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 PROVISIONAL NATIONAL AUTHORISATION APPLICATION**

(submitted by the evaluating Competent Authority)



PINE T PRO BALL

Product type 19

(Z)-13-hexadecen-11-yn-1-yl acetate

Case Number in R4BP: BC-QD061191-52

Evaluating Competent Authority: France

Date: February 2022

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# CONCLUSION

The product PINE T PRO BALL is a capsule suspension (CS) containing (13Z)-Hexadec-13-en-11-yn-1-yl acetate as active substance. The product is used as an attractant (product type 19) by professionalsfor the control of the pine processionary moths (*Thaumetopoea pityocampa)*.

The active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate is a new active substance not already approved under the BPR and is currently going through the EU peer-review process. According to Art. 55(2) of Regulation (EU) No. 528/2012 (BPR) “By way of derogation from point (a) of Article 19(1) and until an active substance is approved, competent authorities and the Commission may authorise, for a period not exceeding three years, a biocidal product containing a new active substance……..If the Commission decides not to approve the new active substance, the competent authorities which granted the provisional authorisation or the Commission shall cancel that authorisation”.

The final Competent Authority Report (Final CAR) presenting the conclusion of the risk assessment of the active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate PT 19 has not been completed yet as the endorsement of the ECHA opinion related to the assessment of the active substance is scheduled for the Biocidal Products Committee meeting 42 (March 2022). However, the conclusion presented for the provisional authorisation of the product PINE T PRO BALL in this Product Assessment Report (PAR) is taking into account the outcomes of the discussions of the BPC Working groups IV 2021 on the active substance.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) (b), (c) and (d) and 19 (2) of Regulation (EU) No 528/2012 and therefore can be provisionally authorised for the uses, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

**General**

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

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

A classification according to Regulation (EC) No 1272/2008[[1]](#footnote-2) is necessary.

Detailed information on classification and labelling is provided in section 2.1.3 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

The biocidal product does not contain any non-active substance (so called “co-formulant(s)”) which is considered as 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.

More information is available in the confidential annex.

The biocidal product contains the active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate which does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered as a candidate for substitution. Therefore, a comparative assessment of the biocidal product is not required.

**Composition**

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer(s) of the biocidal product is listed in section 1.4 of the SPC.

The chemical identity and quantity for the active substance in the biocidal product are met. 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(s) as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

**Physico chemical properties and analytical methods:**

The physico-chemical properties of the biocidal product PINE T PRO BALL have been evaluated and are deemed acceptable for the appropriate use, storage and transportation.

However, the following tests should be submitted at product authorisation (after the approval of the active substance):

- An auto-ignition temperature test

* A flammability test: the statement provided cannot be considered as sufficient

Analytical methods for the determination of active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate in product are available and considered as validated. No analytical method has been provided for the determination of one stabilizer which is a relevant impurity However, it cannot be formed during the formulation and the storage of the product, no additional data is required.

No analytical methods were provided for the relevant matrices: food of plant origin, foodstuffs of animal origin, soil, water, air, animal and human body fluids and tissues because the environmental risk assessment shows that (13Z)-hexadec-13-en-11-yn-1-yl acetate, when used as a biocide, does not affect the levels of (13Z)-hexadec-13-en-11-yn-1-yl acetate found usually in the atmosphere, outside normal range and because the active substance is not classified toxic or very toxic.

**Efficacy:**

Field tests were conducted with the product PINE T PRO BALL to show the efficacy of the mating disruption treatment with the sexual confusion method against pine processionary moth (*Thaumetopoea pityocampa)*.

Based on the elements presented in the frame of provisional authorisation, reduction of pine processionary caterpillars and nests in pine areas is demonstrated, in forest and urban areas, at the following application rates:

* In forests at the dose of 400 balls /ha
* In urban areas (groves, narrow band of trees, isolated trees): 1 ball per 1 m of height and per tree

However due du certain bias or incomplete information in the protocols for the efficacy studies presented, new efficacy studies (especially for urban areas) should be submitted at product authorisation (after the approval of the active substance) in order to confirm the efficacy at the application rates claimed and in various situations (forests, groves, narrow band of trees, isolated trees)

**Risk for human health:**

The assessment of the risk for human health during the use of the product PINE T PRO BALL was carried out for the active substance only (no substance of concern).

Considering the method of application of the product PINE T PRO BALL (outdoors, in the upper part of the pine canopy, using a paintball gun), the professional exposure is considered very low and the risk is acceptable only if the following risk management measures are applied:

- Wear gloves during all phases of use (loading, application and collection of balls on the ground).

- During the application, a safety perimeter (approximately 10 m) must be set to avoid the presence of the general public.

- After application in forests, inspect carefully the area and pick up all the fallen balls.

- After application in urban zone, make sure that no balls or debris are left on the ground.

The risk for the general public is then considered acceptable.

**Risk for consumers via residues in food:**

Dietary exposure related to the product PINE T PRO BALL is considered as not relevant since no contamination of food or feed is expected based on the localized application on the tree trunks.

**Risk for environment:**

Acceptable risks are reached for the environment for the treatment of pine (urban or countryside area) with a paintball application by professional user, considering the very limited exposure of the environment linked to the specific use and mode of application of the biocidal product with:

- the following risk mitigation measures: “After application, inspect carefully the area and pick up all the fallen balls”

- the following instruction of use: “Use the product on rainless days only and if no rainfall is expected within 12 hours of application.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| PINE T PRO BALL |  |
| PHERO-BALL PIN |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | M2i Biocontrol |
| **Address** | 1 rue Royale, 112 Bureaux de la Colline 92210 Saint Cloud France |
| **Authorisation number** | FR-2022-0018 | |
| **Date of the authorisation** | 23/03/2022 | |
| **Expiry date of the authorisation** | 22/03/2025 | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | M2i Biocontrol |
| **Address of manufacturer** | 370 route de Caunézil  46140 Parnac  France |
| **Location of manufacturing sites** | 370 route de Caunézil  46140 Parnac  France |

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

|  |  |
| --- | --- |
| **Active substance** | (Z)-13-hexadecen-11-yn-1-yl acetate |
| **Name of manufacturer** | M2i DEVELOPMENT |
| **Address of manufacturer** | Bâtiment ChemStart’Up  Allée le Corbusier  64170 LACQ  France |
| **Location of manufacturing sites** | Bâtiment ChemStart’Up  Allée le Corbusier  64170 LACQ  France |

### Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | (13Z)-Hexadec-13-en-11-yn-1 acetate |
| **IUPAC or EC name** | (13Z)-Hexadec-13-en-11-yn-1 acetate |
| **EC number** | not allocated |
| **CAS number** | 78617-58-0 |
| **Index number in Annex VI of CLP** | None |
| **Minimum purity / content** | 97 % |
| **Structural formula** | Molecular formulation : C18H30O2 |

#### Candidate(s) for substitution

Not applicable.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| (Z)-13-hexadecen-11-yn-1-yl acetate |  | Active substance | 78617-58-0 | na | 4.46 (technical) |

#### 

#### Information on technical equivalence

Not relevant.

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

According to the assessment, none of the co-formulants contained in the product PINE T PRO BALL is identified as substance of concern for human health and environment.

Please see the confidential annex for further details.

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

The biocidal product contains the active substance “(Z)-13-hexadecen-11-yn-1-yl acetate”, for which the waiving for ED properties testing has been accepted. The active substance has not been identified as having endocrine disrupting properties.

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

Please refer to Confidential Annex for more details.

#### Type of formulation

|  |
| --- |
| CS: capsule suspension |

N.B.: the active substance is micro-encapsulated in a wax emulsion. This emulsion is inserted into paint balls.

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic Acute 1  Aquatic Chronic 1 |
| Hazard statement | H400: Very toxic to aquatic life.  H410: Very toxic to aquatic life with long lasting effects. |
|  | |
| **Labelling** | |
| Pictograms | GHS09GHS 09 |
| Signal words | Warning |
| Hazard statements | H410: Very toxic to aquatic life with long lasting effects. |
| Precautionary statements | P273: Avoid release to the environment.  P391: Collect spillage.  P501: Dispose of contents / container in accordance with local regulations. |
|  | |
| Note |  |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Professional – Mating disruption

|  |  |
| --- | --- |
| **Product Type** | 19 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *Thaumetopoea pityocampa* – Pine processionary moth.  Adult |
| **Field of use** | Outdoor  Pine T pro Ball is a product used for the control of Pine Processionary (*Thaumetopoea pityocampa*), by mating disruption  The product can be applied on all species of softwood affected by the Pine Processionary, in forests and urban areas (maritime pine, Austrian black pine, Aleppo pine, Scots pine, Laricio pine, cedar, Douglas fir or Lambert cypress, etc..). |
| **Application method(s)** | Application of balls using an air gun like paintball gun The balls are loaded into the air gun by means of a closed reservoir. The balls are pulled on the canopy of the trees. Upon impact, the balls burst and the gel formulation is applied to the trunks. A few hours after application, the water contained in the formulation evaporates, leaving a thin film containing the pheromone which will diffuse in the air. |
| **Application rate(s) and frequency** | Forest: 400 balls/ha  Urban areas(groves, narrow band of trees, isolated trees): 1 ball per 1 m of height and per tree |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Three types of pocket are used depending number of balls in each. Details are presented in the next table: |

#### 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

|  |
| --- |
| Pine T Pro Ball must be applied before the appearance of the Pine Processionary moths, in forests and urban areas, once a season before adult emergence, starting in May or June depending on the region and based on regional surveillance.   * The profesional must be trained beforehand to handle the paintball gun. * Pine T Pro Ball balls must be fired into the canopy of the tree, at a height of more than 6m or at the top of the tree. It is advisable to aim at the South/Southwest faces of the trees, which are more appreciated by caterpillars because of their favourable exposure to the sun. * The distribution of balls depends on the configuration of the area to be treated and its level of infestation. It is therefore important to target the edges of the plot and the tallest trees. * Use the product on rainless days and if no rainfall is expected within 12 hours of application * Comply with the instructions of use. * Inform the registration holder if the treatment is ineffective. |

#### Risk mitigation measures

|  |
| --- |
| - Wear gloves during all phases of use (application and collection of balls on the ground).  - During the application, a safety perimeter (approximately 10 m) must be set to avoid the presence of the general public.  - After application in forests, inspect carefully the area and pick up all the fallen balls.  - After application in urban zone, make sure that no balls or debris are left on the ground. |

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

|  |
| --- |
| IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor. |

#### 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, in accordance with local regulations |

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

|  |
| --- |
| Shelf life : 2 years. |

### 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)** |
| Package of 500 balls | 300 x 300 mm | PET/Alu/PE  12/8/140 μm | Pine T Pro Ball packaging is a three layer pocket, which are glued together :  - Outermost layer in PET (polyethylene terephthalate)  - Middle layer in Aluminium  - Inner layer in PE = polyethylene.  Pockets are sealed thanks to the PE inner layer. | Professional | Yes |
| Package of 100 balls | 160 x 230 mm | PET/Alu/PE  12/8/100 μm | Professional | Yes |
| Package of 10 balls | 200 x 40 | PET/Alu/PE  12/12/80 μm | Professional | Yes |

### Documentation

#### Data submitted in relation to product application

#### Efficacy data were provided with the product Pine T Pro Ball. Please refer to the list of references (annex 3.1).

#### Access to documentation

Not relevant.

