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)



Twist-Tie MD2 inPEST®

Product type 19

(Z,E)-Tetradeca-9,12-dienyl acetate active substance included in the Annex I of the Regulation (EU) No 528/2012

Case Number in R4BP: BC-EP053263-37

Evaluating Competent Authority: FR

Date: [day/month/year]

Table of Contents

[Table of Contents 3](#_Toc2155617)

[*1* CONCLUSION 5](#_Toc2155618)

[*2* ASSESSMENT REPORT 6](#_Toc2155619)

[2.1 Summary of the product assessment 6](#_Toc2155620)

[2.1.1 Administrative information 6](#_Toc2155621)

[**2.1.1.1** Identifier of the product 6](#_Toc2155622)

[**2.1.1.2** Authorisation holder 6](#_Toc2155623)

[**2.1.1.3** Manufacturer(s) of the products 6](#_Toc2155624)

[**2.1.1.4** Manufacturer(s) of the active substance(s) 6](#_Toc2155625)

[2.1.2 Product composition and formulation 7](#_Toc2155626)

[**2.1.2.1** Identity of the active substance 7](#_Toc2155627)

[**2.1.2.2** Candidate(s) for substitution 7](#_Toc2155628)

[**2.1.2.3** Qualitative and quantitative information on the composition of the biocidal product 8](#_Toc2155629)

[**2.1.2.4** Information on technical equivalence 8](#_Toc2155630)

[**2.1.2.5** Information on the substance(s) of concern 8](#_Toc2155631)

[**2.1.2.6** Assessment of endocrine disruption (ED) properties of the biocidal product 8](#_Toc2155632)

[**2.1.2.7** Type of formulation 8](#_Toc2155633)

[2.1.3 Hazard and precautionary statements 8](#_Toc2155634)

[2.1.4 Authorised use(s) 9](#_Toc2155635)

[**2.1.4.1** Use description 9](#_Toc2155636)

[**2.1.4.2** Use-specific instructions for use 9](#_Toc2155637)

[**2.1.4.3** Use-specific risk mitigation measures 9](#_Toc2155638)

[**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 9](#_Toc2155639)

[**2.1.4.5** Where specific to the use, the instructions for safe disposal of the product and its packaging 10](#_Toc2155640)

[**2.1.4.6** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 10](#_Toc2155641)

[2.1.5 General directions for use 11](#_Toc2155642)

[**2.1.5.1** Instructions for use 11](#_Toc2155643)

[**2.1.5.2** Risk mitigation measures 11](#_Toc2155644)

[**2.1.5.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 11](#_Toc2155645)

[**2.1.5.4** Instructions for safe disposal of the product and its packaging 11](#_Toc2155646)

[**2.1.5.5** Conditions of storage and shelf-life of the product under normal conditions of storage 11](#_Toc2155647)

[2.1.6 Other information 11](#_Toc2155648)

[2.1.7 Packaging of the biocidal product 11](#_Toc2155649)

[2.1.8 Documentation 12](#_Toc2155650)

[**2.1.8.1** Data submitted in relation to product application 12](#_Toc2155651)

[**2.1.8.2** Access to documentation 12](#_Toc2155652)

[2.2 Assessment of the biocidal product 13](#_Toc2155653)

[2.2.1 Intended use(s) as applied for by the applicant 13](#_Toc2155654)

[2.2.2 Physical, chemical and technical properties 13](#_Toc2155655)

[2.2.3 Physical hazards and respective characteristics 15](#_Toc2155656)

[2.2.4 Methods for detection and identification 16](#_Toc2155657)

[2.2.5 Efficacy against target organisms 18](#_Toc2155658)

[**2.2.5.1** Function and field of use 18](#_Toc2155659)

[**2.2.5.2** Organisms to be controlled and products, organisms or objects to be protected 18](#_Toc2155660)

[**2.2.5.3** Effects on target organisms, including unacceptable suffering 19](#_Toc2155661)

[**2.2.5.4** Mode of action, including time delay 19](#_Toc2155662)

[**2.2.5.5** Efficacy data 19](#_Toc2155663)

[**2.2.5.6** Occurrence of resistance and resistance management 19](#_Toc2155664)

[**2.2.5.7** Known limitations 19](#_Toc2155665)

[**2.2.5.8** Evaluation of the label claims 19](#_Toc2155666)

[**2.2.5.9** Relevant information if the product is intended to be authorised for use with other biocidal product(s) 19](#_Toc2155667)

[2.2.6 Risk assessment for human health 20](#_Toc2155668)

[**2.2.6.1** Assessment of effects on Human Health 20](#_Toc2155669)

