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

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

(submitted by the evaluating Competent Authority)



STOP MITES A

Product type 19

(Z,E)-Tetradeca-9,12-dienyl acetate as included in the Union list of approved active substances Annex I of the Biocidal Products Regulation (BPR)

Case Number in R4BP: BC-UV050255-09

Evaluating Competent Authority: FR

Date: [November 2019]

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# CONCLUSION

***Intended uses***

The biocidal product STOP MITES A is product type 19 containing 100 % of Z,E-DTA and is intended to be used indoor against food moths. The product is an attractive trap made of cardboard with glue mixed with pheromone for non-professional users.

***Physico-chemical and technical properties***

The active substance contained in the biocidal product ((Z,E)-Tetradeca-9,12-dienyl acetate) is listed in Annex I of EU Regulation 528/2012 and the biocidal product does not contain any nanomaterials.

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 light yellow transparent, with a sui generis 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 following management measure should be added for the product: Do not store at temperatures higher than 40°C.

The data on stability of the product Food-Moth trap-GEA P-04086D (similar product) indicates that the product STOP MITES A is expected to be stable 3 years at ambient temperature. The product assessed is not classified according to physical hazard.

***Efficacy***

French competent authorities (FR CA) consider that the efficacy study submitted demonstrates that the product STOP MITES A is efficient as a food moths attractive trap (*Ephestia kuehniella* et *Plodia interpunctella*), fresh product and opened since 3 months.

***Human health***

The active substance and the co-formulants are either not classified according to the CLP regulation for human health or present at concentration sufficient to classify the product.

Consequently, the product is not classified for human health.

The non-active substances of the product does not meet the different conditions described in the Art 3(f) of Regulation (EU) No. 528/2012/EC therefore no substance of concern for the human health are identified in the product.

***Environment***

The active substance and the co-formulants are either not classified as hazardous to the environment under Reg. (EC) 1272/2008, or they are not present at sufficient concentrations to trigger hazard classification on their own. The product is thus not classified for the environment. Moreover, the product does not contain any other biocidal substances from another PT and none of the co-formulants are regulatory identified as endocrine disruptors.

Therefore no SoCs for the environment are considered to be present in the STOP MITES A product.

**GENERAL CONCLUSION: Eligibility for the simplified authorisation procedure**

Following evaluation, the biocidal product STOP MITES A does meet the conditions required for simplified authorisation as defined in Article 25 of 528/2012, i.e.:

1. The active substance (Z,E)-Tetradeca-9,12-dienyl acetate is listed in Annex I of Regulation (EU) 528/2012.

2. The biocidal product does not contain any substances of concern according to the definition described in article 3 (f) of the BPR.

3. The biocidal product does not contain any nanomaterials.

4. The use pattern and associated label claims of the biocidal product have been judged sufficiently effective.

5. The handling of the biocidal product as part of its intended use does not require any PPE.

**Therefore, FR CA considers that the biocidal product shall be authorized.**

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| STOP MITES A | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Evergreen Garden Care France SAS |
| **Address** | Chemin de la sauvegarde 2169134 EcullyFrance |
| **Authorisation number** | **FR-2019-0125** |
| **Date of the authorisation** | **03/01/2020** |
| **Expiry date of the authorisation** | **02/01/2030** |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | GEA srl |
| **Address of manufacturer** | Via Enrico Fermi, 10, 20019 Settimo Milanese Italy |
| **Location of manufacturing sites** | Via Enrico Fermi, 10, 20019 Settimo Milanese Italy |

#### Manufacturer(s) of the active substance(s)

|  |  |
| --- | --- |
| **Active substance** | (9Z,12E)-tetradeca-9,12-dien-1-yl acetate |
| **Name of manufacturer** | GEA srl |
| **Address of manufacturer** | Via Enrico Fermi, 10, 20019 Settimo Milanese Italy |
| **Location of manufacturing sites** | Via Enrico Fermi, 10, 20019 Settimo Milanese Italy |

