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

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

(submitted by the evaluating Competent Authority)



VELUTINA

Product type 18

Permethrin

Case Number in R4BP: BC-LV046847-99

Evaluating Competent Authority: France

Date: May 2020

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# CONCLUSION

The biocidal product VELUTINA is a permethrin PT18 product intended to be used as an insecticide against hornets *Vespa velutina*, for professional and non-professional users.

The product is intended to be applied directly as a drop between the head and the thorax of the hornet that has been previously captured. Once released, it is assumed that the contaminated hornet gets back to the nest and contaminate the entire nest. The objective of the treatment is the destruction of the hornet nest and the reduction of the predation pressure in apiaries.

***Conclusion for physico-chemical properties and analysis methods***

The physico-chemical properties of the product VELUTINA have been described and are considered in accordance with the conditions of use specified in the SPC in the appendix.

The analysis methods are considered to be acceptable.

***Conclusion on efficacy:***

FR CA is of the opinion that the data package provided does not allow to validate the claim of destruction of the nest.

However, the provided efficacy data demonstrate that the product reduces the predation pressure of Asian hornets (*Vespa velutina*) for appiaries containing up to 10 hives in the conditions of use specified in the SPC . Several treatments may be necessary to lower the number of hornets and keep the predation pressure to an acceptable level.

In case of high pressure level, the efficacy of the product VELUTINA is not demonstrated.

***Conclusion of risk characterisation for Human Health***

The risk for professional beekeepers is considered as acceptable without gloves. The risk for non-professional beekeepers is considered as acceptable.

***Conclusion of risk characterisation for Consumer***

Regarding the intended use of VELUTINA, a contamination of honey cannot be excluded.

An estimation of dietary exposure for children and adults was performed. These estimations are considered as a worst case. According to the results, no dietary risk was identified for children and adults considering the directions for use.

***Conclusion of risk characterisation for Environment***

The use of the product is very specific and as no harmonized scenario exists, FR CA has chosen to add a risk mitigation measure as precautionary measures to be sure that the use of VELUTINA product will not lead to unacceptable risk for the aquatic and terrestrial compartments. This approach is very conservative.

Specific instructions of use:

* “The treatment must be carried out with the floor mat supplied with the product”.
* “Capture and processing accessories (net, floor mat, etc) must be cleaned with disposable absorbent paper towels and not with water”.

Risk mitigation measures:

* “Do not use next to the aquatic compartment”.
* “When possible, remove the empty nest and dead insects at the end of the treatment”.
* “Do not use near poultry houses”.
* “Hazardous to bees”.
* “Prevent any release to the environment during the product application phase “

**OVERALL CONCLUSION:**

FR CA considers that the product VELUTINA shall be authorized according to article 19(1) for the following uses:

|  |  |  |
| --- | --- | --- |
| **Target organisms** | **Application rates** | **Use conditions** |
| *Vespa velutina*  Diminution of the predation pressure at the apiary. | One droplet of 25 mg of product / hornet | Professional  Outdoor  5 to 50 hornets per apiary.  To be used in appiaries containing up to 10 hives. |

With the following RMMs:

* Do not use near an aquatic environment.
* Do not use near poultry houses.
* When possible, remove the empty hornet nests at the end of the treatment.
* Prevent any release to the environment during the product application phase.
* Hazardous to bees

Considering the complex application method that requires hornet manipulations and consequently protection equipments to prevent hornet stings, FR CA considers that the product cannot be authorized for non professional uses.

