provided method is validated and acceptable for the product Food-Moth trap-GEA P-04031D.

Table 3.7 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
An analytical method for the determination of ZE-TDA in the biocidal product is available. Specificity, linearity, accuracy and precision were checked and found acceptable.

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)

Main group : Pest Control
Product type 19: Repellents and attractants

The product ANTI-MITES ALIMENTAIRES-GEA-P04031D is intended to be used to attract food moths (male adults of the Mediterranean flour moth *Ephestia Kuehniella* and the Indian meal moth *Plodia interpunctella*), indoor, by non-professional users. The product is a ready to use adhesive trap, consisting of a cardboard covered with a sticky glue containing the active substance ZE-TDA. The trap is activated by the removal of its silicone surface paper.

The product has the objective to protect stored products for human consumption.

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

The active substance contained in the product acts with a mechanism pheromone-like on the target insects, drawing them on the cardboard. The insects are then trapped on the surface layer of glue.

The active substance (Z,E)-Tetradeca-9,12-dienyl acetate is part of the sex pheromone blend naturally produced by the females of the Indian meal moth, *Plodia interpunctella* to call males for mating. The pheromone itself does not have any adverse effects on the target organisms but modifies its behaviour. The active substance interferes with the receptor molecule of the olfactory organs located on the antennae of the males of *Plodia interpunctella* and a couple of related pest species (e.g. *Ephestia*).This reaction is very specific and limited to a defined group of species.

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	Reference	Number in IUCLID section 6.7/Test report title
PT19 Attractant Protection of stored products	FOOD MOTH TRAP-GEA_P-04031D (1.5 mg of pheromone per trap) product freshly opened and 2 months after opening product	*Ephestia kuehniella* (Mediterranean flour moth), *Plodia interpunctella* (Indian meal moth) 120 adults males (30 insects per replicate) from 1 to 3 days old	**Simulated-use test without food competition** Test chamber of 30 m³, following the requirements of the C.E.B. 135 bis standard. Climatic conditions during the test: - Temperature: 24°C ± 2°C - Relative humidity: 65% ± 5% - Light: 1500 lux - Ventilation: none Application rate : 1 trap/30m^3 Exposure of one hour One glue trap is suspended inside the top of a wardrobe, placed at the right back corner of the test chamber. After the activation of the trap, adult food moths are released inside the room from the opposite side to the trap location. At various times over one hour, the number of insects trapped is recorded by the experimenter. Even if all insects are trapped before the end of the experiment; a	The product, in absence of food competition, has proved 100% efficacy against male food moths, with the following time delay: For *Plodia interpunctella:* - within 10 min, at opening - within 25 min, 2 months after opening For *Ephestia kuehniella:* - within 15 min, at opening - within 40 min, 2 months after opening Untreated controls: < 5% mortality	[redacted] 2012 Report N° 1535/0912R Key study	6.7.01 Initial AMM - 2013 - Efficacy data without food competition FOOD MOTH TRAP-GEA_P04031D - At opening and 2 months after opening (2012)

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
			last record is performed after one hour in order to check that the insects were not able to escape from the glue trap. 4 replicates / species at opening and 2 months after opening. Untreated control: 4 replicates			
PT19 Attractant Protection of stored products	FOOD MOTH TRAP-GEA_P-04086D (1.5 mg of pheromone per trap) 34 months aged product freshly opened	*E. kuehniella* (Mediterranean flour moth), *P. interpunctella* (Indian meal moth) 120 adults males (30 insects per replicate) from 1 to 3 days old	**Simulated-use test without food competition** Same test method and test conditions as 6.7.01. Application rate : 1 trap/30 m^3 Exposure of one hour 4 replicates / species Untreated control: 4 replicates	The product, freshly opened, in absence of food competition, has proved 100% efficacy against male food moths, within the following time delay: - within 15 min, for *Plodia interpunctella*, - within 25 min, for *Ephestia kuehniella*. Untreated controls: no mortality	[redacted] 2012 Report N° 1535b/0912R Key study	6.7.02 Initial AMM - 2013 - Efficacy data without food competition FOOD MOTH TRAP-GEA_P04086D - At the end of its shelf-life (2012)
PT19 Protection of stored products	FOOD MOTH TRAP-GEA_P-04025D (1.5 mg of pheromone per trap) Product freshly opened	*E. kuehniella* (Mediterranean flour moth), *P. interpunctella* (Indian meal moth) 120 adults males (30	**Simulated-use test without food competition** Same test method and test conditions as 6.7.01. Application rate: 1 trap/30 m^3 Exposure of one hour	The product, freshly opened, in absence of food competition, has proved 100% efficacy against male food moths, with the following time delay: - within 10 min, for *Plodia interpunctella*, - within 15 min, for *Ephestia kuehniella*. Untreated controls: no mortality	[redacted] 2012 Report N° 1535c/0912R Key study	6.7.03 Initial AMM - 2013 - Efficacy data without food competition FOOD MOTH TRAP-GEA_P0402520D - At the