### Product composition and formulation

#### Identity of the active substance

|  |
| --- |
| **Main constituent(s)** |
| **ISO name** | **(Z,E)-Tetradeca-9,12-dienyl acetate** |
| **IUPAC or EC name** | **(9Z,12E)-Tetradeca-9,12-dien-1-yl acetate** |
| **EC number** | **250-753-6** |
| **CAS number** | **30507-70-1** |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | **97.9%**  |
| **Structural formula** |  |

#### Candidate(s) for substitution

The active substance (Z,E)-Tetradeca-9,12-dienyl acetatecontained in the biocidal product is not candidate for substitution in accordance with article 10 of BPR.

#### Qualitative and quantitative information on the composition of the biocidal product

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| (Z,E)-Tetradeca-9,12-dienyl acetate | (9Z,12E)-Tetradeca-9,12-dien-1-yl acetate | Active Substance | 30507-70-1 | 250-753-6 | 100[[2]](#footnote-3) |

#### Information on technical equivalence

Not relevant

#### Information on the substance(s) of concern

The product STOP MITES A does not contain any substance of concern. Please see the confidential annex for further details.

#### Assessment of endocrine disruption (ED) properties of the biocidal product

Based on available information, and considering the legal deadline for STOP MITES A biocidal product authorization, it is not possible to conclude whether the biocidal product is considered to have ED properties. The assessment of one co-formulant must be further assessed in the frame of REACH (or BPR if the co-formulant is an active substance with no decision yet on ED). Once the conclusion regarding ED properties of this co-formulant is available, the applicant must inform eCA/rMS. If needed, the conditions of authorization shall be revised.

 Please see the confidential annex for further details.

#### Type of formulation

|  |
| --- |
| Ready-to-use adhesive trap |

### Hazard and precautionary statements

**Classification and labelling of the products according to the Regulation (EC) 1272/2008**

| **Classification** |
| --- |
| Hazard category | - |
| Hazard statement | - |
|  |
| **Labelling** |
| Signal words | - |
| Hazard statements | - |
| Precautionary statements | - |
|  |
| Note | **-** |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Food moths - Indoor

|  |  |
| --- | --- |
| **Product Type** | **PT19** |
| **Where relevant, an exact description of the authorised use** | The active substance is released in the air, it acts as the sexual pheromone produced by the females of the food moths of the species *Plodia interpunctella* (Indian-meal moth) .The male insect is attracted by this active substance and is captured on the glue area of the trap. Z,E-TDA causes a disturbance in the sexual behaviour of the males. |
| **Target organism (including development stage)** | *Plodia interpunctella* (Indian-meal moth)*Ephestia khueniella* (Flour moth)Adult males |
| **Field of use** | IndoorProduct intended to be used exclusively indoors, in spaces where foodstuffs (both for human and animal) are stored. |
| **Application method(s)** | Bait applicationThe trap is placed in food storage places (kitchens, living rooms, store rooms…).It is a V-shaped adhesive trap, to be put on shelves and on the cupboards. It must be activated by peeling of the protective film. |
| **Application rate(s) and frequency** | 1 trap (containing 2 mg of Z,E-TDA) in 30 m3 room volume – ready-to-useReplace the trap every three months or when the surface of the trap is saturated with insects. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | PET/Al/PE flow pack (165 x114 mm) of 2 or 3 traps |

#### **2.1.4.2.**  Use-specific instructions for use

|  |
| --- |
| - |

#### **2.1.4.3.** Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

#### **2.1.4.5.** Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| - |

#### **2.1.4.6.** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| - |

### General directions for use

#### Instructions for use

|  |
| --- |
| * Inform the registration holder if the treatment is ineffective.
* Always read the label or leaflet before use and respect all the instructions provided.
* Respect the conditions of use of the product.
* Persistence of action until 3 months after opening.
* Biocidal effect observed one hour after application of the traps.
 |