[**2.2.6.2** Exposure assessment 30](#_Toc2155670)

[**2.2.6.3** Risk characterisation for human health 42](#_Toc2155671)

[2.2.7 Risk assessment for animal health 46](#_Toc2155672)

[2.2.8 Risk assessment for the environment 46](#_Toc2155673)

[**2.2.8.1** Effects assessment on the environment 46](#_Toc2155674)

[**2.2.8.2** Exposure assessment 59](#_Toc2155675)

[**2.2.8.3** Risk characterisation 63](#_Toc2155676)

[2.2.9 Measures to protect man, animals and the environment 68](#_Toc2155677)

[2.2.10 Assessment of a combination of biocidal products 68](#_Toc2155678)

[2.2.11 Comparative assessment 68](#_Toc2155679)

[**2.2.11.1** Screening phase 68](#_Toc2155680)

[**2.2.11.2** Tier IA 68](#_Toc2155681)

[**2.2.11.3** Tier IB 68](#_Toc2155682)

[**2.2.11.4** Tier II 69](#_Toc2155683)

[**2.2.11.5** Overall conclusion 69](#_Toc2155684)

[*3* Annexes 70](#_Toc2155685)

[3.1 List of studies for the biocidal product 70](#_Toc2155686)

[3.2 Output tables from exposure assessment tools 70](#_Toc2155687)

[3.3 New information on the active substance 70](#_Toc2155688)

[3.4 Residue behaviour 70](#_Toc2155689)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 70](#_Toc2155690)

[3.6 Confidential annex 70](#_Toc2155691)

[3.7 Other 70](#_Toc2155692)

# CONCLUSION

***Intended uses***

TWIST-TIE MD2 INPEST is a ready-to-use product intended to be used indoor by professional users as mating disruption device against food moths (product type 19).

***Conclusion of the assessment***

The active substance (Z,E)-Tetradeca-9,12-dienyl acetate contained in the biocidal product TWIST-TIE MD2 INPEST is listed in Annex I of EU Regulation 528/2012.

 The biocidal product TWIST-TIE MD2 INPEST does not contain any nanomaterials.

Efficacy studies submitted demonstrate that the product TWIST-TIE MD2 INPEST is efficient as a food moths mating disruption product (*Ephestia kuehniella* and *Plodia interpunctella)*. Industrial/commercial premises should be cleaned and treated with an insecticide before the application of the product.

No substances of concern are considered to be present in the TWIST-TIE MD2 INPEST product.

The product TWIST-TIE MD2 INPEST is not classified under Reg. (EC) 1272/2008.

The product TWIST-TIE MD2 INPEST should not be used in spaces where un-packaged food or feed is kept.

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

Following evaluation, the biocidal product TWIST-TIE MD2 INPEST does meet the conditions required for simplified authorisation as defined in Article 25 of 528/2012.

**Therefore, the biocidal product shall be authorized for the following use :**

|  |  |  |
| --- | --- | --- |
| **Target organisms** | **Application rate** | **Use conditions** |
| Food moths*Plodia interpunctella**Ephestia kuehniella*Adult males | 1 m of product for 300 m3 volume room | IndoorProfessionals users  |

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| TWIST-TIE MD2 INPEST |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | GEA s.r.l.  |
| **Address** | Via Albert Bruce Sabin, 3120019 Settimo Milanese (MI)Italy |
| **Authorisation number** | **FR-2020-0028** |
| **Date of the authorisation** | **22/07/2020** |
| **Expiry date of the authorisation** | **21/07/2030** |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | GEA s.r.l.  |
| **Address of manufacturer** | Via Albert Bruce Sabin, 3120019 Settimo Milanese (MI)Italy |
| **Location of manufacturing sites** | Via Albert Bruce Sabin, 3120019 Settimo Milanese (MI)Italy |

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

|  |  |
| --- | --- |
| **Active substance** | (9Z,12E)-Tetradeca-9,12-dien-1-yl acetate |
| **Name of manufacturer** | GEA s.r.l.  |
| **Address of manufacturer** | Via Albert Bruce Sabin, 3120019 Settimo Milanese (MI)Italy |
| **Location of manufacturing sites** | Via Enrico Fermi, 10 20019 Settimo Milanese (MI)-ITALY |

|  |  |
| --- | --- |
| **Active substance** | (9Z,12E)-Tetradeca-9,12-dien-1-yl acetate |
| **Name of manufacturer** | GEA s.r.l.  |
| **Address of manufacturer** | Via Albert Bruce Sabin, 3120019 Settimo Milanese (MI)Italy |
| **Location of manufacturing sites** | 21 Finance Drive, Danbury, Connecticut 06810, USA |