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
		insects per replicate) from 1 to 3 days old	Untreated control: 4 replicates 4 replicates / species at opening and 2 months after opening.			beginning of its shelf-life (2012)
PT19 Protection of stored products	FOOD MOTH TRAP-GEA_P-04031D (1.5 mg of pheromone per trap) 20 µg/cm² Product freshly opening and 2 months after opening product	*E. kuehniella* (Mediterranean flour moth), *P. interpunctella* (Indian meal moth) 120 adults : 30 insects per replicate (15 males + 15 females) from 1 to 3 days old	**Simulated-use test with food competition and with a mixed sex population** Same test method and test conditions as 6.7.01, but with females and food inside the test chamber, on the floor. Application rate: 1 trap/30 m^3 4 replicates / species at opening and 2 months after opening. Untreated control: 4 replicates Males and females are counted separately.	The product, in presence of food competition, has proved 100% efficacy against male food moths, with the following time delay For *Plodia interpunctella:* - within 10 min, at opening - within 20 min, 2 months after opening, For *Ephestia kuehniella:* - within 10 min, at opening - within 30 min, 2 months after opening. ≤ 5% females catched Untreated controls: < 5% mortality	[redacted] 2014 Report N° 1728e/0214R Key study	6.7.04 Post-AMM - 2016 - Efficacy data WITH food competition FOOD MOTH TRAP-GEA_P04031D – mix population - At the opening and 2 months after opening (2014)
PT19 Protection of stored products	FOOD MOTH TRAP-GEA_P-04031D (1.5 mg of pheromone per trap) 20	*E. kuehniella* (Mediterranean flour moth), *P. interpunctella* (Indian meal moth)	**Simulated-use test without food competition** Same test method and test conditions as 6.7.01. Application rate: 1 trap/30 m^3	The product, in absence of food competition, has proved 100% efficacy against male food moths, with the following time delay: For *Plodia interpunctella:* - within 15 min, at opening - within 20 min, 2 months after opening	[redacted] 2015 Report N° 1913c-FMT-523/0315R	6.7.05 Minor Change AMM of the shelf-life - 2016 - Efficacy data without food

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
	µg/cm² 3 years aged product freshly opened and 2 months after opening product	120 adults males (30 insects per replicate) from 1 to 3 days old	Exposure of one hour 4 replicates / species at opening and 2 months after opening. Untreated control: 4 replicates	For *Ephestia kuehniella:* - within 15 min, at opening - within 40 min, 2 months after opening Untreated controls: < 5% mortality	Key study	competition FOOD MOTH TRAP-GEA_P04031D –At the opening and 2 months after opening at the end of its 3 years shelf-life (2015)
PT19 Protection of stored products	ORPHEA ANTI TARME ALIMENTARI (1.5 mg of pheromone per trap) 20 µg/cm² 38 months aged product freshly opened and 2 months after opening product	*E. kuehniella* (Mediterranean flour moth), *P. interpunctella* (Indian meal moth) 120 adults males (30 insects per replicate) from 1 to 3 days old	**Simulated-use test without food competition** Same test method and test conditions as 6.7.01. Application rate: 1 trap/30 m^3 Exposure of one hour 4 replicates / species at opening and 2 months after opening. Untreated control: 4 replicates	The product, in absence of food competition, has proved 100% efficacy against male food moths, with the following time delay: For *Plodia interpunctella:* - within 20 min, at opening - within 25 min, 2 months after opening For *Ephestia kuehniella:* - within 20 min, at opening - within 30 min, 2 months after opening Untreated controls: no mortality	[redacted] 2016 Report N° 2090/0616R Key study	6.7.06 Minor Change AMM of the shelf-life - 2016 - Efficacy data without food competition FOOD MOTH TRAP-GEA_P04025D –At the opening and 2 months after opening at the end of its 3 years shelf-life (2016)
PT19 Protection of stored products	FOOD MOTH TRAP-GEA_P-04031D (1.5 mg of pheromone	*E. kuehniella* (Mediterranean flour moth), *P. interpunctella* (Indian meal	**Simulated-use test with food competition and with a mixed sex population** Same test method and test	The product, in presence of food competition, has proved 100% efficacy, against male adults, with the following time delay: For *Plodia interpunctella:* - within 10 min, at opening	[redacted] 2018 Report N° 2375a/0818R	6.7.07 Minor Change AMM duration up to 3 months and [redacted]