#### Risk mitigation measures

|  |
| --- |
| * Do not use in spaces where un-packaged food or feed is kept.
 |

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

|  |
| --- |
| - |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| - |

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

|  |
| --- |
| * Shelf-life: 3 years
* Do not store at temperatures higher than 40°C.
 |

### Other information

|  |
| --- |
|  |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging**  | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Flow-pack | 165 x 114 mm | PET/Al/PE | - | non-professional | Yes |

### Documentation

#### Data submitted in relation to product application

**Physico-chemical properties**

* Physico-chemical properties studies and analytical methods on the biocidal product STOP MITES A were provided by Evergreen Garden Care France SAS.

**Efficacy data**

The following efficacy study was submitted :

## A simulated use test conducted with food competition according to CEB 135bis with the fresh and opened (3 months) product STOP MITES A performed on Indian meal-moth (*Plodia interpunctella)* and Flour moth (*Ephestia kuehniella).*

#### Access to documentation

Evergreen Garden Care France SAS submitted a letter of access (dated of 22/07/2019) to the complete active substance dossier on (Z,E)-tetradeca-9,12-dienyl acetate (CAS 30507-70-1) (third party dossier) for which it has been listed in Article 95 list of the Biocidal Products Regulation on the 24th September 2014,

Evergreen garden Care France SAS submitted a letter of access (dated of 22/07/2019) authorizing French competent authorities to data regarding the following report:

* The analytical report CH-053/2019
* The three years storage stability test report CH-688/2012
* The analytical report CH-686/2012

## Assessment of the biocidal product

### Intended use(s) as applied for by the applicant

Table 2. Intended use # 1 – Food Moths - Indoor

|  |  |
| --- | --- |
| Product Type(s) | PT19 - Repellents and attractants (Pest control) |
| Where relevant, an exact description of the authorised use | The active substance Z,E-TDA is released in the air, it acts as the sexual pheromone produced by the females of the food moths of the species Plodia interpunctella (Indianmeal moth) and Ephestia kuehniella (Flour moth). The male insect is attracted by this active substance and is captured on the glue area of the trap. Z,E-TDA causes a disturbance in the sexual behaviour of the males. |
| Target organism (including development stage) | Plodia interpunctellaIndian mealmothAdults malesEphestia khueniellaFlour mothAdults males |
| Field of use | IndoorProduct intended to be used exclusively indoors, in spaces where foodstuffs (both for human and animal) are stored. |
| Application method(s) | Bait applicationThe trap is placed, at the desired place: in kitchens, living rooms and store rooms.It is a V-shaped adhesive trap, to be put on shelves and on cupboards.It must be activated by peeling of the protective film. |
| Application rate(s) and frequency | 1 trap (containing 2,0 mg of Z,E-TDA) in 30 m3 room volume - no dilutionEvery three months or when the surface of the trap is saturated with insects. |
| Category(ies) of user(s) | General public (non-professional) |
| Pack sizes and packaging material | The traps are packed in a flowpack composed of 3 layers: Polyethylene Terephtalate/ Aluminium/ Polyethylene (PET/Aluminium/PE). |

###

### Physical, chemical and technical properties

The composition of the product STOP MITES A is presented in the separated confidential annex.