### Product composition and formulation

#### Identity of the active substance

|  |
| --- |
| **Main constituent(s)** |
| **ISO name** | (Z,E)-Tetradeca-9,12-dienyl acetate (ZE-TDA) |
| **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** | None |
| **Minimum purity / content** | 979 g/kg |
| **Structural formula** | *TDDA* |

#### Candidate(s) for substitution

(Z,E)-Tetradeca-9,12-dienyl acetate does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

#### Qualitative and quantitative information on the composition of the biocidal product[[2]](#footnote-3)

####

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | **In biocidal mixturewithout carrier** | **In end-product with carrier** |
| (Z,E)-Tetradeca-9,12-dienyl acetate*[Z,E-TDA]* | (9Z,12E)-Tetradeca-9,12-dien-1-yl acetate | Active substance | 30507-70-1 | 250-753-6 | 99.50 (97.41 pure\*) | 1,20 (1,17 pure\*) |

\* based on the minimum purity of 979 g/kg

#### Information on technical equivalence

Both sources described in section 2.1.1.4 were assessed and considered technically equivalent with the active substance listed in the Union list of approved active substance under Regulation (EU) No 528/2012.

Source 1 (GEA srl): Before the entry in force of the Regulation (EU) No 528/2012, a technical equivalence of the source 1 was submitted in January 2013 to French Competent Authorities together with a compensation dossier to the active substance (Annex II). The compensation dossier has been considered valid and the source has been considered equivalent to the reference source. Whereupon GEA srl legal entity has been included in the list of Article 95 for ZE-TDA as product supplier.

Source 2 (GEA srl): Technical equivalence obtained: Decision no. TAP-D-1298727-12-00/F dated of 4th April 2018 by ECHA.

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

The biocidal product 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

According to our assessment, none of the co-formulants contained in the Twist-Tie MD2 inPEST® product are regulatory identified as endocrine disruptors.

Please see the confidential annex for further details.

#### Type of formulation

|  |
| --- |
| VP - Vapour releasing product |

### Hazard and precautionary statements[[3]](#footnote-4)

**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 | P273- Avoid release to the environment |
|  |
| Note | EUH 208: Contains Vitamin E. May produce an allergic reaction.  |

### 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. 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** | Indoor useAt industrial/commercial premises |
| **Application method(s)** | V1.9: Open system: diffusion |
| **Application rate(s) and frequency** | 1 m of product for 300 m3 volume roomAction delay: 1 monthApplication frequency: every 3 months |
| **Category(ies) of users** | Trained professionalProfessional |
| **Pack sizes and packaging material** | Flow-pack size: 218 x 160 mmMaterial: PET/Alu/PELength: 10 m |

#### Use-specific instructions for use

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

#### 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

|  |
| --- |
| * Subdivide the product in more pieces of different size by a pair of scissors
* The product can be directly installed on machinery or on present brackets like electrical ducts, uprights, shelves, etc. by knotting or using cable ties without bothering work activities.
* Preferable height of installation: 1.8-2 m.
* Always read the label or leaflet before use and respect all the instructions provided.
* Inform the registration holder if the treatment is ineffective.
* Industrial/commercial premises should be cleaned and treated with an insecticide before the application of the product.
* Respect the conditions of use of the product.
* The product should be replaced every 3 months
* Biocidal effect is observed one month after application of the product.
* Monitoring traps are recommended before, during and after treatment to assess adult moth populations as part of a pest management program.
 |

#### 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

|  |
| --- |
| * Skin contact: Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.
* Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
* Mouth contact: Wash out mouth with water. Contact poison treatment specialist.
* Keep the container or label available.
 |

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

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains
* Dispose of unused product, its packaging and all other waste (X), in accordance with local regulations.
 |

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

|  |
| --- |
| * Store at 4°C.
* Shelf-life: 1 year
 |

### 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)** |
| Bags | Dimensions: 218 x 160 mm | PET/Alu/PE | Heat sealing | Professional,Trained professional | Yes |

### Documentation

#### Data submitted in relation to product application

Physicochemical properties studies, analytical methods on the biocidal product Twist-Tie MD inPEST and efficacy studies were provided by GEA srl.

Data submitted on the biocidal product are listed in the point 3.1 of Annex.

#### Access to documentation

The applicant GEA srl is the owner of a compensation dossier submitted for the approved active substance. No new data on the active substance are submitted.