## Assessment of the biocidal product

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

Table 2. Intended use # 1 – Mating disruption for Pine Processionary Moth (*Thaumetopoea pityocampa*)

|  |  |
| --- | --- |
| Product Type(s) | PT19 - Repellents and attractants (Pest control) |
| Where relevant, an exact description of the authorised use | Pine T pro Ball/ Phero-Ball Pin is a product used for the control by mating disruption against the Pine Processionary (*Thaumetopoea pityocampa*). It effectively reduces the pest population by interrupting the mating cycle.  The application of Pine T Pro Ball/ Phero-Ball Pin is a method of mating disruption operating by diffusing the pest specific sex pheromone on multiple emission points. By preventing encounters, and therefore mating, this biocontrol solution will disrupt the insect's reproductive cycle and ultimately allows the reduction of its presence in protected pines.  Pine T Pro Ball/Phero-Ball Pin is applied in forests and urban areas, before the appearance of the Pine Processionary moths, once a season, up to 400 balls/ha. The number of balls per hectare varies depending on the area to be protected and the density of the trees. |
| Target organism (including development stage) | Scientific name: Lepidoptera: Common name: other: Pine Processionary Development stage: Adults |
| Field of use | Outdoor  During the application, the balls are loaded into the paint ball gun by means of a closed reservoir. The handling of the balls is carried out with protective gloves to avoid contact with the material. The balls are pulled to the top of the pines (about 10 m from the ground). Upon impact, the balls burst and the gel formulation is applied to the trunks closed to the canopy. After evaporation of the water, a film containing pheromone and oil is left on the trunk. This film is a passive diffuser that will diffuse (Z13)-hexadec-13-en-11-yn-1-yl acetate in a controlled manner within a very short diffusion radius of about 2m.  The product can be applied on all species of trees affected by the Pine Processionary: maritime pine, Austrian black pine, Aleppo pine, Scots pine, Laricio pine, cedar, Douglas fir or Lambert cypress. |
| Application method(s) | Other: Application of balls using an air gun like paintball gun  During the application, the balls are loaded into the paintball gun by means of a closed reservoir. The handling of the balls is carried out with protective gloves to avoid contact with the material. The balls are pulled on the canopy of the trees (about 10 m from the ground). Upon impact, the balls burst and the gel formulation is applied to the trunks. A few hours after application, the water contained in the formulation evaporates, leaving a thin, barely visible film containing the pheromone that will diffuse for about 3 to 4 months. |
| Application rate(s) and frequency | 400 balls/ha -  Pine T Pro Ball is applied once a year before adult emergence, per season, starting in May or June depending on the region and based on regional surveillance. |
| Category(ies) of user(s) | Trained professional |
| Pack sizes and packaging material | Pine T Pro Ball/ Phero-Ball Pin packaging is a three layer pocket, the layers are glued together :  - Outermost layer in PET = polyethylene terephtalate  - Middle layer in Aluminium  - Inner layer in PE = polyethylene.  Pockets are sealed thanks to the PE inner layer.  For easy opening and closer, the pockets are equipped with a zip, clicky type.  Three types of pocket are used depending number of balls in each. Details are presented in the next table:  Balls number Size pockets (mm) Thickness of each layer (μm)  PET Alu PE  500 300 x 300 12/8/140  100 160 x 230 12/8/100  10 200 x 40 12/12/80  For all of them, aluminium layer, which is barrier material to O2, active substance, UV and humidity is at least of 8 μm. |

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comment** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | CIPAC Handbook J - MT 46.3 method (2000) | XP CS PIN (Emulsion, water in oil)  Batch PINB 062018-1  (4.31 % w/w) | Homogeneous slightly yellow opaque liquid.  Transparent beads of about 1.7 cm diameter full of slightly yellow opaque liquid. | Acceptable | Defitraces report  R18-913034-003 |
| Colour at 20 °C and 101.3 kPa | CIPAC Handbook J - MT 46.3 method (2000) | XP CS PIN (Emulsion, water in oil)  Batch PINB 062018-1  (4.31 % w/w) | Homogeneous slightly yellow opaque liquid.  Transparent beads of about 1.7 cm diameter full of slightly yellow opaque liquid. | Acceptable | Defitraces report  R18-913034-003 |
| Odour at 20 °C and 101.3 kPa | The colour, the physical state, the odour of the test item were observed before the accelerated storage procedure. | XP CS PIN  Batch PINB 062018-1  (4.31 % w/w) | Characteristic odour | Acceptable | Defitraces report  R18-913034-003 |
| Acidity / alkalinity | CIPAC MT 75.3 | XP CS PIN  Batch PINB 062018-1  (4.31 % w/w) | The mean pH value of the pure test item was:  **7.14** at 21.0 °C after 1 min.  **7.12** at 21.1 °C after 2 min. | Acceptable | Defitraces report R18-913034-003 |
| Relative density / bulk density | Relative density of the emulsion (OECD 109). | XP CS PIN  M2iDFHE02121-2 (4.31 % w/w) | The mean relative density of the test item (emulsion) was **0.985** ± 0.002 at 20.4 °C. | Acceptable | Defitraces report R18-913034-001 |
| Storage stability test – **accelerated storage** | CIPAC method MT 46.3 (storage at 54 °C for two weeks)  - appearance  - weight of the balls  - a.s. content  - pH  - attrition (balls)  Analytical method validated in the study No. 18-913034-005 | Identification XP CS PIN  Batch PINB 062018-1  Manufacturing date 04 September 2018  Supplier M2I DEVELOPMENT  Packaging Silver plastic bag (PET/Alu/PE)  Storage In darkness at room temperature | The appearance of the test item was considered to be stable after an accelerated storage procedure for 14 days at 54 °C ± 2 °C.  The packaging material (silver plastic bag) was considered to be stable after an accelerated storage procedure for 14 days at 54 °C ± 2 °C; **no significant change of weight was observed**.  No significant change was observed in the content of the active substance after the  accelerated storage procedure for 14 days at 54 °C ± 2 °C.  **Content a.s before: 4.31%**  **Content a.s after: 4.39%**  The test item was considered to be stable.  Before the accelerated storage procedure  The mean pH value of the pure test item was:  **7.14** at 21.0 °C after 1 min.  7.12 at 21.1 °C after 2 min.  After the accelerated storage procedure  The mean pH value of the pure test item was:  **6.98** at 19.9 °C after 1 min.  6.97 at 19.9 °C after 2 min.  Before the accelerated storage procedure  The attrition resistance of the test item was **100.0%.**  After the accelerated storage procedure  The attrition resistance of the test item was **99.8%**. | Acceptable, the product is stable at 54°C | Defitraces report R18-913034-003 |
| Storage stability test – **long term storage at ambient temperature** | Shelf life at ambient temperature for 2 years  GIFAP, CropLife Monograph No.17  - appearance of the product  - packaging stability (including weight change, loss of ball integrity or caking on storage, and if flexible packs: effect of stacking packs)  - weight of the balls  - a.s. content  - pH  - attrition (balls) | Identification XP CS PIN  Batch PINB 062018-1  Manufacturing date 04 September 2018  Supplier M2I DEVELOPMENT  Packaging Silver plastic bag (PET/Alu/PE)  Storage In darkness at room temperature | The appearance of the test item was considered to be stable after an accelerated storage procedure for 2 years at 20 °C ± 2 °C.  The packaging material (silver plastic bag) was considered to be stable after an accelerated storage procedure for 2 years at 20 °C ± 2 °C; no significant change of weight was observed.  A significant change (decrease 9%) was observed in the content of the active substance after the storage procedure for 2 years at 20 °C ± 2 °C but considered as acceptable (below 10%).  Content a.s before: 4.31%  Content a.s after: 3.92%  The test item was considered to be stable.  Before the storage procedure  The mean pH value of the pure test item was:  7.14 at 21.0 °C after 1 min.  7.12 at 21.1 °C after 2 min.  After 2 years at 20 °C ± 2 °C of storage procedure  The mean pH value of the pure test item was:  7.00 at 21.6 °C after 1 min.  6.98 at 21.5 °C after 2 min.  Before the storage procedure  The attrition resistance of the test item was 100.0%.  After 2 years at 20 °C ± 2 °C of storage procedure  The attrition resistance of the test item was 99.4%. | Acceptable, the product is stable 2 years at ambient temperature | PE18-913034-004 |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 including a 'freeze/thaw' cycle  - appearance  - a.s. content ()  - pH | Identification XP CS PIN  Batch PINB 062018-1  Manufacturing date 04 September 2018  Supplier M2I DEVELOPMENT  Packaging Silver plastic bag (PET/Alu/PE)  Storage In darkness at room temperature | At the start of the test, the test item was a homogeneous slightly yellow opaque liquid.  The appearance of the test item was considered to be stable after a low temperature stability at 0 ± 2 °C for 7 days**, no change was observed in the test item aspect.**  **WET SIEVE** TEST after low temperature stability  In compliance with CIPAC Handbook K - MT 185 method (2003)  The mean percentage retention of the test item held on a **75-μm sieve was 0.1%** of the total sieved test item.  DETERMINATION OF pH VALUES  In compliance with  CIPAC Handbook J - MT 75.3 method (2000)  Before the low temperature stability  (Results from study No. 18-913034-003)  The mean pH value of the pure test item was:  **7.14** at 21.0 °C after 1 min.  7.12 at 21.1 °C after 2 min.  After the low temperature stability  The mean **pH** value of the pure test item was:  **7.12** at 18.8 °C after 1 min.  7.09 at 18.8 °C after 2 min.  ATTRITION RESISTANCE OF GRANULES  In compliance with CIPAC Handbook H - MT 178 method (1998)  Before the low temperature stability (Results from study No. 18-913034-003)  The **attrition resistance** of the test item was **100%.**  After the low temperature stability  The attrition resistance of the test item was **100%.** | Acceptable, the product is stable 7 days at 0°C | Defitraces report R18-913034-002 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | The product is packaged in silver plastic bag which can be considered as barrier to light. | Acceptable | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | As the product is packaged in a plastic bag, no mitigation measure is necessary. | Acceptable | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See stability studies above. | - | - |
| Wettability | Not required | - | Product has not to be dissolved in water. | - | - |
| Suspensibility, spontaneity and dispersion stability | Not required | - | Product has not to be dissolved in water. | - | - |
| Wet sieve analysis and dry sieve test | Wet sieve test: Not required  Dry sieve test: Not adapted | - | Wet sieve test: product has not to be dissolved in water.  Dry sieve test: MT170 is not adapted to the balls. | - | - |
| Emulsifiability, re-emulsifiability and emulsion stability | Not required | - | Product has not to be dissolved in water. | - | - |
| Disintegration time | Not relevant | - | Product is not a tablet | - | - |
| Particle size distribution, content of dust/fines, attrition, friability | Emulsion:  Particle size distribution: CIPAC MT 187 test  Balls:  Attrition: MT 178 test (before and after storage) | Identification XP CS PIN  Batch PINB 062018-1  Manufacturing date 04 September 2018  Supplier M2I DEVELOPMENT | The attrition resistance of the test item was 100.0%. | Acceptable | Defitraces report R18-913034-003 |
| Persistent foaming | Not required | - | Product has not to be dissolved in water. | - | - |
| Flowability/Pourability/Dustability | Not required | - | Product has not to be dissolved in water. | - | - |
| Burning rate — smoke generators | Not relevant | - | Product is not applied as smoke. | - | - |
| Burning completeness — smoke generators | Not relevant | - | Product is not applied as smoke. | - | - |
| Composition of smoke — smoke generators | Not relevant | - | Product is not applied as smoke. | - | - |
| Spraying pattern — aerosols | Not relevant | - | Product is not applied as aerosol. | - | - |
| Physical compatibility | Not required | - | Not intended to be applied with other products | - | - |
| Chemical compatibility | Not required | - | Not intended to be applied with other products | - | - |
| Degree of dissolution and dilution stability | Not required | - | Product has not to be dissolved in water | - | - |
| Surface tension | EEC A5 / OECD 115 test (emulsion) | XP CS PIN  M2iDFHE02121-2  (4.31 % w/w) | The measurement of the surface tension of the test item was not possible due to its too high viscosity. | Acceptable | Defitraces report R18-913034-001 |
| Viscosity | OECD 114 test at 20°C and 40ºC (emulsion) | XP CS PIN  M2iDFHE02121-2  (4.31 % w/w) | Taking into account the results obtained at different shear rates, the test item was considered to have non-newtonian properties in the experimental conditions used.  The dynamic viscosity varied as following:  At 20.0 °C ± 0.2 °C, from h(0.003 s-1) = 6814171 mPa.s to h(0.015 s-1) = 256195 mPa.s.  At 40.0 °C ± 0.2 °C, from h(0.003 s-1) = 5220761 mPa.s to h(0.023 s-1) = 795664 mPa.s. | Acceptable | Defitraces report R18-913034-001 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The product PINE T PRO BALL is a pheromone in a wax emulsion. This emulsion is inserted into paint balls (EO containing 100 mg pheromone/ ball (i.e. 4.33% (pure) w/w)). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  The appearance of the product is a homogeneous slightly yellow opaque liquid with a characteristic odour. The ball is a transparent beads of about 1.7 cm diameter full of slightly yellow opaque liquid. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C in packaging silver plastic bag (PET/Alu/PE), neither the active ingredient content nor the technical properties were changed.  After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C. The stability data indicate a shelf life of 2 years at ambient temperature in commercial packaging.  Its technical characteristics are acceptable for an EO formulation. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comment** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Statement | - | Regarding properties of the active substance and all the co-formulants which compose the PHEROBALL PIN product, none of these compounds could induce explosive properties to the product. Therefore, we can conclude that the Pine T Pro Ball product is not expected to present explosive properties. | Acceptable | Report M2iD-DEV-2020-03 “Assessment of potential hazard properties of the active substance (Z)-13-hexadecen-11-yn-1-yl acetate and Pine T Pro Ball product” |
| Flammable gases | Not relevant | - | The product is not a gas | - | - |
| Flammable aerosols | Not relevant | - | The product is not an aerosol | - | - |
| Oxidising gases | Not relevant | - | The product is not a gas | - | - |
| Gases under pressure | Not relevant | - | The product is not a gas | - | - |
| Flammable liquids | EEC A9 |  | This test will be provided. The applicant plans to perform them during the provisional marketing authorization period. In the meantime, the applicant propose a theorical assessment of flash point value.  Final flash point of the product is not expected being below 100°C. | Data requirement |  |
| Flammable solids |  |  | Polymer of the ball is not flammable. | Data requirement |  |
| Self-reactive substances and mixtures | Statement | - | None of the compounds of the biocidal product formulation contains any of the chemical groups listed in section 2.8.1 of the “Guidance on the Application of the CLP Criteria”. | Acceptable | - |
| Pyrophoric liquids | Statement | - | Pheromone is not pyrophoric | Acceptable | - |
| Pyrophoric solids | Statement | - | Polymer of the ball is not pyrophoric | Acceptable | - |
| Self-heating substances and mixtures | Statement | - | The product is a non-flammable containing no flammable ingredients. The product contains a large percentage of water | Acceptable | - |
| Substances and mixtures which in contact with water emit flammable gases | Statement |  | Pheromone is not expected to emit flammable gases in contact with water, neither the polymer of the ball and the other ingredients. | Acceptable |  |
| Oxidising liquids | Statement |  | Regarding the properties of the active substance and all the co-formulants which compose the PHEROBALL PIN product without shell, none of these compounds present oxidising properties. The substance or mixture does not contain oxygen, fluorine or chlorine. Therefore, we can conclude that the product is not expected to have oxidising properties. | Acceptable | Report M2iD-DEV-2020-03 “Assessment of potential hazard properties of the active substance (Z)-13-hexadecen-11-yn-1-yl acetate and Pine T Pro Ball product” |
| Oxidising solids | Statement |  | The final physical state of the biocidal product is shell ball. The shell is a polymer which has no oxidising properties. | Acceptable |  |
| Organic peroxides | Not required |  | Pheromone and other ingredients are not an organic peroxide. | - |  |
| Corrosive to metals | Statement |  | The applicant undertakes to carry out the corrosivity test of Pine T Pro Ball product during the period of the provisional marketing authorization.  The formulation of PHEROBALL PIN product is protected by the polymer shell, which avoid any direct contact with operator’s skin upon application. The product is considered as a solid, therefore the corrosive properties are not considered. | Acceptable | Report M2iD-DEV-2020-03 “Assessment of potential hazard properties of the active substance (Z)-13-hexadecen-11-yn-1-yl acetate and Pine T Pro Ball product |
| Auto-ignition temperatures of products (liquids and gases) | EEC A15 test or N4 test | - | The applicant undertakes to carry out the flash point study of PHEROBALL PIN product during the period of the provisional marketing authorization.  However, regarding flammabilityof the active substance and all the co-formulants which compose the PHEROBALL PIN product, none of these compounds present value below 100°C. Furthermore, the product is composed of more than 75% of water. | Acceptable | Report M2iD-DEV-2020-03 “Assessment of potential hazard properties of the active substance (Z)-13-hexadecen-11-yn-1-yl acetate and Pine T Pro Ball product |
| Relative self-ignition temperature for solids | Not required |  | - | - | - |
| Dust explosion hazard | Not relevant | -- | The product is not a powder and does not produce dust. | - | - |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product PINE T PRO BALL is s not explosive and not oxidizing.  **Data Gap**  Concerning the flammability property of the product, the statement provided cannot be considered as sufficient. According to the CLP guidance document 1272/2008, a test should be provided. |