A long-term stability study of the product STOP MITES A is on-going. The study described below was carried out on a similar product: Food-Moth trap-GEA P-04086D (old composition of the product Food-Moth trap-GEA P-04031D which is reported in the confidential annex). This difference is not expected to have an impact on stability data.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state, colour and odour at 20 °C and 101.3 kPa | No guideline followed | - | 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 light yellow transparent, with a sui generis odour. | Acceptable | IUCLID |
| Acidity / alkalinity | - | - |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Relative density / bulk density | - | - |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 | Nexa Lotte Food Moth Trap Big Version 3648 (Internal Reference of STOP MITES A)Batch: 18215041 |  | Acceptable The product is stable after 8 weeks at 40°C.The product should not be stored above 40°C. | Matteo Brioschi (2018), report number CH-802/2018 |
| Storage stability test – **long term storage at ambient temperature** | - | - | A long-term stability study of the product STOP MITES A is on-going. | The data on stability of the product Food-Moth trap-GEA P-04086D indicates that the product STOP MITES A should be expected to be stable 3 years at ambient temperature. Indeed, the product Food-Moth trap-GEA P-04086D is considered as the worst case as its ZE-TDA content is 0.2138 %. | IUCLID |
| GIFAP Monograph N°17Analytical method validated | Food-Moth trap-GEA P-04086D(old composition of Food-Moth trap-GEA P-04031D)1.69mg of ZE-TDAPackaging: 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 did not 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** |
| **T0** | AS: 1.69 mgpH=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 |

 | Variation of active substance content less than 10% during 36 months→ acceptableThe product Food-Moth trap-GEA P-04086D is stable after 36 months. The data on stability on the old composition can be read across for the new composition (Food-Moth trap-GEA P-04031D). | Nichetti, S., (2013b) – CH-688/2012 |
| Storage stability test – **low temperature stability test for liquids** | - | - |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - |  | Not required as the secondary packaging is a cardboard |  |
| 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 |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | CIPAC MT 46.3 | Nexa Lotte Food Moth Trap Big Version 3648 (Internal Reference of STOP MITES A)Batch: 18215041 | The results of the accelerated storage stability study indicate that the product is stable under these conditions. | Acceptable | Matteo Brioschi (2018), report number CH-802/2018 |
| Wettability |  |  |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Suspensibility, spontaneity and dispersion stability |  |  |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Wet sieve analysis and dry sieve test |  |  |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Disintegration time |  |  |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Persistent foaming |  |  |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Flowability/Pourability/Dustability |  |  |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Burning rate — smoke generators |  |  |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Burning completeness — smoke generators |  |  |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Composition of smoke — smoke generators |  |  |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Spraying pattern — aerosols |  |  |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Physical compatibility | statement |  | Not applicable. The product is not intended to be used with other products or biocidal products | Acceptable | IUCLID |
| Chemical compatibility | statement |  | Not applicable. The product is not intended to be used with other products or biocidal products | Acceptable | IUCLID |
| Degree of dissolution and dilution stability |  |  |  | Not relevant as the product is ready-to-use adhesive trap |  |
| Surface tension | statement |  | The study does not need to be conducted because surface activity is not a desired property of the material | Acceptable | IUCLID |
| Viscosity | statement |  | The study does not need to be conducted because the substance is a solid  | Acceptable | IUCLID |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The product STOP MITES A 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 light yellow transparent, with a sui generis 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 STOP MITES A is expected to be stable 3 years at ambient temperature.  |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | statement | - | None of the 2 constituents of the biocidal product possesses explosive properties and the product is unlikely to exhibit explosive properties. | Acceptable | IUCLID |
| Flammable gases | - | - | - | Not relevant as the product is a solid |  |
| Flammable aerosols | - | - | - | Not relevant as the product is not an aerosol |  |
| Oxidising gases | - | - | - | Not relevant as the product is a solid |  |
| Gases under pressure | - | - | - | Not relevant as the product is not a gas under pressure |  |
| Flammable liquids | - | - | - | Not relevant as the product is a solid |  |
| Flammable solids | statement | - | None of the 2 constituents of the biocidal product is flammable and the product is unlikely to be flammable. | Acceptable | IUCLID |
| Self-reactive substances and mixtures | - | - | There are no chemical groups present in the molecule, which are associated with explosive or self-reactive properties. | Acceptable |  |
| Pyrophoric liquids | - | - | - | Not relevant as the product is a solid |  |
| Pyrophoric solids | - | - | No data provided |  |  |
| Self-heating substances and mixtures | - | - | No data provided |  |  |
| Substances and mixtures which in contact with water emit flammable gases | - | - | - |  |  |
| Oxidising liquids | - | - | - | Not relevant as the product is a solid |  |
| Oxidising solids | statement | - | None of the 2 constituents of the biocidal product possesses oxidising properties and the product is unlikely to exhibit oxidising properties. | Acceptable | IUCLID |
| Organic peroxides | - | - | Not applicable. The substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria. | Acceptable |  |
| Corrosive to metals | - | - | The product does not contain any component able to corrode metals. | Acceptable |  |
| Auto-ignition temperatures of products (liquids and gases) | - | - | - | Not relevant as the product is a solid |  |
| Relative self-ignition temperature for solids | - | - | No data provided |  |  |
| Dust explosion hazard | - | - | No data provided |  |  |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| 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. |