Post-authorization data:

* The long-term storage stability study (48 months) has to be provided as a post-authorization data.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| VELUTINA | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Spring |
| **Address** | 4, rue Blaise Pascal  Z.I du Bois de Leuze  13310 Saint-Martin-de-Crau  France |
| **Authorisation number** | **FR-2021-0010** | |
| **Date of the authorisation** | **23/02/2021** | |
| **Expiry date of the authorisation** | **22/02/2022** | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | Spring |
| **Address of manufacturer** | 4, rue Blaise Pascal  Z.I du Bois de Leuze  13310 Saint-Martin-de-Crau  France |
| **Location of manufacturing sites** | 4, rue Blaise Pascal  Z.I du Bois de Leuze  13310 Saint-Martin-de-Crau  France |

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

|  |  |
| --- | --- |
| **Active substance** | Permethrin |
| **Name of manufacturer** | Tagros |
| **Address of manufacturer** | Jhaver Centre, Raja Annamalai  Building, IVth Floor  72 Marshall Road, Egmore  600008 Chennai  India |
| **Location of manufacturing sites** | A-4/1&2, Spicot Industrial Complex  Pachayankuppam Cuddalore  607005, Tamilnadu  India |

### 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** | Permethrin |
| **IUPAC or EC name** | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate |
| **EC number** | 258-067-9 |
| **CAS number** | 52645-53-1 |
| **Index number in Annex VI of CLP** | 613-058-00-2 |
| **Minimum purity / content** | ≥ 93% w/w sum of all isomers |
| **Structural formula** | Image illustrative de l’article Perméthrine |

#### Candidate(s) for substitution

#### The active substance contained in the biocidal product is not candidate for substitution in accordance with Article 10 of BPR.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Technical Content (%)** | **Pure content (%)** |
| --- | --- | --- | --- | --- | --- | --- |
| Permethrin | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 0.086 | 0.080 |
| Propan-2-ol |  | Solvant | 67-63-0 | 200-661-7 | 0.1263 |  |

#### Information on technical equivalence

The plant production of the technical active substance is authorized at EU level, it is the plant location indicated in the CAR.

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

The product VELUTINA contains the following substance of concern: Propan-2-ol.

Please see the confidential annex for further details.

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

According to our assessment, none of the formulants contained in the product VELUTINA are identified as endocrine disruptors.

However, there are indications that one co-formulant shows some effect on endocrine organs.

Base on available information, it is not possible to conclude whether this co-formulant should be considered to have ED properties or not. This co-formulant is currently assessed in the frame of REACH Regulation. In case this co-formulant is finally identified as ED, the biocidal product will be considered as ED and the authorisation of the family products will have to be revised accordingly.

#### Type of formulation

|  |
| --- |
| AL – Any other liquid |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Corrosive to metal category 1  Aquatic Chronic 1 |
| Hazard statement | H410: Very toxic to aquatic life with long lasting effects.  H290: May be corrosive to metals. |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H410: Very toxic to aquatic life with long lasting effects.  H290: May be corrosive to metals. |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand.  P102: Keep out of reach of children.  P103: Read carefully and follow all instructions.  P273: Avoid release to the environment.  P391: Collect spillage.  P501: Dispose of the contents/container in an approved hazardous waste collection centre, in accordance with local, regional, national and/or international regulations. |
|  | |
| Note |  |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Hornet Treatment – Professional

|  |  |
| --- | --- |
| **Product Type** | PT18 – Insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** | The product Velutina is a ready-to-use insecticide to be applied directly on yellow-legged hornets *Vespa velutina* which is finally released. This has to be done on as many hornets as possible without exceeding 50 hornets per day per apiary.  The product is to be used for the diminution of the predation pressure at the apiary. The destruction of the nest is not guaranteed.  The product should only be used in apiaries containing up to 10 hives. |
| **Target organism (including development stage)** | *Vespa velutina*, adults. |
| **Field of use** | Outdoor. |
| **Application method(s)** | Direct treatment of hornets.  Each captured hornet is treated with a droplet of product applied between the head and the thorax. The hornet is then released. |
| **Application rate(s) and frequency** | One droplet of 25 mg of product / hornet |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | 50 mL LDPE pipette with a LDPE cap. |