<table>
<tr><th>PT and use number</th><th>Test product</th><th>Function / Test organism(s)</th><th>Test method / Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th><th>Number in IUCLID section 6.7/Test report title</th></tr>
<tr><td></td><td>per trap) 20 µg/cm²

Fresh opened and 3 months after opening product</td><td>moth)

120 adults : 30 insects per replicate (15 males + 15 females) from 1 to 3 days old</td><td>conditions as 6.7.04.

Application rate: 1 trap/30 m³

Exposure of one hour

4 replicates / species at opening and 3 months after opening.

Untreated control: 4 replicates.

Males and females are counted separately.</td><td>- within 15 min, 3 months after opening

For Ephestia kuehniella:
- within 10 min, at opening
- within 20 min, 3 months after opening.

≤ 5% females catched

Untreated controls: < 5% mortality</td><td>Key study</td><td>[redacted] – 2018 - Efficacy data WITH food competition FOOD MOTH TRAP-GEA_P04031D –mix population - At the opening and 3 months after opening (2018)</td></tr>
<tr><td>PT19

Protection of stored products</td><td>FOOD MOTH TRAP-GEA_P-04031D

(1.5 mg of pheromone per trap) 20 µg/cm²

Fresh opened and 3 months after opening product</td><td>E. kuehniella (Mediterranean flour moth),

P. interpunctella (Indian meal moth)

120 adults : 20 insects per replicate (10 males + 10 females) from 1 to 4 days old</td><td>Simulated-use test with food competition and with a mixed sex population

2 types of tests setups:
- Test chamber of 27.5m³,
- Closed cupboards of 0.56m³ kept not hermetically closed and opened once a day for 10 seconds

Climatic conditions during the test in both type of set ups:
- Temperature: 21°C ± 2°C</td><td>The average percentage of the male population reduction after 96h:

Plodia interpunctella
<table><tr><th></th><th colspan="2">Cupboard</th><th colspan="2">Test chamber</th></tr><tr><th></th><th>Treated</th><th>Control</th><th>Treated</th><th>Control</th></tr><tr><td>Fresh trap</td><td>82%</td><td>4%</td><td>94%</td><td>4%</td></tr><tr><td>Aged trap</td><td>80%</td><td>2%</td><td>86%</td><td>6%</td></tr></table>
Ephestia kuehniella
<table><tr><th></th><th colspan="2">Cupboard</th><th colspan="2">Test chamber</th></tr><tr><th></th><th>Treated</th><th>Control</th><th>Treated</th><th>Control</th></tr><tr><td>Fresh trap</td><td>90%</td><td>32%</td><td>82%</td><td>2%</td></tr><tr><td>Aged trap</td><td>84%</td><td>16%</td><td>80%</td><td>4%</td></tr></table></td><td>[redacted]

Report N° 2047.BCD.SAG22

Supportive data (tested application rates higher than the claimed doses)</td><td>6.7.08

AMM 2023 – New Efficacy study WITH food competition FOOD MOTH TRAP-GEA_P04031D –4 days testing period - mix population - At the opening and 3 months after opening (2023)</td></tr>
</table>