### Methods for detection and identification

[Description of analytical methods used for the analysis of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product]

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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** | **Precision** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| **(13Z)-hexadec-13-en-11-yn-**  **1-yl acetate** | (13Z)-hexadec-13-en-11-yn-1-yl acetate is analysed after 4 extractions (heptane) from the formulation and quantified by gas chromatography using a flame ionisation detector (GC-FID).  The nominal value of the active substance is 100 mg/ball (4% w/w). | 4,35% w/w (n=5) RSD=0.55% | Calibration solutions of the reference item at five concentrations between 50% and 150% of the expected concentration were analysed.  The response of the detector during the analysis of (13Z)-hexadec-13-en-11-yn-  1-yl acetate was linear within the range of 91.83 x 10-3 g/kg to 255.39 x 10-3 g/kg  (y = 1.45E-02 x – 2.58E-01; r = 0.9997). | No interference was observed in solvent blank, formulation blank, reference item and test item at the retention times of (13Z)-hexadec-13-en-11-yn-1-yl acetate. | 121,41 x 10-3 g/kg (n=2)  129,17 x 10-3 g/kg  (n=2) | 101.2% | <2% | Not required | **R18-913034-005** |
| **Relevant impurity: HCDD (3Z, 23Z)-hexacosa-3,23-dien-5,21-diyne** | A GC-FID method was developed for the quantification of the three identified possible impurities: Isomer (E-HDA), HCDD and Dodec-3-yn-1-yl acetate / (extraction with acetonitrile, column “Supelco SLB-5ms 30 m x 0.25 mm x 0.25µm”, FID 280°C) | 1,47 g/kg (n=6; injected separately) RSD=2.9% | 0.36 – 357.9 mg/L (0,46.10-3 – 455,29.10-3 g/kg) (prepared by serial dilution) (n=11) r2=99.98% | no interferences at the retention time of tested substance (chromatograms are provided) | with 2 distinct solutions | 98.6% and 102.6% | <3% | 0.36 mg/L | Servajean (2017a) Report 16-64-073-ES  Magnet Stephanie, 2018  N°CHRONO: M2ID-ANA-2018-18  N°PROJET: M2ID-RECH 1632 |

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| **Analytical methods for plant material and foodstuffs of animal origin** | | | | | | | | | |
| **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** |
| No analytical method has been submitted because the environmental risk assessment shows that **(13Z)-hexadec-13-en-11-yn-1-yl acetate**, when used as a biocide, does not affect the levels of **(13Z)-hexadec-13-en-11-yn-1-yl acetate** found usually in the atmosphere, outside normal range. | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for soil, water, air and animal and human body fluids and tissus** | | | | | | | | | | | |
| **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** |
| No analytical method has been submitted because the environmental risk assessment shows that **(13Z)-hexadec-13-en-11-yn-1-yl acetate**, when used as a biocide, does not affect the levels of **(13Z)-hexadec-13-en-11-yn-1-yl acetate** found usually in the atmosphere, outside normal range. | | | | | | | | | | | |
| **Conclusion on the methods for detection and identification of the product** | | | | | | | | |
| Analytical methods for the determination of active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate and its impurities are available and considered as validated.  No analytical methods were provided for the relevant matrices: food of plant origin, foodstuffs of animal origin, soil, water, air, animal and human body fluids and tissus because the environmental risk assessment shows that (13Z)-hexadec-13-en-11-yn-1-yl acetate, when used as a biocide, does not affect the levels of (13Z)-hexadec-13-en-11-yn-1-yl acetate found usually in the atmosphere, outside normal range, and because the active substance is not classified toxic or very toxic. | | | | | | | | |

### Efficacy against target organisms

#### Function and field of use

Pest Control (Main Group 3).

PT19, Attractant

PINE T PRO BALL product is based on (13Z)-Hexadec-13-en-11-yn-1 acetate, a pheromone naturally produced by the *Thaumetopoea pityocampa* female moth. It acts as an attractant used for mating disruption by sexual confusion.

PINE T PRO BALL is aimed to be used into a passive diffuser. The product can be applied to all tree species affected by the Pine processionary moth such as maritime pine, Austrian black pine, Aleppo pine, Scots pine, Laricio pine, cedars, and Douglasfiror Lambert cypress, to disrupt mating in order to control the pine processionary caterpillar.

The PINE T PRO BALL product is considered as a biocidal product as is purpose is to protect the human health from inflammatory skin reaction caused by caterpillar’s bristles.

PINE T PRO BALL product is formulated as balls that are applied using an air gun/ paintball gun. The balls are pulled on the canopy of the trees (about 10 m from the ground). Upon impact, the balls burst and the gel formulation is applied to the trunks. A few hours after application, the water contained in the formulation evaporates, leaving a thin, barely visible film containing the pheromone.

PINE T PRO BALL is intended to be applied before the appearance of the Pine  
Processionary moths, once a season, in forests up to 400 balls/ha, and urban areas at the application rate of 1 ball per meter of height and per tree.

The number of balls per hectare varies depending on the area to be protected and the density of the trees.

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

PINE T PRO BALL aims to disrupt mating in pine trees in order to control the pine processionary caterpillar by reducing the number of nests to protect the human and animal populations from the irritant effect of the hairs from the caterpillars.

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

Mating disruption aims to disrupt chemical communication by organisms of a same species, pest insects in this present case, using very specific and non-harmful substances: the pheromones. The mate-finding behavior in males is disturbed or disrupted by the progressive and passive release of relatively large amounts of synthetic female sex pheromone in the atmosphere,

By sensing the smell of female “everywhere” the male is unable to find his way to the females, he is “confused.” This leads to fewer matings within the treated area, fewer offspring and consequently less damage in the crop.

#### Mode of action, including time delay

The active substance (13Z)-Hexadec-13-en-11-yn-1 acetate acts by mating disruption, which is a biocontrol technique based on the diffusion of a sex pheromone cloud thanks to a passive diffuser on the top of the tree parcels. The presence of pheromone above the parcels disturbs chemical communication between the invaded moths and disrupts mate localization and/or courtship, thus preventing mating and blocking reproductive cycle resulting into a decrease of lepidopters population.

According to the applicant, the duration of diffusion is about 3 to 4 months covering the flight period of the butterflies. Nevertheless, this duration has not been demonstrated with the efficacy data provided.

#### Efficacy data

The applicant claims both a reduction of pine processionary caterpillars in pine areas and reduction of pine processionary nests.

BPR Efficacy guidance Vol II part B/C does not provide requirements and criteria for such uses. Therefore, eCA has considered that 70% to 80% of reduction of both pine processionary caterpillars and nests is the minimum threshold for a sufficient efficacy.

No laboratory tests have been performed. Indeed, the applicant explained that it is due to the short living of the *T. pityocampa* adults: usually females die after egg laying (from 24 to 48 hours) after emergence and males can persist for 3-4 days (Zang & Paiva, 1998)[[2]](#footnote-3).

eCA agreed with this waiving

Therefore the efficacy data submitted are only carried out in the field.