## Assessment of the biocidal product

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

Table 1. Use # 1 – Mating disruption technique on food moths

|  |  |
| --- | --- |
| **Product Type** | PT19 |
| **Where relevant, an exact description of the authorised use** | Product intended to be used exclusively indoors, in spaces where foodstuffs (both for human and animal) are produced and stored. The twist-tie for mating disruption is a product to be used by professional and trained professional users in food industries, storehouses, supermarkets, mills, feed factories and all those places where foodstuffs for example: wheat, cereals, biscuits, bread, pasta, chocolate, cocoa, candy, dried fruit, nuts etc., are stocked. The pheromone concentration of the twist-tie is 50 times higher than the one used for monitoring food moths, so it saturates the receptor feelers of Plodia interpunctella and Ephestia kuehniella males, making them impossible to find the females. This disorientation avoids mating and, consequently, the infestation proliferation. |
| **Target organism (including development stage)** | *Plodia interpunctella*, food moths, Adults*Ephestia kuehniella*, food moths, Adults |
| **Field of use** | Indoor useAt Industrial/commercial premises, with no potential for contamination outdoors and no potential for contamination of food. |
| **Application method(s)** | V1.9: Open system: diffusion1. Open the aluminium bag.2. Subdivide the product in more pieces of different size by a pair of scissors in order to obtain a homogeneous pheromone distribution.The product can be directly installed on machinery or on present brackets like electrical ducts, uprights, shelves, etc. by knotting or using cable ties without bothering work activities.Preferable height of installation: 1.8 - 2 m. The installation height is widely variable in relation to the characteristics of the building and of the outbreaks of infestation.A network of monitoring traps is recommended before, during and after the mating disruption technique is active, to assess adult moth population. |
| **Application rate(s) and frequency** | 1 m for 300 m3 Period of time needed for biocidal effect: 1 monthResiduality effect until: 3 months. |
| **Category(ies) of users** | Trained professionalProfessional |
| **Pack sizes and packaging material** | Flow-pack size: 218 x 160 mmMaterial: PET/Alu/PELength: 10 m |

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | EPA OPPTS 830.6302 | Active substance concentration 1.2 % w/w, in the end-user BP | Solid | Acceptable | Nichetti S., 2019, CH-852/2018 |
| Colour at 20 °C and 101.3 kPa | EPA OPPTS 830.6303 | Active substance concentration 1.2 % w/w, in the end-user BP | Dark blue (shortcode BL 4) | Acceptable | Nichetti S., 2019, CH-852/2018 |
| Visual observation | Active substance concentration 1.2 % w/w, in the end-user BP | Grey | Nichetti S., 2019, CH-411/2019 |
| Odour at 20 °C and 101.3 kPa | EPA OPPTS 830.6304 | Active substance concentration 1.2 % w/w, in the end-user BP | Characteristic odour | Acceptable | Nichetti S., 2019, CH-852/2018 |
| Acidity / alkalinity | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid and it is not soluble in water. | Not relevant as it is a ready-to-use solid product | - |
| Relative density / bulk density | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is a solid twist-tie string. Thus it is not physically possible. | Not relevant as it is a ready-to-use solid product | - |
| Storage stability test – **accelerated storage** | Justification for non-submission of data | - | The study does not need to be conducted because the formulation should be stored at 4°C. | Acceptable  | - |
| Storage stability test – **long term storage at ambient temperature** | EPA OPPTS 830.6313 | Active substance concentration 1.2 % w/w, in the end-user BP | Data after one year at 4°C do not show any significant difference in terms of aspect and active ingredient content.

|  |  |  |
| --- | --- | --- |
| test | initially | After 6 months |
| packaging | Flow pack (PET –ALU – PE) labelled A |
| ZE-TDA content | 1.09 % w/w | 1.08 % w/w (-0,9%) |
| appearance | Dark blue twist-tie, with characteristic odour | Dark blue twist-tie, with characteristic odour |
| Compatibility of the packaging | / | The container did not present any deformation or loss of sample or evident corrosion phenomena |
| Weight variation | A: -0,03% |
| test | After 1 year |
| packaging | Flow pack (PET –ALU – PE) labelled B, C and D |
| ZE-TDA content | 1.09 % w/w  |
| appearance | Dark blue twist-tie, with characteristic odour |
| Compatibility of the packaging | The container did not present any deformation or loss of sample or evident corrosion phenomena |
| Weight variation | B: -0,01%C: -0.01%C: 0.03% |