#### 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

|  |
| --- |
| * Always read the label or leaflet before use and respect all the instructions provided. * The product is not intended to be used in apiaries containing more than 10 hives. * The product Velutina is a ready-to-use insecticide to be applied directly on the Asian hornet (or yellow-legged hornet) *Vespa velutina,* with a specific device (net + sheet + transparent guide) provided with the product. * First, each hornet has to be captured with a net and immobilised. * Secondly, a droplet of the product is applied between the head and the thorax of the hornet, which is finally released. * Only one droplet is sufficient to treat one hornet. * The product is to be used to decrease the predation pressure. The destruction of the nest of not guaranteed. * The product should only be used in apiaries containing up to 10 hives. * The product is not to be used in case of high infestation. * Beyond a frequentation of 25 hornets per hour on the whole apiary, the product VELUTINA loses its effectiveness due to a too populous nest or too many nests. Beyond 50 hornets per hour over the entire apiary, the product is no longer effective. * Treat as many hornets as possible, with a maximum of 50 hornets per day per apiary, over a short period (one day during 1 to 2 hours = 5 to 50 hornets). It is recommended to treat 5 to 10 hornets per apiary and per day at the beginning of the summer; 10 to 25 hornets / apiary / day in mid-summer; 25 to 50 hornets / apiary / day at the end of summer. * Observe the results 3 days later. If hornets are still present around the hives, renew the treatment as many times as needed. * A better effectiveness is awaited if treatment is performed early on the season (July-August), when the hornets’ nests are still small. * Capture and processing accessories (net, floor mat, etc.) must be cleaned with disposable absorbent paper towels and not with water. * The treatment must be carried out with the floor mat supplied with the product. * In case of inefficacy further control methods must be adopted. * Inform the registration holder if the treatment is ineffective. |

#### Risk mitigation measures

|  |
| --- |
| * During use of the product, it is strongly suggested to wear protective suit and gloves protecting from hornet. * Hazardous to bees. * Do not use near an aquatic environment. * Do not use near poultry houses. * When possible, remove the empty hornet nests at the end of the treatment. * Prevent any release to the environment during the product application phase. |

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

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

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

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

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

|  |
| --- |
| * Keep out of reach of children and domestic animals. * 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)** |
| Pipette | 50 mL | LDPE | a LDPE cap | Professional and non-professional | Yes |

### Documentation

#### Data submitted in relation to product application

Not relevant.

#### Access to documentation

SPRING SARL has access to data of the active substance Permethrin with a Letter of Access from LIMARU NV, one applicant who has access to the complete Tagros dossier applicant of active substance Permethrin submitted at EU level.

## Assessment of the biocidal product

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

The product Velutina is a specific method of fight against the Asian hornet (or yellow-legged hornet) *Vespa velutina* to be used outdoors, by beekeepers only (professional and non-professional), on apiaries*.* It is a ready-to-use insecticide to be applied directly on the Asian hornet*,* with a specific device provided with the product. First, each hornet has to be captured with a net and immobilised. Secondly, a droplet of the product (25 mg) is put between the head and the thorax of the hornet, which is finally released. Treat as many hornets as possible, with a maximum of 50 hornets per day per apiary. Back at their nest, the product will diffuse in the nest *via* the vector hornet. By this way, many adults, and possibly the queen, receive a dose of the biocidal product, and die. This may lead to the destruction of the colony, and in any case, allows a reduction of the predation pressure of the hornets on the apiaries. The effect is observed 3-5 days after application on hornets.

It is intended to be used by professional and non-professional beekeepers only.

Table 2. Intended use # 1 – Hornet Treatment – Professional and Non-professional.

|  |  |
| --- | --- |
| Product Type(s) | PT18 – Insecticides, acaricides and products to control other arthropods |
| Where relevant, an exact description of the authorised use | The product Velutina is a ready-to-use insecticide to be applied directly on yellow-legged hornets *Vespa velutina*. |
| Target organism (including development stage) | *Vespa velutina*, adults. |
| Field of use | Outdoor |
| Application method(s) | Direct treatment of hornets.  Each captured hornet is treated with a droplet of product (25 mg), put between the head and the thorax. The hornet is then released. |
| Application rate(s) and frequency | 25mg of product / hornet |
| Category(ies) of user(s) | Professional and non-professional (beekeepers only) |
| Pack sizes and packaging material | 50 mL LDPE pipette with a LDPE cap. |