First, the effective dose test of the product PINE T PRO BALL has been then identified following a specific experimental protocol design in 2016, in the frame work of “Optim’Phero project”.

Then, 14 field trials were performed:

* Nine studies have been performed in forest: 5 trials in France, one in Israel and 3 in Spain.
* Five trials have been performed in urban zones in France.

The sites were selected on the basis of a history of lepidoptera defoliating pest infestation, in areas representative of typical forest and woodland. Trials were carried out to evaluate the efficacy of the product PINE T PRO BALL when applied directly on trees with a paintball gun against *Thaumetopoea pityocampa*:

* The trial conducted in 2015-2016 (Massif de la Montagnette - France) was considered as a pre-test because the aim was to optimize the diffusion regarding the *T. pityocampa* flight behaviour.
* The trial conducted in 2016-2017 (Col d’Eze - France) aimed to test the dosage of 400 balls (40 g of a.s.)/ha.
* The trials conducted from 2017 to 2020 (French and Spanish forests) aimed to confirm the efficacy of the dose of 400 balls (40 g a.s)/ha.
* The trials conducted in urban zones in France from 2016 to 2020 aimed to test the efficacy in urban zones (groves, narrow band of trees, isolated trees) with range doses of 5 to 30 balls/tree.

In all the field tests, efficacy was assessed:

* By counting the number of pine processionary moths trapped (adult males) and,
* By counting the winter nests (before and after the trial) to reveal the consequences of mating disruption in terms of population dynamics.