 | AcceptableThe product is stable after 1 year at 4 °C. The product should be stored at 4°C.  | Nichetti S., 2019, CH-852/2018 |
| Storage stability test – **low temperature stability test for liquids** | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid. | Not relevant as it is a ready-to-use solid product | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Justification for non-submission of data | - | The formulation is contained in an opaque packaging and no exposure with light is expected, thus the test is not performed.  | 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** | CIPAC MT 46.3 | Active substance concentration 1.2 % w/w, in the end-user BP | No effects on temperature and humidity were observed after storage for one year at 4°C | Acceptable | Nichetti S., 2019, CH-852/2018 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | CIPAC MT 46.3 | Active substance concentration 1.2 % w/w, in the end-user BP | No effects on container material was observed after storage for one year at 4°C | Acceptable | Nichetti S., 2019, CH-852/2018 |
| Wettability | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is not diluted in water | Not relevant as the product is a ready-to-use pheromone dispenser string | - |
| Suspensibility, spontaneity and dispersion stability | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is not diluted in water | Not relevant as the product is a ready-to-use pheromone dispenser string | - |
| Wet sieve analysis and dry sieve test | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is not diluted in water | Not relevant as the product is a ready-to-use pheromone dispenser string | - |
| Emulsifiability, re-emulsifiability and emulsion stability | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid. | Not relevant as the product is a ready-to-use pheromone dispenser string | - |
| Disintegration time | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is not a table | Not relevant as the product is a ready-to-use pheromone dispenser string | - |
| Particle size distribution, content of dust/fines, attrition, friability | Justification for non-submission of data | - | The study does not need to be conducted because of the formulation type | Not relevant as the product is a ready-to-use pheromone dispenser string | - |
| Persistent foaming | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is not diluted in water | Not relevant as the product is a ready-to-use pheromone dispenser string | - |
| Flowability/Pourability/Dustability | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid | Not relevant as the product is a ready-to-use pheromone dispenser string | - |
| Burning rate — smoke generators | Justification for non-submission of data | - | The product is not a smoke generator | Not relevant as the product is a ready-to-use pheromone dispenser string | - |
| Burning completeness — smoke generators | Justification for non-submission of data | - | The product is not a smoke generator | Not relevant as the product is a ready-to-use pheromone dispenser string | - |
| Composition of smoke — smoke generators | Justification for non-submission of data | - | The product is not a smoke generator | Not relevant as the product is a ready-to-use pheromone dispenser string | - |
| Spraying pattern — aerosols | Justification for non-submission of data | - | The product is not an aerosol  | Not relevant as the product is a ready-to-use pheromone dispenser string | - |
| Physical compatibility | Justification for non-submission of data | Statement  | The product is not intended to be used with any other products  | Acceptable | IUCLID |
| Chemical compatibility | Justification for non-submission of data | Statement | The product is not intended to be used with any other products | Acceptable | IUCLID |
| Degree of dissolution and dilution stability | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is not diluted in water | Acceptable | - |
| Surface tension | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid | Acceptable | - |
| Viscosity | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid | Acceptable | - |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The biocidal product is a carrier-based product containing 1.2% w/w of ZE-TDA. It it a dark blue or grey ready-to-use twist-tie (string) with characteristic odour. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. As the active ingredient is volatile, effect at high temperature on the stability of the formulation has not been performed. The stability data indicates a shelf life of at least 1 year at 4°C when stored in a flow pack made from PET –ALU – PE. The product should be stored at 4°C.  |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Justification for non-submission of data | - | The study does not need to be conducted because there are no chemicals groups present in the molecule, which are associated with explosive or self-reactive properties, and hence, the classification procedure does not need to be applied. | Acceptable | IUCLID |
| Flammable gases | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid | Not relevant as the product is a solid | - |
| Flammable aerosols | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is not an aerosol | Not relevant as the product is not an aerosol | - |
| Oxidising gases | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid | Not relevant as the product is a solid | - |
| Gases under pressure | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid | Not relevant as the product is not a gas under pressure | - |
| Flammable liquids | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid | Not relevant as the product is a solid | - |
| Flammable solids | Justification for non-submission of data | - | The study does not need to be conducted because there are no flammable substances present in the composition.Hence, the classification procedure does not need to be applied. | Acceptable  | IUCLID |
| Self-reactive substances and mixtures | Justification for non-submission of data | - | The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied. | Acceptable  | IUCLID |
| Pyrophoric liquids | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid | Not relevant as the product is a solid | - |
| Pyrophoric solids | Justification for non-submission of data | - | The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied. | Acceptable  | IUCLID |
| Self-heating substances and mixtures | Justification for non-submission of data | - | The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied. | Acceptable  | IUCLID |
| Substances and mixtures which in contact with water emit flammable gases | Justification for non-submission of data | - | The study does not need to be conducted because none of the components is expected to emit flammable gases when it is in contact with water. | Acceptable  | IUCLID |
| Oxidising liquids | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid | Not relevant as the product is a solid | - |
| Oxidising solids | Justification for non-submission of data | - | The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied. | Acceptable | IUCLID |
| Organic peroxides | Justification for non-submission of data | - | The study does not need to be conducted because none of the components falls under the definition of organic peroxides according to GHS and the relevant UN Manual tests and criteria. | Acceptable | IUCLID |
| Corrosive to metals | Justification for non-submission of data | - | The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with corrosive properties and hence, the classification procedure does not need to be applied. | Acceptable | IUCLID |
| Auto-ignition temperatures of products (liquids and gases) | Justification for non-submission of data | - | The study does not need to be conducted because the formulation is solid | Not relevant as the product is a solid | - |
| Relative self-ignition temperature for solids | Justification for non-submission of data | - | The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied. | Acceptable | IUCLID |
| Dust explosion hazard | Justification for non-submission of data | - | The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied. | Acceptable | IUCLID |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product does not present explosive and oxidising properties. No flammability phenomena is expected. Thus, the preparation is not classified as Flammable.The product is therefore not classified for any physical hazards. |