### Methods for detection and identification

The composition of the product (Food-Moth trap-GEA P-04031D) tested for the determination of the active ingredient content is provided in the confidential annex.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sample | Test substance | Analytical method | Fortification range/ number of measurements | Linearity | Specificity | Recovery rate (%) | Repeatability | reference |
| Mean |
| Food-Moth trap-GEA P-04086D(old composition of Food-Moth trap-GEA P-04031D) | ZE-TDA | GC-FID | 3 levels: 75, 100 and 125% of the nominal concentration2 measurements at each level | 5 concentrations between 35.22 and 82.18 µg/mLR2>0.99 | No interference has been observed at the retention time of ZE-TDA | 99.6% at 75%97.5 at 100% and 98.2% at 125% | 6 determinations RSD=0.53% | Nichetti, S., (2013b) – CH-686/2012 |

Specificity and accuracy of the method have been provided on the new composition of the product Food-Moth trap-GEA P-04031D in the study below.

Report: Brioschi M. 2019, ANTI-MITES ALIMENTAIRES-GEA\_P-04031 D (Food Moth Trap-GEA\_P-04031D): Integration to the Validation of the analytical method for the determination of the active ingredient content

Report no CH-053/2019

Test facilities: ChemService S.r.l. Controlli e Ricerche GLP Studies Department Via F. lli Beltrami, 15 20026 Novate Milanese – MI - Italy

Validation data:

|  |  |
| --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed and chromatograms have been provided:* Solvent blank (hexane)
* Z9,E12-TDA test substance
* Internal standard (propyl benzoate)
* Test item solution (= formulation blank)

There is no interference at the retention time of the active substance, therefore the specificity is demonstrated. |
| Accuracy | Accuracy was determined by analysis of 6 fortified samples at 3 fortification levels. The accuracy results are expressed as the recovery rate.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n |
| 75% | 107.4-104.9 | 106.1 | - | 2 |
| 100% | 108.7-108.2 | 108.4 | - | 2 |
| 125% | 104.4-107.6 | 106.0 | - | 2 |

 |

The analytical method is fully validated for the determination of the active substance ZE-TDA in the product Food-Moth trap-GEA P-04031D.

The read across is acceptable as the differences between the two products in the composition is not expected to have an impact on the analytical method.

It is concluded that the provided method is validated and acceptable for the product STOP MITES A.

Analytical method for the determination of ZE-TDA residues is not required in the framework of a simplified authorization.

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The analytical method is validated for the determination of the active substance ZE-TDA in the product.Analytical method for the determination of ZE-TDA residues is not required. |

### Efficacy against target organisms

#### **Function and field of use**

Main Group 03: Pest Control

Product Type 19: Repellents and attractants

STOP MITES A is a ready to use trap consisting of a cardboard carrying the pheromone Z,E-9,12-Tetradecadien-1-yl acetate (ZE-TDA) and is covered with a layer of adhesive glue. The trap is activated by peeling the protective adhesive.