It has to be noted that to correct the bias due to normal fluctuating population levels accross time, the average number of nests has been calculated by the Henderson and Tilton formula and corrected taking into account the natural dynamics in the control plot over the 2 years. Indeed, the *Thaumetopoea pityocampa* population dynamic is very singular, relies on several factors such as climate suitability, active dispersal capabilities and habitat distribution/host trees density. Clearly the unit of measure, the number of nests per pine in the treated area, need to be connected and corrected according to the trends of the general pine processionary moth population dynamic in the local geographic area to expressed the fair efficiency of the mating disruption application as a sort of a non-treated control.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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** |
| PT 19- Attractant  Reducing population of pine processionary caterpillars and nests in trees | *Forest*  Optim’  Phero project | Pine T Pro Ball ((13Z)-Hexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary  moth  *Thaumetopoea pityocampa*  Adult, male | Mating disruption by deposition of balls using a paintball  Field trial  Pre-test performed in the Massif of Montagnette (departement 13) in France. | The experimental surface and the control area both of 6 hectares  Each area is gridded to install the dispensers at each intersection of the mesh. Shooting is done  on the tallest trees in order to optimize the impact.  In the test area, 5 pheromone traps were put in place. They were placed in the middle of the area along an alignment axis, along a path. Similarly, 6 pheromone traps are installed in the control area,  located nearby the study site but over a larger area.  A total of 11 traps were set.  80 balls (0.12 g of pheromone/ball) were fired per hectare, i.e. one dose of 10 g/ha of pheromone.  Sentinel traps (pheromone traps) were monitored every 2 weeks for the duration of the adults' flight.  Sentinel traps are used to caught male butterflies. They are positionned in control and treated plots. These traps are designed to simulate the behaviour of adult females. Comparison between control and treated plots is performed.  The assessment in the control and the mating disruption area is done by counting winter nests of the pine processionary in 5 sub areas (A, B, C, D, E) of 10 trees each, both in February 2015 (before treatment) and February 2016 (after treatment). | Results for the number of male pine processionary moths captures:   |  |  | | --- | --- | |  | Number of pine processionary trapped | | Control | 739 | | Treated area | 166 |   =>Only 22.5% of the catches came from the Pine T Pro Ball area, that demonstrate the effect of the mating disruption treatment and the slowdown density of the *T. pityocampa* population inside.  Results for the number of winter nests:   |  |  |  | | --- | --- | --- | |  | Nb winter nest Feb 2015 (before treatment) | Nb winter nest Feb 2016 (after treatment) | | Control | 12.2 | 14.2 | | Treated area | 8.2 | 9.8 |   =>The Pine T Pro Ball treatment has allowed to decrease the pine processionary population by 2.68%.  This trial demonstrate that the rate of 10 g/ha is not sufficient. | VI.2 Proof of concept trial (site Montagnette-2015-2016)  EFFICACY DATA and RELEVANT INFORMATIONS  R.I = 2  Supportive data |
| *Forest* | Pine T Pro Ball ((13Z)-Hexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary  *Thaumetopoea pityocampa* | Mating disruption by deposition of balls using a paintball | The trial was conducted at Col d’Eze in the Grande Corniche departmental park in France.  Four different numbers of balls/ha (100;200;400;1000) were tested in 2 forest plots of 4 hectares each (except the 400 balls/ha modality and the 100 balls/ha modality which have been tested on one plot of 4 ha only) and even an application in two times (100 + 100), the first 100 balls/ha before the flight and the second application (100 balls/ha) in the middle of the pest flight curve. This doubling of the dose is intended to verify both the double-dose effect on the capture of male butterflies and the persistence of action of the microencapsulated pheromone used in the balls.  It has been included in the protocol the installation of 5 sentinel traps per control and mating disruption plots, checked every 15 days in order to follow the population dynamics on both sides and to control the effectiveness of the disruption treatment too. Outside plots five additional traps were suspended every 25 meters at a distance of 100 meters from the edge of the plots. Thus, two control areas were selected to follow, throughout the adult flight period, the natural fluctuations of the pine processionary moth population. Caterpillar nest counts were performed in January 2016 before the Pine T Pro Ball treatment and were replicated the following winter in January 2017. This enumeration has been carried out in the 3 plots sampled of 30 trees each. | Results of moths capture counting:   |  |  | | --- | --- | |  | Nb moths caught | | Untreated area | 49.6 | | Treated area | 7.6 |   Results of nests counting:   |  |  |  | | --- | --- | --- | |  | Before treatment | After treatment | | Untreated area | 7 | 5.5 | | Treated area | 54 | 14 |   => Reduction up to 85% of moths capture and 74% of nests number in pine trees of the treated area at the dose of 400 balls/ha. | VI.3 Minimum effective dose tests: forest areas (site Col d’Eze, 2016-2017)  EFFICACY DATA and RELEVANT INFORMATIONS  RI=2 |
| *Forest* | Pine T Pro BallHexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary  *Thaumetopoea pityocampa* | Mating disruption by deposition of balls using a paintball | The trial was conducted at Col d’Eze in the Grande Corniche departmental park in France.  300 balls/ha and 400 balls/ha have been tested in two plots as a replication. At last, three control plots were defined. On each experimental plots selected for the study, a 10x10m square mesh was constructed by SIG (Geographic Information System) in order to better distribute the Pine T Pro Ball balls over the 4 hectares area. Treatments have been performed before the adults started flying (last week of June).  The protocol included five sentinel traps (Cameratrap® model loaded with Process'Attract pheromone diffuser) distributed in the middle of each plot in order to monitor the pine processionary moth every 15 days until the end of the T. pityocampa flight and to control the "disruption effect on the males present in the "mating disruption" plots compared to the controls | Results for the number of males pine processionary moths captures:   |  |  | | --- | --- | |  | Number of pine processionary trapped | | Control | 28.5 | | 300 balls/ha | 26.8 | | 400 balls/ha | 16.3 |  * no statistically difference were highlighted in the different numbers of male moths captured between treated plots and those non-treated analysed in an ANOVA test followed by a posthoc Tukey test) ; Nonetheless, there is evidence that the sentinel traps from the 400 balls/ha treated plots tend to catch consistently less pine processionary moths than the rest of the test system   Results for the number of winter nests before and after treatment:   |  |  |  | | --- | --- | --- | |  | Before treatment | After treatment | | control | 22 | 18 | | 300 balls/ha | 65 | 37 | | 400 balls/ha | 77 | 41 |   % reduction (readjusted in relation to natural dynamics)  300 balls/Ha : 29 %  400 balls/Ha : 35.9 %  Results of this trial showed low reduction of the number of nests, between 29 and 36 % for 300 and 400 balls/ha respectively in winter 2018 | VI.5 a-1 Efficacy trials in forest area  a-1 Col d’Eze (France)  (2017-2018)  EFFICACY DATA and RELEVANT INFORMATIONS  RI = 2 |
| *Forest* | Pine T Pro Ball ((13Z)-Hexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary  *Thaumetopoea pityocampa* | Mating disruption by deposition of balls using a paintball | Mating disruption treatments took place within three Pine planted forests in the northern Negev, with *T. pityocampa* pine cultivar. The sites «Ovira or Driva” and “Lashich or Shachariya” were treated with 300 balls/ha of Pine T Pro Ball while a third site “Tsafit or Tzafit” was treated with a dose rate of 400 ball/ha of Pine T Pro Ball. A control plot was also defined near the treated area in each site. In all paired plots significant population of pine processionary moth were identified before the applications.  Two new parameters have  been also assessed: observation of the number of early feeding spots and the measure of egg clusters. | Results are only illustrated in histogram, no raw data provided  Cumulative moth trapping within monitoring    The results showed significant regression in catches in mating disruption treated plots compared to the number of adults captured in the untreated plots.  Comparison of mean pine processionary moth nest per tree (March 2017):    It has to be noted that the two sites treated with the dose rate of 300 balls/ha registered a real decline in the number of winter nests. A high significant difference is observed in Ovira or Dvira forest sites | a-2: Israel (Zvi Mandel -2016-2017)  EFFICACY DATA and RELEVANT INFORMATIONS  Supportive data |
| Forest - grove | Pine T Pro Ball ((13Z)-Hexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary moth *(Thaumetopoea pityocampa).* | *Assessment of the moth reduction with mating disruption using traps monitoring.* | Etang du Corra (French department of Yvelines (78):  The trial is divided in 3 mating disrupted areas (Zone 1, Zone 2, Zone 3).  The first zone (Zone 1) is composed of 6 young individual pine trees.  The Zone 2 is a grove of 17 pines  Zone 3 is a grove of 35 pines.  The pines trees were treated with the Pine T Pro Ball the 25/07/2019 with 10 balls per tree.  The traps were installed the same day. One trap in the mating disturbed area (MD area) and one trap outside of the disturbed area (non-MD area) were placed in each area (Zone 1, Zone 2, Zone 3).  The observation of traps was done at 3 dates in August (week 32, S32), September (week 36, S36) and in October (week 39, S39). | Traps results in Zone 1, Zone 2, Zone 3    The captures were very low in the non-MD area but no males were found in the MD area, which shows a significant effect of MD reducing the males number even if the application of the balls was done late in the season (the flight was already started).  The number of nests was only evaluated one single year in mating disruption area, which does not allow nests number comparison  => This test has been considered as supportive data since application has been performed after moth’s flight starting, which explains low number of captures. Furthermore, nests number before the application is unknown, thus the estimation of nests reduction number was not possible. | DELMAS L., 2021, report n°M2iD-ESS-2021-02, “EFFICACY TRIALS of the Pine T Pro Ball  for Mating Disruption of Pine Processionary Moth  (*Thaumetopoea pityocampa*)  2019-2020 FRANCE”  Supportive data |
| *Forest* | Pine T Pro Ball ((13Z)-Hexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary moth *(Thaumetopoea pityocampa).* | *Assessment of the moth reduction with mating disruption using traps monitoring.*  *Evaluation of the number of nests before the application and the year after application.* | Forêt de Gréolières (French department of Alpes-Maritimes (06)):  The trial is divided in 2 sites (Suy and Combes).  The Suy site is 3ha and the Combes site is 1,6ha.  The Suy site is composed of 640 pine trees and the Combes site is composed of 160 pine trees.  The pines trees were treated with the Pine T Pro Ball the 07/07/2019 with an average of 350 - 400 balls/ha.  The traps were installed this same day. One trap in the mating disturbed area (MD area) and one trap outside of the disturbed area (non-MD area) were placed in Suy and Combes sites. The traps were observed from July to September 2019. | Results of flight monitoring:   |  |  | | --- | --- | | Site Combes | Nb moths caught | | Untreated area (Non – MD area) | 0 | | Treated area (MD area) | 0 |  |  |  | | --- | --- | | Site Suy | Nb moths caught | | Untreated area (Non – MD area) | 1 | | Treated area (MD area) | 0 |   Results of nest count:   |  |  |  | | --- | --- | --- | | Site Combes | Before treatment | After treatment | | Treated area (MD area) | 65 | 39 |  |  |  |  | | --- | --- | --- | | Site Suy | Before treatment (2019) | After treatment (2020) | | Treated area (MD area) | 325 | 115 |   The moths’ pressure was very low on both sites in 2019. Indeed, only 1 capture was found in non-MD area of Suy site and no moth was found in the MD areas of the two sites (Suy and Combes).  However, a reduction of nests has been observed in the MD area between 2018 and 2019. In the Combes site a reduction of 40% of the nest is observed between 2018 and 2019. In the Suy site, the nests reduction reaches 64% between 2018 and 2019.  => An absence of captures in the MD area (low pressure) for the two sites and a diminution up to 40-64% of the nests was observed, showing the efficacy of the mating disruption product for nest reduction at 400 balls/ha. | DELMAS L., 2021, report n°M2iD-ESS-2021-02, “EFFICACY TRIALS of the Pine T Pro Ball  for Mating Disruption of Pine Processionary Moth  (*Thaumetopoea pityocampa*)  2019-2020 FRANCE”  RI : 2 |
| *Forest* | Pine T Pro Ball ((13Z)-Hexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary moth *(Thaumetopoea pityocampa).* | *Assessment of the moth reduction with mating disruption using traps monitoring.*  *Evaluation of the number of nests before the application and the year after application.* | Catalonia (Spain) in 2020:  The trial is divided in 5 zones and each zone had a treated plot and untreated plot. The plots size range is from 0.44ha to 10ha.  Application with respectively:  Zine 1 & 2: 160 balls/ha  Zone 3: 550 balls/ha  Zone 4:180 balls/ha  Zone 5: 70 balls/ha  The number of nests was evaluated in January 2020 (before application) and in January 2021 (after application). The number of adults moths was also followed in the treated and untreated plots using traps. | Results of nests counting before and after treatment in treated area:   |  |  |  | | --- | --- | --- | | Zone | Before treatment (2020) | After treatment  (2021) | | 1 | 400 | 81 | | 2 | 39 | 0 | | 3 | 29 | 16 | | 4 | 52 | 8 | | 5 | 48 | 105 |   Results of nests counting before and after treatment in untreated area:   |  |  |  | | --- | --- | --- | | Zone | Before treatment (2020) | After treatment (2021) | | 1 | 68 | 137 | | 2 | 15 | 13 | | 3 | 25 | 19 | | 4 | 21 | 4 | | 5 | 48 | 118 |   Results of moths captures in treated and untreated areas:    Efficacy of mating disruption on moths population in treated and untreated areas:    => Efficacy of product in forest has been demonstrated by nests reduction up to 92 - 100%, and by moths captures up to 53 - 68 % respectively in zone 1 and 2 at 160 balls/ha. | DELMAS L., 2021, report n°M2iD-ESS-2021-03, “EFFICACY TRIALS of the Pine T Pro Ball  for Mating Disruption of Pine Processionary Moth  (*Thaumetopoea pityocampa*)  2020 SPAIN”  RI : 2 |
| *Forest: Rural pine forest* | Pine T Pro Ball ((13Z)-Hexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary moth *(Thaumetopoea pityocampa).* | *Evaluation of the number of nests after application.* | Lakidain, Navarra, (Spain):  The Pine T Pro Ball application was performed on the edges of the path that ascends through the pine forest using 250 balls /0.5 ha (168 linear meters of path). The balls are distributed on both sides of the path, covering a depth of 15 m.  The application was implemented the 02/07/2020.  To attest the number of nests, 10 observed areas (composed of 10 trees each) were evaluated (number of nests) 4 months after application in the treated and untreated areas. Traps were placed in the treated areas and the non-treated areas, to monitor the pest. | Results of the flight monitoring and nest count:   |  |  |  | | --- | --- | --- | | Lakidain | Nb moths caught | Nb nest | | Untreated area | ND | 11 | | Treated area | ND | 4 |   => Despite low pressure, the nests number reduced to 63% (with regard to the untreated area) on a base of 200 trees in each plot at the dose of 250 balls/ha.  The trap placed in the treated area does not show any catch and the untreated plot trap has disappeared, thus it is not possible to conclude about moth captures efficacy. | DELMAS L., 2021, report n°M2iD-ESS-2021-03, “EFFICACY TRIALS of the Pine T Pro Ball  for Mating Disruption of Pine Processionary Moth  (*Thaumetopoea pityocampa*)  2020 SPAIN”  RI: 3  The dose tested is higher (500 balls/ha) than the claimed dose |
| *Forest: Peri-urban pine forest* | Pine T Pro Ball ((13Z)-Hexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary moth *(Thaumetopoea pityocampa).* | *Evaluation of the number of nests after application.* | Zizur, pinar de Ardoi, Navarra, (Spain) :  Application was performed on two bands:  - the southern edge of the pine forest with 125 balls/0.5 ha  - on the north edge of the delimited plot with 250 balls/0.5 ha | Results of the flight monitoring and nest count:   |  |  |  | | --- | --- | --- | | Zizur | Nb moths caught | Nb nest | | Untreated area | ND | 7 | | Treated area | ND | 0 |   => The Pine T Pro Ball application allowed a nests reduction of 100% (with regard to the untreated area) in low pest pressure condition at the dose of 250 balls/0.5 ha (500 balls/ha).  No conclusion can be made on the efficacy of the product on the males moths (trap lost). | *DELMAS L., 2021, report n°M2iD-ESS-2021-03, “EFFICACY TRIALS of the Pine T Pro Ball*  *for Mating Disruption of Pine Processionary Moth*  *(Thaumetopoea pityocampa)*  *2020 SPAIN”*  RI: 3  The dose tested is higher (500 balls/ha) than the claimed dose |
| Urban zone: groves, isolated trees | Pine T Pro Ball ((13Z)-Hexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary  *Thaumetopoea pityocampa* | Mating disruption by deposition of balls using a paintball | Cannes - 2016 (France)  2016: dose response in small areas in 6 sites (5 to 27 balls per tree). Trap captures and number of winter nests have been assessed and compared with the natural population dynamics observed in the controls plots associated. | Results 2016:    Results suggested that a minimum dose rate exposure of around 10 balls may be interesting in the case of a narrow group of 13 or more pines as well up than 25 balls may be efficient in the case of an isolated tree. Dose-rate between 1 to 10 balls/tree was not sufficient. | VI.4 Minimum effective dose tests: groves, narrow band of trees, isolated (2016-2017)  EFFICACY DATA and RELEVANT INFORMATIONS  Supportive data (qualitative results) |
| Urban zone: groves, isolated trees | Pine T Pro Ball ((13Z)-Hexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary  *Thaumetopoea pityocampa* | Mating disruption by deposition of balls using a paintball | Hospital Centre of Avignon (department 84) – France -2017:  Six small groves composed by 3 to 7 pines were selected for treatment by mating disruption with a dose rate of 30 balls/tree.  The grove 1 received finally the double dose: 60 balls/tree were fired. (30 balls/pine at 28/06/2017 followed by another application of 30 balls/pine because of the rain.  The groves 2 to 6 treated with 30 balls/tree (03/07/2017 for grove 2 and 28/06/2017 for the other groves). Two other groves defined by 5 and 8 pines respectively, were untreated and used as control. Pine T Pro Ball applications were performed before the moth flight. | The mean male moth captures did not allow to demonstrate a measurable effect or the mating disruption treatment all along the *T. pityocampa* flight in 2017  Results for the number of winter nests:   |  |  |  | | --- | --- | --- | | Mesures | Before treatment (2017) | After treatment(2018) | | Control (n\*=13) | 6.5±9.2 ns | 8.5±6.4 ns | | Treated area (n=28) | 24.67±11.36 a | 12.16 ± 5.38 b |   \*: number of trees  *Letters indicate the statistical results obtained after analysis with Wilcxon test (a,b: statistical difference (p≤0.05; ns: non significant*)    => In this urban zone, the treatment have a significant impact on the pine processionary moth population with 58% (±21%) of decline in the number of winter nests.  However the height of pines is not known therefore the claimed application rate of 1 ball per meter of height and per tree cannot be validated. | VI.4 Minimum effective dose tests: groves, narrow band of trees, isolated (2017-2018)  RI : 2  Supportive data |
| Urban zone: groves, isolated trees | Pine T Pro Ball ((13Z)-Hexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary moth *(Thaumetopoea pityocampa).* | Assessment of the moth reduction with mating disruption using traps monitoring.  Evaluation of the number of nests before the application and the year after application. | Tours de Seysses Résidence:  The trial started in 2020 and is set-up for 3 years.  Individual pines and pines groves are spread in six parts of the residence.  24 pines have been treated  The treatment has been done the 10/06/2020 with the application of 260 balls in 24 pines (average of 11 balls per pine as trees height between 8 and 15 m).  To assess the moth reduction with mating disruption, 2 traps are placed in the treated area and 1 trap is placed outside the treated area  The number of nests is also evaluated before the application and the year after the application. 250 nests were present in 2020 before the first application. | Results of moths caught counting:   |  |  | | --- | --- | |  | Nb moths caught | | Untreated area | 64 | | Treated area | 13 |   Results of nests counting:   |  |  |  | | --- | --- | --- | |  | Before treatment | After treatment | | Treated area | 250 | 48\* |   => Reduction up to of 80% of moths capture and the number of nests in pine trees of the treated area with the claimed dose of 1 ball per meter of height and per tree. | DELMAS L., 2021, report n°M2iD-ESS-2021-02, “EFFICACY TRIALS of the Pine T Pro Ball  for Mating Disruption of Pine Processionary Moth  (*Thaumetopoea pityocamp*a)  2019-2020 FRANCE”  RI : 2 |
| Urban zone: groves, isolated trees | Pine T Pro Ball ((13Z)-Hexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary moth *(Thaumetopoea pityocampa).* | Assessment of the moth reduction with mating disruption using traps monitoring. | Fontaine Roseraie Résidence (Toulouse – France):  This trial has been performed in 2019 and 2020 on 2 isolated pine trees. The pines are 12 meters high and 8 meters large and close to each other.  Two first applications were done :   * In June 2019: 20 balls per tree. * In June 2020:20 balls per tree.   To assess the efficacy of the product, 1 trap is put in a tree (MD area) and another trap is put outside of the residence in hardwood (non MD area) | Results of flight monitoring:   |  |  |  | | --- | --- | --- | |  | Before treatment (2019) | After treatment  (2020) | | Untreated area (non – MD) | 5 | 3 | | Treated area (MD) | 3 | 1 |   The pressure was very low for the 2 years (maximum 5 captures in non-MD area). Nevertheless, for the 2 years application, less males were caught in the MD area than in the untreated area. Indeed, in 2019, 3 males were caught in the treated area while 5 were found in the non-MD area. In 2020, only 1 adult was caught versus 3 in the non-MD area.  There is no data collected on nests  This trial has been considered as supportive data since no data were collected for nests and there was very low pressure, thus impact of product on the moths captures and nests reduction was not clearly demonstrated.  Moreover, the application rate (20 balls/tree) is not correlated to the one claimed with regard to the height of the pines (12 m) | DELMAS L., 2021, report n°M2iD-ESS-2021-02, “EFFICACY TRIALS of the Pine T Pro Ball  for Mating Disruption of Pine Processionary Moth  (*Thaumetopoea pityocampa*)  2019-2020 FRANCE”  Supportive data |
| Urban zone - Groves | Pine T Pro Ball ((13Z)-Hexadec-13-en-11-yn-1 acetate)  (0.1 g of active substance/ball) | Pine processionary moth *(Thaumetopoea pityocampa).* | *Assessment of the moth reduction with mating disruption using traps monitoring.*  *Evaluation of the number of nests before the application and the year after application.* | Jean de La Fontaine school in Gujan-Mestrats (France) :  An average of 10 balls per trees were applied in 2020 on the 17 trees of the grove. The number of nests was counted before the application and the year after the application.  For flight monitoring, one trap was placed in the treated grove and another trap was placed in an isolated tree in the untreated area. | Results of moths caught counting:   |  |  | | --- | --- | |  | Nb moths caught | | Untreated area | 25 | | Treated area | 3 |   Results of nests counting:   |  |  |  | | --- | --- | --- | |  | Before treatment  (2020) | After treatment | | Treated area | 20 | 0-3\* |   => Reduction up to of 88% of moths capture and 85% of nests in pine trees of the treated area, with 10 balls/pine. However the height of pines is not known therefore the claimed application rate of 1 ball per meter of height and per tree cannot be validated. | DELMAS L., 2021, report n°M2iD-ESS-2021-02, “EFFICACY TRIALS of the Pine T Pro Ball  for Mating Disruption of Pine Processionary Moth  (*Thaumetopoea pityocampa*)  2019-2020 FRANCE”  Supportive data |

Field tests were conducted with the product PINE T PRO BALL to show the efficacy of the mating disruption treatment with the sexual confusion method against pine processionary moth.