### Methods for detection and identification

|  |
| --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *ZE-TDA (active substance)* | GC-FID | 75% of nominal content (0.9% w/w) / 2 | 29.61 – 69.09 µg/mL r2 > 0.99n=5 | Yes\*\* | 101.28, 101.09 | 101.2 | 0.95\* (n= 6) | Not applicable | Brioschi M., 2018, CH-411/2018 |
| 100% of nominal content (1.2 % w/w) / 2 | 100.88, 100.52 | 100.7 |
| 125% of nominal content (1.5% w/w) / 2 | 101.85, 101.99 | 101.9 |

\* Based on repeatability test

\*\* A comparison of the chromatograms of the solvent wash, ZE-TDA test substance, propyl benzoate internal standard, placebo and test item solutions shows that the ZE-TDA peak was well separated and there were no interferences with the placebo.

The analytical method is fully validated for the determination of the active substance ZE-TDA in the product TWIST-TIE MD2 inPEST®.

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 identificationof the product** |
| The analytical method is validated for the determination of the active substance ZE-TDA in the product.Analytical methods for the determination of ZE-TDA residues is not required in the frame of a simplified national authorisation. |

### Efficacy against target organisms

#### Function and field of use

Main Group 03: Pest Control

Product Type 19: Repellents and attractants

The product TWIST-TIE MD2 INPEST is a ready-to-use twist-tie (blue silicone ferrite rod of circular-cross section (Ø: 3 mm), impregnated with the pheromone), intended to be used as an attractant (product type 19) against food moths (*Plodia* *interpunctella* and *Ephestia kuehniella*), in food industries, storehouses, supermarkets, mills, feed factories and all those places where foodstuffs (for example: wheat, cereals, biscuits, bread, pasta, chocolate, cocoa, candy, dried fruit, nuts etc.,) are stocked.

The product is subdivided in more pieces of different size by a pair of scissors and can be directly installed on machinery or on present brackets like electrical ducts, uprights, shelves, etc. by knotting or using cable ties without bothering work activities.

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

According to the uses claimed applicant, the product TWIST-TIE MD2 INPEST 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 m for 300 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. 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 (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.

Delay of action: 1 month

#### Efficacy data

The applicant submitted both laboratory study (*Plodia interpunctella*) and field studies (*Plodia interpunctella* and *Ephestia kuehniella*).

In the field, the efficacy of the product has been evaluated in terms of:

* **mating inhibition level (I%):** i.e. the comparison between the number of captures in the untreated areas in comparison to the number of captures in the treated areas along the study period;
* **reduction of the food moth population**: i.e. comparison between the food moth populations before the start of the treatment and the food moth population after the product application.

Results are summarized in the table below.