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
			- Relative humidity: 40% ± 5% - Photoperiod: 8:16 L:D Food inside both type of tests set ups, on the floor Exposure of 4 days After the activation of the trap, adult food moths are released inside the room from the opposite side to the trap location. At various times over one hour, the number of insects trapped is recorded by the experimenter. Even if all insects are trapped before the end of the experiment; a last record is performed after one hour in order to check that the insects were not able to escape from the glue trap 5 replicates / setup <u>Application rates:</u> • 2 traps per test chamber of 27.5m^3 • 1 trap per cupboard of 0.56m^3	The ratio 4:1 (efficacy criteria of efficacy guidance version 2021 not applicable) was not accomplished in test with fresh traps for *Ephestia kuehniella.* The captures in the untreated traps could be explained as due to randomness reasons as they were placed in cupboards, where the space is reduced compared to the test chambers and it could be easier for the insects to find the traps. In all the other tests the ratio of 4:1 was achieved. Statistical analysis showed the treatement effect was significant for population reduction in both species.		

3.5.3 Efficacy assessment

In the frame of this second simplified authorisation, the submitted efficacy data have been performed with products having different patterns or compositions but with the same content of active substance (i.e. 1,5 mg of Z,E-TDA per trap). Please, also refer to the confidential PAR for more information.

The efficacy of the product ANTI-MITES ALIMENTAIRES-GEA_P04031D has been proven through several simulated-use tests, with and without food competition, against *E. kuehniella* (Mediterranean flour moth) and *P. interpunctuella* (Indian meal moth). Simulated-use tests were performed in 30 m^3 rooms and 0.56 m^3 cupboards.

The simulated-use tests showed also that the product is efficient against *Ephestia kuehniella* and *Plodia interpunctualla* with fresh and 36 months aged product. It has also been demonstrated that the product remains efficient 3 months after opening.

3.5.4 Conclusion on efficacy

Based on the efficacy data presented, it can be concluded that the product ANTI-MITES ALIMENTAIRES-GEA_P04031D is efficient to attract food moths (adult males of *Ephestia kuehniella* and *Plodia interpunctella*) up to 3 months after opening, at the application rate of 1 trap (containing 1,5 mg of Z,E-TDA) for 30 m^3 area, therefore the efficacy of the claimed application rates, of 1 trap (containing 1,5 mg of Z,E-TDA) for 20 m^3 area when the trap is placed outside a cupboard or 1 trap (containing 1,5 mg of Z,E-TDA) for 1.5m^3 when placed inside a cupboard, are demonstrated.

3.5.5 Occurrence of resistance and resistance management

Treatment by synthetic pheromones could theoretically result in selection of altered blends or higher pheromone production in females (Svensson et al., 2002). The continuous exposure by mating disruption to the most commonly produced pheromone blend in a pest population may select for uncommon pheromone phenotypes and gradually alter the chemical communication system of the population and contribute to the potential for the development of resistance to mating disruption (Evenden et Haynes, 2001).

Evidence for increased emission rates in females after long-term exposure to high doses of pheromone has been reported from both field and laboratory studies. Haynes and Baker (1988) observed an increasing pheromone emitted in *Pectinophora gossypiella*, whereas Shani and Clearwater (2001) in *Ephestia cautella* even if selection pressure imposed by long-term exposure to high doses of pheromone did not result in resistance to pheromones.

Similarly, Svennson et al. (2002) observed significant heritable variation in pheromone production of *Plodia interpunctella* but no increase in the mating ability in population under selective pressure. The authors did not find any evidence for resistance evolution towards mating disruption due to a shift in the pheromone blend even if, due to the few generations of selection conducted in the study, they cannot rule out the possibility that resistance can evolve after more generations of selection.

From these studies, it seems that mating disruption impose a selection pressure, but the consequent resistance development is not obvious at all. Indeed, the resistance to pheromone is considered unlikely by many authors. For instance, Witzgall et al. (2010) stated that resistance to mating disruption is a remote risk in many species, because

changes in female pheromone biosynthesis or male response are unlikely to lead to a new communication channel that is unaffected by synthetic pheromone treatments that do not precisely match the female-produced blend. Whereas Liu & Haynes, (1994) showed after 49 generations within a pure mutant colony, that males responded equally well to both mutant and normal pheromones.