The applicant claims both a reduction of pine processionary caterpillars in treated areas and a reduction of pine processionary nests.

PINE T PRO BALL is intended to be applied before the appearance of the Pine Processionary moths, once a season, in forests at respectively up to 400 balls/ha in forests, and in urban areas (groves, narrow band of trees, isolated trees) at the application rate of 1 ball per meter of height and per tree. The number of balls per hectare varies depending on the area to be protected and the density of the trees.

The product tested in some studies before 2019 differs slightly from the product PINE T PRO BALL. Nevertheless, the read across is acceptable as the co-formulant (anti-foam agent) present in the tested formulation and removed from the current composition of PINE T PRO BALL hasn’t impact on the efficacy of the product. Furthermore, the tested product contains 4% w/w of active substance which is bit lower than the content of active substance in PINE T PRO BALL (4.12 % w/w).

* **For use in forests**:

Four trials conducted in forest demonstrate nest reduction at the claimed dose of 400 balls (40 g of active substance) / ha. Moths capture has been demonstrated in three of them.

- The first test conducted in 2016-2017 (site Col d’Eze, France), shows 85% of reduction of moths capture and 74% of nests reduction at the dose of 400 balls/ha.

- The second trial, conducted in 2017-2018, in the same trial site of 2016-2017 (site Col d’Eze, France), shows some evidences that the sentinel traps from the 400 balls/ha treated plots tend to catch consistently less pine processionary moths than the rest of the test system (16.3 against 28.5 in the control), and only 36 % of the reduction of pine processionary caterpillar nests with 400 balls/ha in winter 2018. The applicant explained this drop by the decrease of processionary pine dynamic population.

* The third trial conducted in 2019 (Forêt de Gréolières) doesn’t demonstrate reduction of capture’s moth in treated areas because of low pressure of moths. However, a nests reduction of 40 to 64% was observed in both treated areas at the dose of 400 balls/ha.
* The last trial provided and conducted in Catalonia (Spain) in 2020 showed 53 to 68 % of capture moths reduction, and 92 – 100% of nests reduction in treated areas, at the dose of 160 balls/ha.

The trials conducted in Lakidain and Zizur (Spain) are not accepted as the tested dose (500 balls/ha) was higher than the claimed dose (400 balls/ha).

Supportive data have been provided with trials in Israel and France.

* Trial in Israel demonstrates regression in catches is also shown. Specific assessments have been also performed: the observation of the number of early feeding spots and the measure of egg clusters. The evaluation of these two new parameters demonstrates with the treatment at 300 balls /ha less early feeding spots per tree in comparison of the natural *T. pityocampa* larvae behaviour in the untreated plot. This decrease is also confirmed with the number of egg clusters which was significantly reduced in the 300 balls/ha treated plot in Dvira forest.
* Trial in Etang du Corra (France) where the application has been performed after moths’ flight starting and explains low number of capture. Furthermore, nest number before the application is unknown, thus the estimation of nests reduction number was not possible.

Efficacy conclusion for use in forests: based on the submitted trials, it can be concluded that the product PINE T PRO BALL shows efficacy of the mating disruption treatment against pine processionary moth by both a reduction of pine processionary caterpillars and a reduction of pine processionary nests, in forests at the dose of 400 balls/ha.

* **For use in urban areas** (groves, narrow band of trees, isolated trees):

Three trials demonstrate nests and moth capture reduction:

* A first trial (site Avignon) with small planted grove plots trials, which assessed the number of winter nests in trees between winter of 2017 and 2018, demonstrated a significant decline in the number of nests after treatment (58%) at 30 balls/ha (height of trees unknown), but not on all the sites.
* A second trial (site Tour de Seysses) with individual pines and pines groves spread in six parts of a residence, treated with the dose 11 balls/pine (height of trees between 8 and 15m), showed a reduction of 80% of moths capture and nests number.
* A thirst trial (site Jean de la Fontaine) with 17 trees treated with 10 balls/ha (height of trees unknown), in a residence showed a reduction of 88% of moths capture and up to 85% of nests in pine trees of the treated area.

Efficacy conclusion for use in urban areas: The field tests conducted in urban zones (on isolated trees) showed both a reduction of moths capture and nests number. The application rate claimed of 1 ball per meter of height and per tree showed a sufficient efficacy on at least one site tested.

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| **Conclusion on the efficacy of the product** |
| Based on the elements presented in the frame of provisional authorisation, reduction of pine processionary caterpillars and nests in pine areas is demonstrated , in forest and urban areas, at the following application rates:   * In forests at the dose of 400 balls /ha * In urban areas (groves, narrow band of trees, isolated trees): 1 ball per 1 m of height and per tree   However due du certain bias or incomplete information in the protocols for the efficacy studies presented, new efficacy studies (especially for urban areas) should be submitted at product authorisation, in order to confirm the efficacy at the application rates claimed and in various situations (forests, groves, narrow band of trees, isolated trees) with significant level of infestations. |

#### Occurrence of resistance and resistance management

No report has described resistance to the active substance (13Z)-Hexadec-13-en-11-yn-1 acetate due to mating disruption treatment.

The authorization holder should report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management at the renewal of the active substance.

#### Known limitations

It is recommended not to apply the product when rainfall is announced within 12 hours.

#### Evaluation of the label claims

Based on the elements presented and the claims of the applicant, FR eCA considers that efficacy of PINE T PRO BALL was demonstrated for the following uses:

* In forests at the dose of 400 balls /ha
* In urban areas (groves, narrow band of trees, isolated trees): 1ball per 1 m of height and per tree.

To ensure a satisfactory level of efficacy and avoid the development of resistance, 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) None.

### Risk assessment for human health

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | No data available for the product.  The active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate is not classified for Skin corrosion and irritation.  The product is not classified for Skin corrosion and irritation. |
| Justification for the value/conclusion | According to the rules laid down in Regulation (EC) No 1272/2008 (CLP) (calculation method), taking into account all the co-formulants, the product is not classified.  Please refer to Confidential Annex for further details. |
| Classification of the product according to CLP | Not classified |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | No data available for the product.  The active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate is not classified for Eye irritation.  The product is not classified for Eye irritation. |
| Justification for the value/conclusion | According to the rules laid down in Regulation (EC) No 1272/2008 (CLP) (calculation method), taking into account all the co-formulants, the product is not classified.  Please refer to Confidential Annex for further details. |
| Classification of the product according to CLP | Not classified |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | No data available for the product.  The active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate is not classified for respiratory tract irritation.  The product is not classified for respiratory tract irritation.  According to the rules laid down in Regulation (EC) No 1272/2008 (CLP) (calculation method), taking into account all the co-formulants, the product is not classified.  Please refer to Confidential Annex for further details. |
| Classification of the product according to CLP | Not classified. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | No data available for the product.  The active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate is not classified for skin sensitisation.  The product is not classified for skin sensitisation. |
| Justification for the value/conclusion | According to the rules laid down in Regulation (EC) No 1272/2008 (CLP) (calculation method), taking into account all the co-formulants, the product is not classified.  Please refer to Confidential Annex for further details. |
| Classification of the product according to CLP | Not classified |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | No data available for the product. |
| Justification for the value/conclusion | The product is not classified for skin sensitisation and is not expected to be respiratory sensitizer. |
| Classification of the product according to CLP | Not classified |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | No data available for the product.  The active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate does not present any acute oral toxicity.  The product is not classified for acute oral toxicity. |
| Justification for the selected value | According to the rules laid down in Regulation (EC) No 1272/2008 (CLP) (calculation method), taking into account all the co-formulants, the product is not classified.  Please refer to Confidential Annex for further details. |
| Classification of the product according to CLP | Not classified |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | No data available for the product. |
| Justification for the selected value | No test with the active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate for acute toxicity via inhalation was necessary since:  - vapour pressure is < 0.01 Pa (1.2 10-3 Pa at 25°C)  - the product is not a powder and is not applied in a manner that generates exposure to aerosols, particles or droplets of an inhalable size (MMAD <50 μm).  According to the rules laid down in Regulation (EC) No 1272/2008 (CLP) (calculation method), taking into account all the co-formulants, the product is not classified for acute toxicity via inhalation. |
| Classification of the product according to CLP | Not classified |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | No data available for the product.  The active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate does not present any acute dermal toxicity. |
| Justification for the selected value | According to the rules laid down in Regulation (EC) No 1272/2008 (CLP) (calculation method), taking into account all the co-formulants, the product is not classified for acute dermal toxicity.  Please refer to Confidential Annex for further details. |
| Classification of the product according to CLP | Not classified |

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | (13Z)-Hexadec-13-en-11-yn-1-yl acetate |
| Value(s)\* | No dermal absorption derived for the substance |
| Justification for the selected value(s) | Considering the specific context of application via a passive diffuser such as paintballs (PINE T PRO BALL) and the resulting very low exposure, no dermal absorption study was necessary for the active substance.  No dermal contact with the product is neither expected during the product application. No dermal absorption has to be derived. |

***Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)***

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, no co-formulant has been identified as SOC.

***Available toxicological data relating to a mixture***

Not relevant.

***Other***

Not relevant.

#### Exposure assessment

**Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product**

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | NA | no | NA | NA | no | no | - |
| Dermal | NA | no | NA | NA | no | no | - |
| Oral | NA | no | NA | NA | no | no | No |

***List of scenarios***

***Primary exposure***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1. | Paintball gun loading | Balls loaded into the paintball gun | professionals |
| 2. | Post application | Collection of the balls fallen on the ground during application | professionals |

**Professional users:**

Pine T pro Balls are packed in plastic/aluminium bags (500 balls per package) and are protected by a biodegradable polymer shell that prevents any passage of the active substance to the outer compartment. In addition, the protection of the shell prevents any inhalation of the active substance when opening the ball bag or when loading the ball into the Paint ball gun.

For the application, the balls are loaded into the paint-ball gun thanks to a closed reservoir. The handling of balls is performed using protective gloves to prevent any contact with the material. The balls are shot on the top of the pine trees (about 10 meters from the ground). Under impact, the balls burst and gel formulation is applied on the trunks closed to canopy. After water evaporation, a film containing pheromone is left on the trunk. This film is a passive diffuser that will slowly diffuse the (Z13)-hexadec-13-en-11-yn-1-yl- acetate on a controlled way in a very short diffusion radius of around 2 meters. Indeed, due to its low vapour pressure (VP = 1,2.10-3 Pa at 20°C), the active substance is located at the top of the trees in the air compartment. Furthermore, thanks to the high position of the film containing the pheromone (close to canopy), and knowing that the content of the pheromone decreases with distance from the point of emission, its concentration at human level can therefore be considered as very low.