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Reference** | **Results** | **FR comments** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual observation | Product Velutina Batch number: 1860 Containing 0.080% w/w of permethrin | Demangel B., 2018 Report no. 17-919062-002, Défitraces | Brown viscous liquid (before and after 14 days at 54 ± 2°C). | Acceptable |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa | No guideline required | Product Velutina Batch number: 1860 Containing 0.080% w/w of permethrin | Demangel B., 2018 Report no. 17-919062-002, Défitraces | The product Velutina has a characteristic odour. | Acceptable |
| Acidity / alkalinity | CIPAC MT 75.3 | Product Velutina Batch number: 1860 Containing 0.080% w/w of permethrin | Demangel B., 2018  Report no. 17-919062-002,  Défitraces | Before storage, the pH of the pure test item Velutina was 4.42 at  19.9°C after 1 min.  After 14 days at 54 ± 2°C in its commercial packaging (transparent LDPE pipette), the pH of the pure test item Velutina was 4.43 at 19.0°C after 1 min. | Acceptable |
| Relative density / bulk density | OECD 109  (pycnomete  method) | Product Velutina Batch number: 1860 Containing 0.080% w/w of permethrin | Demangel B., 2018  Report no. 17-919062-001,  Défitraces | The mean relative density of the test item Velutina was D (20°C /  4°C) = 1.341 ± 0.001. | Acceptable |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  Method validated in study No. 17-919062-004 | Product Velutina Batch number: 1860 Containing 0.080% w/w of permethrin | Demangel B., 2018  Report no. 17-919062-002,  Défitraces | |  |  |  | | --- | --- | --- | |  | T=0 | After 14 days at 54°C | | Physical state | Brown viscous liquid with a  characteristic odour (after  homogenisation) | Brown viscous liquid with a characteristic odour (without  homogenisation) | | Packaging | Transparent LDPE pipettes  (commercial packaging) | No sign of degradation or leak | | AS content (% w/w) | 0.0750 | 0.0780 | | Variation (%) | / | +4% | | pH pure test item | 4.42 at 19.5°C after 1 min | 4.43 at 18.8°C after 1 min | | Weight | 82 g | 81.4 g | | Variation of weight % | / | -0.7% |   In commercial packaging (transparent LDPE pipette) | Acceptable  The preparation is stable 14 days at 54°C. |
| Storage stability test – **long term storage at ambient temperature** |  |  | Demangel B., 2019  Certificate of stability after 6 and 12  months,  Défitraces | The storage stability study has been performed with a transparent LDPE pipette.   |  |  |  |  | | --- | --- | --- | --- | |  | T=0 | After 6 months at 20°C | After 12 months at 20°C | | Physical state | Brown viscous liquid with a characteristic odour(after homogenisation) | No change | No change | | Packaging | Transparent LDPE pipettes (commercial packaging) | No change | No change | | AS content (% w/w) | 0.0750 | 0.0769 | 0.0766 | | Variation (%) | - | +2.53% | +2.13 | | The preparation is stable 12 months but some data are required: pH and weight of the packaging. The long-term storage stability study (48 months) is on-going and final study is requested in post-registration. |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | Product Velutina Batch number: 1860 Containing 0.080% w/w of permethrin | Demangel B., 2018  Report no. 17-919062-001,  Défitraces | |  |  | | --- | --- | | Observations | Cones 1 & 2 | | At the start of the test | Brown opaque liquid with solid particles in suspension | | After 7 days at 0 ± 2°C | Brown opaque liquid with solid particles in suspension | | After 7 days at 0 ± 2°C wet sieve test | Mass retention: 0.0%. No residue of the test item on a 75µm sieve. | | After the undisturbed period and inverting the cones | Brown opaque liquid with solid particles in suspension |   The appearance of the test item was considered to be stable after a low temperature stability for 7 days at 0 ± 2°C, no change was observed in the appearance of the test item. | The preparation is stable 7 days at 0°C. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | - | Not required according to the Assessment Report of permethrin  (Product Type 18, April 2014): permethrin does not absorb >290 nm which indicates that the molecule is not photosensitive | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | - | See correspondant sections | Concerning the impact of humidity, according to the composition, no modification of the product is expected. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | - | See the storage stability test | - |