Evenden & Haynes, (2001) suggests that mating disruption using the most commonly produced pheromone blend in a pest population, may select for uncommon pheromone phenotypes and gradually alter the chemical communication system of the population and contribute to the potential for the development of resistance to mating disruption.
However, resistant strains could potentially be selected even if it is a remote possibility. To date, there are only a few reports on the development of resistance of insects to sex pheromones (Rizvi et al., 2021; Harari and Sharon, 2022).

Tabata et al. (2007a,b) reported a case of resistance to pheromone based control strategies after 10 years of permanent treatment. *Adoxophyes honmai* showed resistance to treatments with a single pheromone component. The efficacy of mating disruption was re-established by use of the full pheromone blend instead of the previously used single compound.

Another case of resistance to pheromone was observed in *Trichoplusia ni*: a mutation occurred in a laboratory culture of this species, causing a dramatic change in the composition of the pheromone produced by mutant females compared to the wild type. The studies on wild-type and mutant colonies of *T. ni* (Haynes and Hunt, 1990; Liu and Haynes, 1994; Evenden and Haynes, 2001) showed that changes of the communication channel can occur and may lead to evolution of resistance to mating disruption.

Literature on this topic mainly concerns mating disruption that use higher doses of a.s., e.g. 0,2-0,3 mg per m^3 per day against *E. kuehniella* and *P. interpunctella* (Ryne et al., 2007). On the contrary, the tested product emits the a.s. in minute quantities and thus development of resistance is not expected.

To conclude, the possibility of resistance development due to pheromone based control strategy seems to be remote even if it cannot be completely excluded.

Although so far resistance against pheromone based control strategies has not been showed on the target organisms *P. interpunctella* and *E. khueniella*. It is a relevant issue and needs to be addressed on a longer-term basis. This includes a monitoring of the scientific literature related to the resistance of the target organisms to the active substance (Z,E)-Tetradeca-9,12-dienyl acetate at the renewal.

The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

3.5.6 Known limitations

There are no known limitations for the product Anti-mites alimentaires-GEA_P04031D.

3.5.7 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

According to Article 25 and Article 20 (1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the product fulfils all conditions for a simplified authorisation procedure.

3.6.1 Assessment of effects on human health

There are no human health data available for the product. The assessment, and classification and labelling are based on the agreed endpoints for the active substance and available information for the non-active substances.
The classification of the product ANTI-MITES ALIMENTAIRES-GEA_P04031D has been set according to the calculation rules laid down in the CLP Regulation 1272/2008/EC.

The product ANTI-MITES ALIMENTAIRES-GEA_P04031D is not classified for human health.

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

No substances of concern regarding human health were identified as none of the non-active substances fulfil the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)).
Two ingredients contained in the co-formulant have a UE-OEL. According to the document "Harmonised approach to consider a co-formulant as a substance of concern (SoC) based on its workplace exposure limits" (CG-45)", since the product is intended to be used solely by general public, these two ingredients are not considered as SoC.

3.6.3 Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of the non-active substances, refer to the respective section of the confidential annex.

3.6.4 Exposure assessment and risk characterisation for human health

Not relevant

3.6.5 Dietary risk assessment

Not relevant

3.7 Risk assessment for animal health

Not relevant.

3.8 Risk assessment for environment

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the product fulfil all conditions for a simplified authorisation procedure.

3.8.1. Classification

The classification of the product has been calculated based on the classification rules for

mixtures according to CLP Regulation (EC) N° 1272/2008 and the product is not classified for the environment.
Moreover, there is no need for risk mitigation measure to protect the environment.

3.8.1.1 Substance(s) of concern

The product ANTI-MITES ALIMENTAIRES-GEA_P04031D does not contain any environmental substance of concern (SoC) according to the EU guidance on SoC (Article 3(f) of the BPR, Guidance on BPR, Volume IV, Part B+C, version 2.0-2017).

3.8.1.2 Screening for endocrine disruption relating to non-target organisms

For the assessment of endocrine-disrupting properties of non-active substance(s), refer to the respective section of the confidential annex.

3.9 Assessment of a combination of biocidal products

Not relevant.

3.10 Comparative assessment

Not relevant, the active substance is not candidate for substitution or exclusion.

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Not relevant.

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 is available.