In conclusion:

No inhalation of the active substance is expected when opening the ball bag or when loading the balls into the paintball gun.

The application of the balls is performed via a paintball gun.

During the collection of the balls fallen on the ground, exposure via dermal route is also considered as very low.

Moreover, gloves are worn during all phases.

* Thus, professional exposure to the product, before, during and after PINE T PRO BALL product application, is considered very low.

***Secondary exposure***

**General public:**

The product Pine T Pro Ball is applied in the zone to be treated once a year before adult emergence, starting in May or June depending on the region.

Before application, a safety perimeter (approximately 10 meters) is to be set and marked to avoid the presence of the general public.

During application, the projection speed of the balls is to be set to the minimum. The shooting must take place from 5 to 10 meters from the target, and must be located inside the land and not towards the outside. Consequently, the shooting will avoid the traffic lanes, the houses, the animals or people.

In case of a ball misses the tree and falls after shooting, it will burst when impacting the ground and it is very unlikely that some balls will remain intact.

Regarding the potential debris ending up on the ground, the active substance being trapped in the matrix, if any diffusion occurs, it will be on a very slow mode.

After application in urban zone, no balls or debris are to be left on the ground.

In forest zone, which is less frequented by the general public, the only debris that can be left on the ground because they are not found, are therefore expected to be in non accessible spots.

In conclusion:

No secondary exposure of the general public is foreseen as balls will be directly shot and burst in the canopy of pine trees (7-10 meters high).

The content of the pheromone decreases with distance from the point of emission, its concentration at 2 meters from the ground (human level) is therefore very low.

Moreover, the balls fallen on the ground will be collected.

* Thus, sufficient measures are followed before, during and after application of the formulated pheromone in order to protect the general public. In these conditions, the exposure to the pheromone of the general public can be considered very low.

***Industrial exposure***

Not applicable. The product PHEROBALL PIN is intended for professional use only.

***Professional exposure***

*Scenario [n]*

1

***Non-professional exposure***

Not relevant. The product PHEROBALL PIN is intended for professional use only.

***Exposure of the general public***

***Monitoring data***

None

***Dietary exposure***

Not relevant as no contamination of food or feed is expected based on the localized application on the tree trunks.

#### Risk characterisation for human health

No reference values have been derived.

**Maximum residue limits or equivalent**

Not required.

***Risk for industrial users***

Not applicable. The product PHEROBALL PIN is intended for professional use only.

***Risk for professional users***

Considering the method of application of the product PINE T PRO BALL and the characteristics of the product, the resulting exposure is very low and the risk for professional users is acceptable.

Local effects

Not relevant

***Risk for non-professional users***

Not applicable. The product PINE T PRO BALL is intended for professional use only.

***Risk for the general public***

Considering the method of application of the product PINE T PRO BALL and the characteristics of the product, the resulting exposure is very low and the risk for the general public is acceptable.

Local effects

Not relevant

**Conclusion for professional users and general public**

The assessment of the risk for human health during the use of the product PINE T PRO BALL has been carried out for the active substance only (no substances of concern have been identified).

Considering the method of application of the product PINE T PRO BALL (outdoors, in the upper part of the pine canopy, using a paintball gun), the professional exposure is considered very low and the risk is acceptable only if the following risk management measures are applied:

- Wear gloves during all phases of use (loading, application and collection of balls on the ground).

- During the application, a safety perimeter (approximately 10 m) must be set to avoid the presence of the general public.

- After application in forests, inspect carefully the area and pick up all the fallen balls.

- After application in urban zone, make sure that no balls or debris are left on the ground.

The risk for the general public is then considered acceptable.

***Risk for consumers via residues in food***

Not relevant as no contamination of food or feed is expected based on the localized application on the tree trunks.

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

Not relevant

### Risk assessment for animal health

As for general public, the risk for animal health is considered acceptable.

### Risk assessment for the environment

PHEROBALL-PIN is a PT19 product containing (13Z)-Hexadec-13-en-11-yn-1-yl acetate (CAS No. 78617-58-0, 4.46% w/w technical value) as active substance. The product formulation is contained in small balls designed to be applied outdoor with air/paintball guns in the upper third of the pine tree canopy for the management of the caterpillar moth infestation.

No substance of concern is present in the product, therefore the risk assessment is conducted with the active substance only.

#### Effects assessment on the environment

No new environmental studies have been carried out with the product PHEROBALL-PIN. All data pertaining to the active substances are therefore derived from the application for approval of the active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on PNEC values** | | | | | |
|  | **PNECSTP** | **PNECwater** | **PNECsed**  **(EPM)** | **PNECsoil initial (EPM)** | **PNECoral,birds** |
|  | [mg/L] | [mg/L] | [mg/kgww] | [mg/kgww] | [mg/kg] |
| (13Z)-Hexadec-13-en-11-yn-1-yl acetate | n.r | 4.50E-05 | n.r | 6.78E-04 | n.r |

*PNECsediment:*

As PNEC sediment is derived by EPM from the freshwater data, the risk ratio PEC/PNECsediment is the same than PEC/PNECsurfacewater. Thus, the risk for the sediment compartment is not presented. Moreover, this calculation is not relevant since the exposure is considered negligible for this type of application.

*PNECSTP:*

PNECSTP was not calculated in the CAR of the active substance. Indeed, it is not relevant since the exposure of the environment is considered negligible for this type of application.

***Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required***

The active substance, (13Z)-Hexadec-13-en-11-yn-1-yl acetate is classified H400/H410, with acute and chronic M-factors of 10. By calculations, the product PINE T PRO BALL is therefore classified H400/H410 for the environment according to Regulation (EC) No.1272/2008 (CLP) (please refer to the revised CAR of the active substance dated January 2021).

***Further Ecotoxicological studies***

No new ecotoxicological studies have been carried out with the product PINE T PRO BALL.

***Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk. |
| Justification | Available ecotoxicity data on the active substance pheromone are considered sufficient to assess the toxicity of the product.  In addition, as explained in section 2.2.8 of the PAR, the particular mode of application of the product leads to negligible environmental exposure.   * Based on this assessment, no additional ecotoxicological study with the product was conducted to address this point. |

***Supervised trials to assess risks to non-target organisms under field conditions***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Supervised trials to assess risks to non-target organisms under field conditions. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. It is not relevant for the product PINE T PRO BALL used as its final form is a gel stuck to the trunk of the trees. In addition, as explained in section 2.2.8 of the PAR, the particular mode of application of the product leads to negligible environmental exposure.  Therefore, no additional study is deemed necessary to address this point. |

***Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. It is not relevant for the product PINE T PRO BALL used as its final form is a gel stuck to the trunk of the trees. In addition, as explained in section 2.2.8 of the PAR, the particular mode of application of the product leads to negligible environmental exposure.  Therefore, no additional study is deemed necessary to address this point. |

***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Studies on secondary ecological effect. |
| Justification | As explained in section 2.2.8 of the PAR, the particular mode of application of the product leads to negligible environmental exposure.   * Therefore, no additional study is deemed necessary to address this point. |

***Foreseeable routes of entry into the environment on the basis of the use envisaged***

As the active substance is used in a passive diffuser, the main route of emission to the environment is by gaseous phase to the atmosphere where the active substance becomes diluted. Therefore, no deposition of the substance on the ground is expected as the substance is not carried away by particles contrary to active diffusers that propel the active substances with a vector. Environmental exposure is considered very limited but calculations of redeposition via air to water and soil have been conducted to support this statement.

***Further studies on fate and behaviour in the environment (ADS)***

As explained in section 2.2.8 of the PAR, the particular mode of application of the product leads to negligible environmental exposure. Then, no new studies on fate and behavior in the environment have been carried out with the product PINE T PRO BALL.

***Leaching behaviour (ADS)***

No data is available

***Testing for distribution and dissipation in soil (ADS)***

No data is available

***Testing for distribution and dissipation in water and sediment (ADS)***

No data is available

**Distribution**

No data is available

***Testing for distribution and dissipation in air (ADS)***

No data is available

***If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Overspray study to assess risks to aquatic organisms or plants under field conditions. |
| Justification | The product PINE T PRO BALL is not intended to be used by spray.   * Based on this assessment, no additional study with the product was conducted to address this point. |

***If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Overspray study to assess risks to bees and non-target arthropods under field conditions. |
| Justification | The product PINE T PRO BALL is not intended to be used by spray.   * Based on this assessment, no additional study with the product was conducted to address this point. |

#### Exposure assessment

General information

|  |  |
| --- | --- |
| Assessed PT | PT19 |
| Assessed scenarios | - |
| ESD(s) used | None |
| Approach | - |
| Distribution in the environment | Volume IV Part B+C, 2017 |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: No Formulation No Use: Yes Service life: No |
| Remarks |  |

##### ***Emission estimation***

##### Redeposition *via* the air compartment

As the active substance is used in a passive diffuser, the main route of emission to the environment is by gaseous phase to the atmosphere.

As explained in the Guidance document on semiochemical active substances and plant protection products-2016, the semiochemical diffuses continuously from the device into the air where the active substance becomes diluted (2A Passive non-retrievable dispensers according to the guidance). Therefore, no deposition of the substance on the ground was expected as the substance is not carried away by particles contrary to active diffusers that propel the active substances with a vector and no environmental exposure was expected.

At WG-IV-2021, it was nevertheless agreed that quantitative exposure calculations were needed to support this statement.

For this quantitative assessment, it is considered that the active substance can also adsorb on air particles and may subsequently deposit on the ground (soil or surface water). A standardised scenario, the Gaussian plume model OPS, is proposed in the Volume IV Part B+C (2017) to estimate deposition fluxes, usually used for the calculation of PECsoil after air redeposition. It is further used to estimate the PECsurfacewater.

All the calculations are conducted according the equations of the Volume IV Part B+C (2017).

1. Elocalair calculations:

|  |  |  |  |
| --- | --- | --- | --- |
| **Elocalair calculations** | | | |
| **Parameters** | **Value** | **Unit** | **Ref** |
| Qai, the quantity of active substance applied / ha | 40 | g/ha | Maximum application rate |
| Tmax | 2160 | h | 3 months |
| FAI | 1 | [-] | - |
| Tday | 24 | h | Passive dispenser |
| Fapplication,floor | 1 | [-] | - |
|  | | | |
| **Elocalair** | 4.44E-04 | kg/d/ha | O – Qai x FAI x Fapplication,floor x (Tday / Tmax) x 1.10E-03 |

1. DEPtotal,ann calculations (equation 47 of the Volume IV Part B+C, 2017):

The total deposition flux during emission episode (DEPtotal) was calculated without considering any emission from the STP (ESTPair), as it does not correspond to the emission pattern of the pheromone.

|  |  |  |  |
| --- | --- | --- | --- |
| **DEPtotal,ann calculations** | | | |
| **Parameters** | **Value** | **Unit** | **Ref** |
| CONjunge x SURFaer | 1.00E-04 | Pa | D |
| VP | 1.20E-03 | Pa at 20°C | S |
| **Fass,aer** | 7.69E-02 | - | O – Equation 21 |
| DEPtotal | 5.06E-07 | kg/d | O - Equation 46 |
| Temission | 90 | d | 3 months |
| DEPstd,aer | 1.00E-02 | mg/m²/d | D |
| DEPstd,gas | 4.00E-04 | mg/m²/d | D value |
|  | | | |
| **DEPtotal,ann** | 1.25E-07 | mg/m²/d | O – Equation 47 |

##### Accidental exposure pathways

In addition to redeposition of the a.s *via* air, two accidental situations are examined:

- the professional user misses his target (the pine trunk) and the ball falls to the ground,

- the product leaches to the ground following heavy rainfall.