|  |
| --- |
| **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 | Twist-Tie MD2 inPEST® | *Plodia interpunctella* (Indian meal-moth)adults | Laboratory test  | Two test chambers of 36.29 m³(1 treated chamber and 1 untreated control chamber) Artificial infestation with 30 adults (15 males + 15 females) are used.The climatic conditions were maintained at 25 °C + 2°C; 42 % RH + 5% RH, The application with Twist-Tie MD2 inPEST® was carried out on a period of 10 days, using 1 m of product for 300 m3 volume. One Biotest, filled with specific substrate, was used to monitor pest oviposition in each chamber | Based on the count of new-born larvae into the biotests of each chamber, an inhibition of 91.7% in the mating activity has been achieved in the treated chamber. | Rovetto I., 2020, report no. 2024.BCD.SAG19R.I =1 |
| PT19 | Protection of stored products | Twist-Tie MD2 inPEST® | *- Ephestia kuehniella* (Mediterranean flour moth)*- Plodia interpunctella* (Indian meal-moth)adults |  Field test (food factories - 3 sites) | Twist-Tie MD2 inPEST® was placed along/underneath machinery and storage shelters, close to the floor or at a maximum height of 1.8-2.0 m, where flour or other raw or packaged materials were present. The device was fixed to machinery and shelters by a knot or using plastic strips, positioning portions of device with different lengths (from 0.4 m to 5 m) in order to uniformly cover the area to be protected.In each trial location, two applications of Twist-Tie MD2 inPEST® were performed, with 3 months interval. At the second application, the device placed at the first application was removed and replaced with new Twist-Tie MD2 inPEST®. In order to monitor the presence of the 2 species and the effects of the mating disruption technique on the pest populations, in each trial site glue traps with normal pheromone concentration, glue traps with higher pheromone concentration, water traps and biotests were controlled once a week during the whole trial period.Dose application : 1m for 300m3Cleaning operations and an insecticide treatment with thermal fogger system were carried out before applications of Twist-Tie MD2 inPEST® | The monitoring with glue traps (normal and higher concentration) showed a clear and quick reduction of the pest presence in the treated areas since the first weeks after the mating disruption devices first application, followed by a significant reduction of the adult emergence of the next generation.On the other hand, in the control areas it was detected a progressive increase of the pest presence, reaching a peak of captures in June for *Plodia interpunctella* and in July for *Ephestia kuehniella.*Average moth mating inhibition (I%) on 3 sites

|  |  |  |
| --- | --- | --- |
| Sites | 1st Application | 2nd Application |
|  | E.kuehniella | P.interpunctella | E.kuehniella | P.interpunctella |
| **Molino Ardani Area 1** | 85% | 93% | 89% | 95% |
| **Molino Ardani Area 2** | 58% | 39% | 33% | 16% \* |
| **Mangimificio Mucedola s.r.l** | 94% | 96% | 93% | 0% \* |

*\*decrease of food moth population caused by Automn temperatures)***Trial 2015.BCD.SAG18 – Novaterra Zeelandia S.p.A.**In the treated area it was observed a clear reduction of the pest presence since the first weeks after the mating disruption devices placement on June 25th and the same was observed after product replacement performed on September 25th.In this site, it was not possible to calculate the moth mating inhibition (I%), because of the chosen untreated area (a small laboratory) in which only few captures were detected.For all sites, an additional statistical analysis (Bootstrap resampling technique) has been conducted comparing the food moth population of the period of treatment to the food moth populations of the previous years (2015-2017), detecting a significant reduction  | Rovetto I., 2019, report no. 2012-2015.BCD.SAG18Rovetto I., 2020, Amendment 1 to the final report no. 2012-2015.BCD.SAG18R.I = 2 |
| PT19 | Protection of stored products | Twist-Tie MD2 inPEST® | *Ephestia kuehniella* (Mediterranean flour moth)adults | Field test (pasta factory) | Monitoring of the infestation with glue traps of the field is available for a 1-year period, before the start of the treatment.The product was placed along/underneath machinery and storage shelters, according to the instruction of use, applying 1 m of product for 300 m3 volume.Six applications were performed, with 3 months interval (i.e. 18 months trial) starting from July 2017 until October 2018.No treated area was considered because there was no area with the same structural characteristics of the treated area.Glue traps with normal concentration of pheromone were used to monitor the presence of the test organisms and the effects of the mating disruption technique on the test organisms populations. There were controlled monthly during the whole trial period.Volume treated: 10850 m3Cleaning operations and insecticide treatment with dryfog system (using Pyrethrum-based products) were performed before the first positioning of Twist-Tie MD2 inPEST. | The six applications of the product have proved an optimal efficacy for the control of the target pest *Ephestia kuehniella,* in terms of control of the food moth population during the treatment period in comparison with the previous year, with a reduction of 91% of the population after cleaning and insecticide treatment.  | Caimi, M.Piombo C., 2019 report no. Lab. Ent. Test 5\_2020RI=2 |
| PT19 | Protection of stored products | Twist-Tie MD2 inPEST® | *Plodia interpunctella* (Indian meal-moth)adults | Field testfood industry (cereals and legumes) | Monitoring of the infestation with glue traps of the field is available for a 1-year period, before the start of the treatment.The product was placed along/underneath machinery and storage shelters, according to the instruction of use, applying 1 m of product for 300 m3 volume.Three applications were performed, with 3 months interval (i.e. 7 months trial) starting from May 2019 until November 2019.No treated area was considered because there was no area with the same structural characteristics of the treated area.Glue traps with normal concentration of pheromone were used to monitor the presence of the test organisms and the effects of the mating disruption technique on the test organisms populations. There were controlled monthly during the whole trial period.Volume treated: 33620 m3Cleaning operations and insecticide treatment with dryfog system (using Pyrethrum-based products) were performed before the first positioning of Twist-Tie MD2 inPEST. | The three applications of the product have been effective for the control of the target pest *Plodia inteprunctella,* in terms of control of the food moth population during the treatment period in comparison with the previous year, with a reduction of 90% of the population after cleaning and insecticide treatment.  | Caimi, M.Piombo C., 2019 report no. Lab. Ent. Test 6\_2020RI=2 |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| The mating disruption device TWIST-TIE MD2 INPEST has demonstrated to maintain a low level of infestation after cleaning and insecticide treatment with a reduction in the target organisms infestation and the mating (up to more than 90%). 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 product TWIST-TIE MD2 INPEST against Indian-meal moth (*Plodia interpunctella*) and Flour moth (*Ephestia kuehniella*) at the rate of one meter in 300 m³. Industrial/commercial premises should be cleaned and treated with an insecticide before the application of the product. |