#### **Organisms to be controlled and products, organisms or objects to be protected**

According to the uses claimed applicant, the product STOP MITES A is a ready to use product intended to be used to control food moths. The target organisms to be controlled are male adults of the Indian meal-moth (*Plodia interpunctella*) and the Mediterranean flour moth (*Ephestia kuehniella)*. The products intended to be protected are dried food and feedstuffs, e.g. nuts, muesli, cookies, chocolate, flour, rice, dried fruits, fodder, etc. that is stored in closed or re-closed package.

Application rate: 1 trap (containing 2,0 mg of Z,E-TDA) in 30 m3 volume room.

#### **Effects on target organisms, including unacceptable suffering**

Male adults of *Plodia interpunctella* and *Ephestia kuehniella* are attracted and confused by the pheromone. Some will be trapped on the glue. Trapped moths will die. Confused and trapped male moths are prevented from finding the females. Mating is disrupted, reproduction is inhibited and infestation of feedstuff is reduced.

#### **Mode of action, including time delay**

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.

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

#### **Efficacy data**

|  |
| --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| PT19 | Protection of stored products | NEXA LOTTE FOOD MOTH TRAP BIG VERSION 3648Fresh and Opened product (3 months after opening).ready-to-use adhesive trap.(This name of the product is the internal reference of STOP MITES A) | *- Ephestia kuehniella* (the Mediterranean flour moth)*- Plodia interpunctella* (the Indian meal-moth)(Adults 1 to 3 days old food moths). | Simulated use test (CEB 135 bis) | Test chamber of 30 m³1 sample/ test chamber for each replicate30 adults (15 males + 15 females) are used per replicate and 4 replicates are conducted.The trial is conducted on a total number of 30 x 4 = 120 insects.The climatic conditions were maintained at 24 °C + 2°C; 65 % RH + 5% RH,light 1500 lux, without ventilationPresence of food competitionOne glue trap containing the pheromone is placed on a shelf at a 1 m height on one wall of the test chamber. | Synthesis of the **TT 100 (Trapping time 100% = time to have 100% insects trapped**):Fresh product :*Plodia interpunctella* : **Males 10min** & Females N/A*Ephestia kuehniella* : **Males 10min** & Females N/AOpened product (+3mois):*Plodia interpunctella* : **Males 15min** & Females N/A*Ephestia kuehniella*: **Males 30min** & Females N/AN/A: unavailable results because females were not trappedLow mortalities observed for untreated batches (< 5%) The efficacy is assessed by the counts of moths trapped within a time frame of one hour. | Serrano B., 2018 Report 2375c/0818RRI 1 |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| In conclusion, in accordance with the requirement of the efficacy guidance part B/C, French competent authorities (FR CA) consider that the elements presented in the dossier are sufficient to demonstrate the efficacy of the fresh and opened (3 months) product STOP MITES A against Indian-meal moth (*Plodia interpunctella*) and Flour moth (*Ephestia kuehniella*) at the rate of one trap in 30 m³. |

#### Occurrence of resistance and resistance management

As indicated in the CAR of ZE-TDA, the effect of this pheromone is very specific and limited to a defined group of species. Female *P. interpunctella* attract males via a pheromone blend, which contains the active substance. The heritability of the blend composition is comparatively low and leaves a potential for the evolution of resistance against mating disruption (Svensson 2002). In another moth species, Tabata et al. (2007) reported a case of resistance to pheromone based control strategies after 10 years of permanent treatment with a single compound out of a more complex pheromone blend. The efficacy of mating disruption was re-established by use of the full pheromone blend instead of the previously used single compound. Factors increasing the potential for resistance in *P. interpunctella* may be (a) an isolated population under permanent treatment, and (b) the use of only one component of the natural pheromone blend in control strategies.

Although so far resistance against pheromone based control strategies has not been observed in *P. interpunctella* it is a relevant issue and needs to be addressed on a longer term basis. This includes a check of the scientific literature to re-evaluate potential risks every ten years, and additionally an assessment of the most important areas of application (households, industrial, storage facilities with enclosed populations) to identify potential sources of resistance as well as a survey among the professional users of the biocidal product focused on efficacy.