For the rare cases where the trained professionals miss their target, the following RMM is applied:

"After application, inspect carefully the area and pick up all the fallen balls."

According to the applicant, the product dries 12 hours after application, then adheres perfectly to the trunk and the pheromone starts diffusing. There is no loss of active substance if it is raining after this waiting period because the dry product is stable in presence of water. Indeed, the dry product is a film made of hydrophobic materials (oil, waxes, pheromone nearly insoluble…) that prevent the leaching of the active substance. Therefore, a use instruction related to the efficacy of the product already states that it is recommended to apply the balls to the trees on a rain-free day and if no rainfall is expected within 12 hours of application, the minimum time for the formulation to dry and become hydrophobic.

Even if the instruction of use is accidentally disregarded, it has to be taken into consideration that the product is applied on the trunk, just below the canopy, about 10 m from the ground. Thus, the formulation will be protected by the structures of the trees (branches, tufts of needles) that constitute the canopy. If the rainwater still reaches the formulation, largely hydrophobic, it will be spread over the 10 m length of the trunk before reaching the ground.

For all these reasons, emissions to the soil during a raining event are considered negligible and thus, a quantitative evaluation is not carried out and no PEC are calculated.

***Fate and distribution in exposed environmental compartments***

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Groundwater |
| Emission | + | - | - | - | - | ++ | + | - |

-: no exposure

+: limited exposure

++: exposure

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 278.43 | g/mol |  |
| Vapour pressure (at 20°C) | 0.0012 | Pa | CAR (2020), Experimental value, extrapolated at 20°C |
| Water solubility (at X°C) | 0.12 | mg/l | CAR (2020), Experimental value |
| Log Octanol/water partition coefficient | 3.75 | Log 10 | CAR (2020), Experimental value |
| Organic carbon/water partition coefficient (Koc) | 847.6 | l/kg | CAR (2020), QSAR (KOCWIN v2.0, Kow method) |
| Henry’s Law Constant (at 25°C) | 5.7 | Pa/m3/mol | CAR (2020), Experimental value |
| Biodegradability | - | - | No experimental data available. QSAR (BIOWIN v4.10) indicates that the substance is not P/vP in a Woe approach (CAR,2020) |
| DT50 for biodegradation in surface water | 1.00E+06 | d (at 12ºC) | No data available, very worst case value is used in exposure assessment |
| DT50 for degradation in soil | 1.00E+06 | d (at 12ºC) | No data available, very worst case value is used in exposure assessment |
| DT50 for degradation in air | 3.5 | hr | CAR (2020), QSAR (AOPWIN v1.92) |

##### ***Calculated PEC values***

##### Redeposition via the air compartment

Very conservative input values have been taken into account in the PEC calculations, even though the mode of use and the nature of the active substance theoretically result in very limited exposure:

* 10 years of continuous application, which is not the intended use,
* k values derived from very worst case DT50soil and DT50surfacewater default values of 1E6 days, while pheromone generally degrades rapidly in the environment,
* A depthsoil of 0.05 m,
* No degradation in the atmosphere, although a DT50 in air of 3.5 hours (maximal value) is stated for this active substance.

k values for soil and water were derived from these worst case input values and from e-fate parameter values defined for the active substance in this document:

|  |  |
| --- | --- |
| **SOIL** | |
| Kbiosoil | 6.93E-07 |
| Kvolat | 3.92E-04 |
| kleach | 3.75E-04 |
| Totalremoval | 7.67E-04 |
| **SURFACE WATER** | |
| kbiowater | 6.93E-07 |

Equations for the calculations of PECsoil after air redeposition in Volume IV Part B+C (2017) are used and are adapted to estimate the PECsurfacewater.

1. Concentration in Soil

|  |  |  |  |
| --- | --- | --- | --- |
| **PECsoil calculations** | | | |
| **Parameters** | **Value** | **Unit** | **Ref** |
| **DEPtotal,ann** | 1.25E-07 | mg/m²/d | Emission calculation |
| DEPTHsoil | 0.05 | m | D |
| RHOsoil | 1700 | kg/m3 | D |
| ksoil = Totalremoval | 7.67E-04 | - | S – no biodegradation |
| **Dair** | 1.47E-09 | mg/kg/d | O – equation 58 |
|  | | | |
| **PECsoil = Cdepsoil10(0)** | 1.80E-06 | mg/kg | O – equation 60 |

1. Concentration in Surface water

|  |  |  |  |
| --- | --- | --- | --- |
| **PECsurfacewater calculations** | | | |
| **Parameters** | **Value** | **Unit** | **Ref** |
| **DEPtotal,ann** | 1.25E-07 | mg/m²/d | Emission calculation |
| DEPTHwater | 0.5 | m | D |
| RHOwater | 1000 | kg/m3 | D |
| Kwater | 6.93E-07 | - | S – no degradation |
| **Dair** | 2.50E-10 | mg/kg/d | O – adapted equation 58 |
|  |  |  |  |
| **PECsurfacewater = Cdepsurfacewater10(0)** | 1.80E-06 | mg/L | O – adapted equation 60 |

Considering the worst-case input values leading to very low PEC values for soil and surface water, it was concluded during the WG-IV-2021 that exposure for this specific product can be considered negligible.

***Primary and secondary poisoning***

Primary poisoning

It is not believed that gels without food attractant are in a form that could be sufficiently appetent to bird or mammals so they would be at risk (ESDTP18, 2008).

Secondary poisoning

As negligible exposure is foreseen (see [Environmental exposure assessment](#_Environmental_exposure_assessment)), no quantitative risk assessment is needed.

#### Risk characterisation

***Atmosphere***

Conclusion:Concerning the atmosphere, emissions to air from biocidal uses are not relevant. The pheromone degrades quickly in the air due to the low DT50 value of 3.5h (maximum value).

***Aquatic compartment including Sewage treatment plant (STP), terrestrial compartment, groundwater.***

Considering the worst-case input values and the very low PEC values for soil and surface water, it was concluded during the WG-IV-2021 that the exposure for this specific product can be considered negligible. Therefore, based on this qualitative assessment, no RCR was calculated and the risks were considered acceptable.

As a note:

According to the former Guidance “Guidance for Waiving of Data Requirements for Pheromones for Inclusion in Annex I/IA of Directive 98/8/EC”, a natural background of 375 g of Straight Chain Lepidopteran Pheromones/ha/year was generally understood to result in exposure levels which comparable to natural emissions and safe for non-target species. This value is no longer used as a threshold *stricto sensu* in more recent PPP Guidances (OECD Guidance Document 93)[[3]](#footnote-4), but it shows that the maximum active substance emissions (40 g of pheromone/ha/year) are approximately 10 times lower than the background value of 375 g/ha/year used in the initial guidelines.

***Non-target Insects***

According to the OECD Guidance Document 93, semiochemicals are more target specific than conventional insecticides and are expected to dissipate rapidly in the atmosphere. Indeed, when adult processionnary moths search for mates at the top of pine trees, it is crucial that the signals exchanged between males and females are species-specific enough for an effective mating. Therefore, the processionary's signals will not interfere with the intra-species communications of other insects.

Concerning the toxicity to other arthropods, the non-target insects actually exposed *via* the air compartment would be limited to those that also live at the top of the pines, where the product is sufficiently concentrated and where they are already in a disturbed environment because of the processionary caterpillar invasion. The others, living nearby would be exposed to much lower concentrations (considered negligible in soil and water). Moreover, in the SCLP RAR of PPP (2021), acetate pheromones does not present any toxicity for bees and no data on other arthropod species was considered necessary because of the negligible exposure.

***Primary and secondary poisoning***

Primary poisoning

It is not believed that gels without food attractant are in a form that could be sufficiently appetent to bird or mammals so they would be at risk (ESDTP18, 2008).

Secondary poisoning

As negligible exposure is foreseen (see [Environmental exposure assessment](#_Environmental_exposure_assessment)), no quantitative risk assessment is needed and no risk is foreseen for secondary poisoning.

***Mixture toxicity***

As negligible exposure of the environment is foreseen for the active substance, mixture toxicity assessment is not relevant.

***Aggregated exposure (combined for relevant emission sources)***



*Figure 1: Decision tree on the need for estimation of aggregated exposure*

Not relevant.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| Acceptable risks are reached for the environment for the treatment of pine (urban or forest area) with a paintball application by professional user, considering negligible exposure of the environment with:  - the following RMMs: “After application, inspect carefully the area and pick up all the fallen balls.”,  - the following instruction of use: “Use the product on rainless days only and if no rainfall is expected within 12 hours of application”. |

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

*??*

### Assessment of a combination of biocidal products

Not relevant.

# Annexes

## 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)** |
| VERONES Valérie | 2018 | Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 °C ± 2 °C on XP CS PIN (Emulsion, water in oil)  DEFITRACES  Report No. 18-913034-003  GLP  Unpublished | Y | M2i |
| VERONES Valérie | 2018 | Physico-chemical tests on XP CS PIN (Emulsion, water in oil)  DEFITRACES  Report No. 18-913034-001  GLP  Unpublished | Y | M2i |
| VERONES Valérie | 2021 | Physico-chemical tests and chemical stability after a storage procedure for 24 months at 20 °C ± 2 °C on XP CS PIN (Emulsion, water in oil)  DEFITRACES  Report No. 18-913034-004  GLP  Unpublished | Y | M2i |
| VERONES Valérie | 2018 | Physico-chemical tests after a low temperature storage procedure for 7 days at 0 ± 2 °C on XP CS PIN (Emulsion, water in oil)  DEFITRACES  Report No. 18-913034-002  GLP  Unpublished | Y | M2i |
|  | 2020 | Report M2iD-DEV-2020-03 “Assessment of potential hazard properties of the active substance (Z)-13-hexadecen-11-yn-1-yl acetate and Pine T Pro Ball product”  Non GLP  Unpublished | Y | M2i |
| VERONES Valérie | 2018 | Validation of the analytical method for the determination of (13Z)-Hexadec-13-en-11-yn-1-yl acetate In XP CS PIN  DEFITRACES  Report No. 18-913034-005  GLP  Unpublished | Y | M2i |
| MAGNET Stéphanie | 2018 | Identification of SCLP impurity (13Z)-Hexadec-13-en-11-yn-1-yl acetate by GC-MS  N°CHRONO: M2ID-ANA-2018-18  N°PROJET: M2ID-RECH 1632  GLP  Unpublished | Y | M2i |
| Martin JC. | 2017 | OPTIMPHERO Report On Product Efficiency 2015 2018  Non GLP  Unpublished | Y | M2i |
| Léa Delmas |  | DELMAS L., 2021, report n°M2iD-ESS-2021-02, “EFFICACY TRIALS of the Pine T Pro Ball  for Mating Disruption of Pine Processionary Moth  (*Thaumetopoea pityocampa*)  2019-2020 FRANCE” | Y | M2i |
| Léa Delmas |  | DELMAS L., 2021, report n°M2iD-ESS-2021-03, “EFFICACY TRIALS of the Pine T Pro Ball  for Mating Disruption of Pine Processionary Moth  (*Thaumetopoea pityocampa*)  2020 SPAIN” | Y | M2i |
| DE COZAR K. | 2018 | « Summary of mating disruption field trials on the pine processionary  (according to the Optim’Phero project report) »  M2i Development  M2iD-FAI-2018-17 V01  Non GLP  Unpublished | Y | M2i |
| M2i | 2019 | « Efficacy trials argument: Efficacy data and relevant information »  M2i Development  Unpublished | Y | M2i |

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 [↑](#footnote-ref-2)
2. Female calling behaviour and male reponse to the sex pheromone in *Thaumetopoea pityocampa* (Den. & Schiff)(Lep., *Thaumetopoeidae*) [↑](#footnote-ref-3)
3. Guidance document on semiochemical active substances and plant protection products Series on Pesticides No. 93, 2018 [↑](#footnote-ref-4)