#### 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

The product should be used in conjunction with monitoring traps and should be used continuously in the time to attain its highest level of efficacy, as for all the products used for mating disruption technique.

The product must be applied after cleaning and insecticide application to ensure sufficient effectiveness.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product TWIST-TIE MD2 INPEST has shown a sufficient efficacy for the control of Indian-meal moth (Plodia interpunctella) and flour moth (Ephestia kuehniella) population.

The application rates validated are the following:

1 m for 300 m3 volume room

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)

The biocidal product is not intended to be use with any other biocidal products.

### Human health

According to the document CA-Nov16-Doc.4.3, the carrier is a type A carrier. Therefore, it has not been considered as a part of the composition of the biocidal product.

The biocidal product TWIST-TIE MD2 INPEST does not meet the classification criteria for skin corrosion and irritation, eye irritation, respiratory tract irritation, skin sensitization, respiratory sensitization and acute toxicity.

Therefore, the biocidal product is not classified for human health effects.

No substance of concern has been identified.

The product TWIST-TIE MD2 INPEST should not be used in spaces where un-packaged food or feed is kept.

### 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.

### 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 are considered to be present in the TWIST-TIE MD2 INPEST product.

Exposure to all environmental compartments is considered to be insignificant.

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

See SPC.

### Assessment of a combination of biocidal products

TWIST TIE MD2 INPEST is not intended to be used with other biocidal products.

# Annexes[[4]](#footnote-5)

## 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)** |
| Nichetti S. | 2019 | Twist-Tie MD2: One Year Storage Stability (at 4°C) and Corrosion Characteristics Report no. CH-852/2018 (interim report)ChemServcie Srl - Controlli e Ricerche | yes | GEA srl |
| Brioschi M. | 2018 | Twist-Tie MD2 : Validation of the analytical method for the determiantion of the active ingredient contentReport no. CH-411/2018ChemServcie Srl - Controlli e Ricerche | yes | GEA srl |
| Rovetto I.,  | 2020 | Laboratory trial to determine the efficacy of Twist-Tie MD2 inPEST® mating disruption technique against food moth (*Plodia interpunctella*)report no. 2024.BCD.SAG19 | yes | GEA srl |
| Rovetto I., Rovetto I.,  | 20192020 | Evaluation of the efficacy of Twist-Tie MD2 inPEST® mating disruption technique against Plodia interpunctella and Ephestia kuehniella in food factories in Italyreport no. 2012-2015.BCD.SAG18Amendment 1 to the final report no. 2012-2015.BCD.SAG18 | yes | GEA srl |
| Caimi, M.Piombo C.,  | 2019 | EVALUATION OF THE EFFICACY OF TWIST-TIE MD2 INPEST® MATING DISRUPTION TECHNIQUE AGAINST PLODIA INTERPUNCTELLA IN A FOOD INDUSTRY IN ITALY report no. Lab. Ent. Test 5\_2020 | yes | GEA srl |
| Caimi, M.Piombo C.,  | 2019 | EVALUATION OF THE EFFICACY OF TWIST-TIE MD2 INPEST® MATING DISRUPTION TECHNIQUE AGAINST EPHESTIA KUEHNIELLA IN A PASTA FACTORY IN ITALY report no. Lab. Ent. Test 6\_2020 | yes | GEA srl |
|  |  |  |  |  |
|  |  |  |  |  |

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. Please delete as appropriate. [↑](#footnote-ref-3)
3. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-4)
4. 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-5)