#### Known limitations

There is no known limitation.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product STOP MITES A has shown a sufficient efficacy for the control of Indian-meal moth (Plodia interpunctella) and flour moth (Ephestia kuehniella) until 3 months after opening.

To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the recommendations proposed in the SPC have to be implemented.

#### Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Not relevant as the product is not intended to be authorised or use with other biocidal product(s).

### Considerations for human health

The product STOP MITES A has been considered in relation to the simplified authorisation procedure (under Reg. (EU) 528/2012, chapter V, article 25).

The active substance and the co-formulants of product are either not classified as hazardous to the health under the CLP regulation, or they are not present at sufficient concentrations to trigger hazard classification (their concentration in the product are under the generic and specific limit concentrations). FR CA therefore considers that the biocidal product STOP MITES A does not meet the classification criteria for skin corrosion and irritation, eye irritation, respiratory tract irritation, skin sensitization, respiratory sensitization (ADS), or acute toxicity.

The product is not classified for human health effects.

On this basis, the STOP MITES A product meets conditions of art. 25 from the human health perspective.

### Considerations for animal health

There are no substances of concern present and the product is not classified, therefore the

FR CA considers that there is no concern for animal health

### Considerations for the environment

The product STOP MITES A has been considered in relation to the simplified authorization procedure (under Reg. (EU) 528/2012, chapter V, article 25).

An assessment of potential SoCs (Substances of Concern) has been made. The active substance and the co-formulants are either not classified as hazardous to the environment under Reg. (EC) 1272/2008, or they are not present at sufficient concentrations to trigger hazard classification on their own. The product is thus not classified for the environment. Moreover, the product does not contain any other biocidal substances from another PT and none of the co-formulants are regulatory identified as endocrine disruptors. Therefore no SoCs are considered to be present in the STOP MITES A product.

On this basis, the product STOP MITES A can be authorized from an environmental perspective under the simplified authorization procedure (Reg. (EU) 528/2012, chapter V, article 25).

### Measures to protect man, animals and the environment

To avoid risks to man, animals and the environment, comply with the instruction for use.

### Assessment of a combination of biocidal products

STOP MITES A is not intended to be authorised for the use with other biocidal products.

### Comparative assessment

Not relevant.

# Annexes[[3]](#footnote-4)

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title.Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| Serrano B. | 2018 | LABORATORY EVALUATION OF THE EFFICACY OF A FOOD MOTH TRAP |  |  |
| Matteo Brioschi | 2018 | NEXA LOTTE FOOD MOTH TRAP BIG VERSION 3648 Determination of the Accelerated storage stability and Corrosion characteristics ChemService S.r.l. Controlli e Ricerche, Study No. CH 802/2018.GLP, Unpublished. | Y | Evergreen Garden Care France SAS |
| Nichetti, S | 2013b | ANTI-MITES ALIMENTAIRES-GEA\_P-04031 D(Food Moth Trap-GEA\_P-04031D):Integration to the Validation of the Analytical Methodfor the Determination of the Active Ingredient ContentCH-688/2012 | Y | GEA |
| Matteo Brioschi | 2019 | ANTI-MITES ALIMENTAIRES-GEA\_P-04031 D (Food Moth Trap-GEA\_P-04031D): Integration to the Validation of the analytical method for the determination of the active ingredient contentReport no CH-053/2019 | Y | GEA |
| Nichetti, S | 2013b | Report CH-686/2012 | Y | GEA |

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. Considering the « CA-Nov16-Doc.4.3 - Final - Carrier based products” document, the STOP MITES A is a “carrier” biocidal product (CASE A), and therefore the carrier component is not considered as part of the composition of the biocidal product. [↑](#footnote-ref-3)
3. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-4)