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)**
[redacted]	2013	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	Storage stability tests - Accelerated storage stability and corrosion characteristics	FOOD MOTH TRAP: Determination of the accelerated storage stability and corrosion characteristics	Study report	ChemService Controllie Ricerche GLP Studies Department Via F.lli Beltrami, 15 20026 Novate Milanese - MI - (Italy) GEA s.r.l	yes (incl. QA statement)	yes
[redacted]	2015	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	Post-AMM - 2016 - Storage stability tests - Three years storage stability and corrosion characteristics	FOOD MOTH TRAP: Three Years Storage Stability and Corrosion Characteristics Study report	Study report	ChemService Controllie Ricerche GLP Studies Department Via F.lli Beltrami, 15 20026 Novate Milanese - MI - (Italy) GEA s.r.l	yes (incl. QA statement)	yes

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)
[redacted]	2024	4.1 Explosiveness (explosiveness, other) 4.2 Flammability (flammable solids) 4.8 Self-reactive substances and mixtures (self-reactive substances)	key study, explosive properties: Martinez M.P. 2024 CH-0092-2024	Determination of the Flammability on Anti-Mites Alimentaires-GEA_P04031D and Determination of the Explosive properties by preliminary Differential Scanning Calorimetry (DSC) analysis on Pheromone adhesive mixture (adhesive mixture + TDDA) (S-04031D) Report No.: CH–0092-2024	Study report	LabAnalysis Life Science Srl - Sede di Milano GEA s.r.l	yes (incl. QA statement)	yes
[redacted]	2019	5 Methods of detection and identification (analytical methods)	key study, flammability: Martinez M.P. 2024 CH-0092-2024	ANTI-MITES ALIMENTAIRES-GEA_P-04031D-PLACEBO: Integration to the Validation of the Analytical Method for the Determination of the Active Ingredient Content	Study report	ChemService S.r.l. Controlli e Ricerche GEA s.r.l	yes (incl. QA statement)	yes

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)**
				(GLP Study CH-686/2012) Report No.: CH – 053/2019				
[redacted]	2012	6.7.1 Initial AMM - 2013 - Efficacy data without food competition FOOD MOTH TRAP-GEA_P04031D - At opening and 2 months after opening (2012)	Efficacy Data - 1535b_0912R - Registration Food Moth Trap GEA - P04086D.pdf	LABORATORY EVALUATION OF THE EFFICACY OF A FOOD MOTH TRAP. Experimental product: "FOOD MOTH TRAP_P-04031D" Report No.: 1535/0912R	Study report	T.E.C. LABORATORY 1 rue Jules Védrines F-64600 Anglet (FRANCE) GEA s.r.l	yes (incl. QA statement)	yes
[redacted]	2012	6.7.2 Initial AMM - 2013 - Efficacy data without food competition FOOD MOTH TRAP-GEA_P04086D at the end of its shelf-life (2012)	Efficacy Data - 1535b_0912R - Registration Food Moth Trap GEA - P04086D.pdf	LABORATORY EVALUATION OF THE EFFICACY OF A FOOD MOTH TRAP. Experimental product: "FOOD MOTH TRAP_P-04086D" Report No.: 1535b/0912R	Study report	T.E.C. LABORATORY 1 rue Jules Védrines F-64600 Anglet (FRANCE) GEA s.r.l	yes (incl. QA statement)	yes
[redacted]	2012	6.7.3 Initial AMM - 2013 - Efficacy	Efficacy Data - 1535c_0912R - Registration	LABORATORY EVALUATION OF THE EFFICACY	Study report	T.E.C. LABORATORY 1 rue Jules Védrines	no	yes

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)
		data without food competition FOOD MOTH TRAP-GEA_P-040252D at the beginning of its shelf-life (2012) .	Food Moth Trap GEA - P04025D.pdf	OF A FOOD MOTH TRAP. Experimental product: "FOOD MOTH TRAP_P-04025D" Report No.: 1535c/0912R		F-64600 Anglet (FRANCE) GEA s.r.l		
[redacted]	2014	6.7.4 Post-AMM - 2016 - Efficacy data WITH food competition FOOD MOTH TRAP-GEA_P-04031D - mix population - At opening and 2 months after opening (2014)	1728e-0214R_PO336-Food moths.pdf	LABORATORY EVALUATION OF THE EFFICACY OF A FOOD MOTH TRAP. Experimental product: "FOOD MOTH TRAP_P-04031D" Report No.: 1728e/0214R	Study report	T.E.C. LABORATORY 1 rue Jules Védrines F-64600 Anglet (FRANCE) GEA s.r.l	no	yes
[redacted]	2015	6.7.5 Minor Change AMM of the shelf-life - 2016 - Efficacy data without food competition FOOD MOTH TRAP-GEA_P040	Efficacy Data - 1913c-FMT-523_0315R - Registration Food Moth Trap GEA - P04031D 2015.pdf	LABORATORY EVALUATION OF THE EFFICACY OF A FOOD MOTH TRAP. Product tested at its expiry date. Experimental product: "FOOD MOTH	Study report	T.E.C. LABORATORY 1 rue Jules Védrines F-64600 Anglet (FRANCE) GEA s.r.l	no	yes

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)**
		31D - At opening and 2 months after opening at the end of its 3 years shelf-life (2015)		TRAP_P-04031D" Report No.: 1913c-FMT-523/0315R				
[redacted]	2016	6.7.6 Minor Change AMM of the shelf-life - 2016 - Efficacy data without food competition FOOD MOTH TRAP-GEA_P04025D - At opening and 2 months after opening after the end of its 3 years shelf-life (2016)	Efficacy Data - 2090_0616R - Registration Food Moth Trap_Orphea 2016.pdf	LABORATORY EVALUATION OF THE EFFICACY OF A FOOD MOTH TRAP Complementary report to the report TEC n°1535c/0912r sample: orphea anti tarme alimentari cod. p-04025 or lotto 09 of 30/11/12 tested 38 months after its production date Report No.: 2090/0616R	Study report	T.E.C. LABORATORY 1 rue Jules Védrines F-64600 Anglet (FRANCE) GEA s.r.l	no	yes
[redacted]	2018	6.7.7 Minor Change AMM duration up to 3 months and change of	Report 2375a Food Moth Trap GEA_P-04031D.pdf	LABORATORY EVALUATION OF THE EFFICACY OF A FOOD MOTH TRAP « FOOD MOTH	Study report	T.E.C. LABORATORY 1 rue Jules Védrines F-64600 Anglet (FRANCE)	no	yes

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)**
		glue Technomelt PS 8432 - 2018 - Efficacy data WITH food competition FOOD MOTH TRAP-GEA_P04031D - mix population - At opening and 3 months after opening (2018)		TRAP_P-04031D » Report No.: 2375a/0818R		GEA s.r.l		
[redacted]	2023	6.7.8 Renewal AMM 2023 - New Efficacy study WITH food competition FOOD MOTH TRAP-GEA_P04031D - 4 days testing period - mix population - At opening and 3 months after opening (2023)	2047.Final Report_Anti-Mites Alimentaires GEA P-04031D_Simulated use test.pdf	Simulated-use Trials to Determine the Efficacy of Anti-Mites Alimentaires-GEA_P-04031D Report No.: 2047.BCD.SAG22	Study report	SAGEA Centro di Saggio s.r.l. Via San Sudario, 15 12050 Castagnito d'Alba (CN) Italy GEA s.r.l	no	yes
[redacted]	2024	6.7.9 Minor Change AMM	2026.Final Report_Anti-Mites Alimentaires	Simulated-use Trials to Demonstrat	Study report	SAGEA Centro di Saggio s.r.l. Via	no	yes

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)
		withdrawal [redacted] - Comparative Efficacy study WITH food competition FOOD MOTH TRAP-GEA_P04031D - 4 days testing period - mix population - At opening and 3 months after opening (2024)	GEA P-04031D_Simulated use test.pdf	e the Efficacy Equivalence of Anti-Mites Alimentaires-GEA_P-04031D compared to the same trap without [redacted] Report No.: 2026.BCD.SAG23		San Sudario, 15 12050 Castagnito d'Alba (CN) Italy GEA s.r.l		

4.4 References

4.4.1 References other than list of studies for the biocidal product

Not relevant

4.4.2 Guidance documents

Not relevant

4.4.3 Legal texts

Not relevant

4.5 Confidential information

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