| Wettability | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Suspensibility, spontaneity and dispersion stability | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Wet sieve analysis and dry sieve test | CIPAC MT 39.3 and 185 | Product Velutina Batch number: 1860 Containing 0.080% w/w of permethrin | Demangel B., 2018  Report no. 17-919062-001,  Défitraces | |  |  | | --- | --- | | After 7 days at 0 ± 2°C wet sieve test | Mass retention: 0.0%. No residue of the test item on a 75µm sieve. | | Acceptable |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Disintegration time | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Persistent foaming | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Flowability/Pourability/Dustability | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Burning rate — smoke generators | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Burning completeness — smoke generators | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Composition of smoke — smoke generators | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Spraying pattern — aerosols | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Physical compatibility | - | - | - | Not applicable. VELUTINA is a ready-to-use product and is not  intended to be used in conjunction with any other products or active substances. | - |
| Chemical compatibility | - | - | - | Not applicable. VELUTINA is a ready-to-use product and is not  intended to be used in conjunction with any other products or active substances. | - |
| Degree of dissolution and dilution stability | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Surface tension | OECD 115 | Product Velutina  Batch number: 1860  Containing 0.080%  w/w of permethrin | Demangel B., 2018  Report no. 17-919062-001,  Défitraces | Due to the composition of the product Velutina, the experimental  measurements of surface tension were unsuccessful. The explanation of the notifier:”Indeed, the method of the ring is not suitable given the viscosity of the product. The method of the plate was tried but did not give satisfactory results. As it is technically impossible to carry out the measure, no particular request is expected.  Study N ° 17-919062-001 has therefore been amended in this sense in order to cancel this measure (refer to Amendment N ° AMD-P-1-17-919062-001 presented on page 30 of this study for more technical detail on the impossibility of carrying out this measurement).In addition, the product does not contain hydrocarbon so no risk is expected regarding aspiration toxicity.” | Acceptable.  the surface tension should be measured on aqueous solution of the product |
| Viscosity | OECD 114 | Product Velutina  Batch number: 1860  Containing 0.080%  w/w of permethrin | Demangel B., 2018  Report no. 17-919062-001,  Défitraces | The mean dynamic viscosity of the product Velutina was found to be 1265 mPa\*s at 20.0 ± 0.2°C and 215 mPa\*s at 40.0 ± 0.2°C. The test item was considered to have newtonian properties in the  experimental conditions used. | Acceptable  However, the result could not conclude on the Newtonian properties as the viscosity has not been determined at different shear rate. |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The product VELUTINA is an any other liquid (AL) formulation. 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 brown viscous liquid with a characteristic odour. There is no effect of high temperature nor low temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The long-term storage stability study (48 months) is on-going and final study is requested in post-registration. However, based on the stability data available a shelf life of at least 2 years at ambient temperature when stored in transparent LDPE pipette (commercial packaging material) is proposed.  Its technical characteristics are acceptable for an AL formulation. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Reference** | **Results** | **FR comment** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Statement | - | - | Test is not required as the product Velutina contains more than 93% w/w of honey and water, which are inert components and not classified as explosive. Furthermore, there are no chemical groups associated with explosive properties present in the molecules.  The product Velutina is not explosive. | Acceptable, the product as no explosive properties. |
| Flammable gases | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Flammable aerosols | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Oxidising gases | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Gases under pressure | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Flammable liquids | Statement | - | - | The product Velutina is not flammable.  Test is not required as the product Velutina contains more than 93% w/w of honey and water, and only 4.21% w/w of an ingredient classified as Flam. Liq. 2, H225. | Acceptable, no further data required |
| Flammable solids | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Self-reactive substances and mixtures | - | - | - | The product Velutina is not self-reactive.  Test is not required as the product Velutina contains more than 93% w/w of honey and water, which are inert components and not classified as self-reactive. Furthermore, no other component contained in the product is classified as self-reactive. | - |
| Pyrophoric liquids | Statement | - | - | The product Velutina is not a pyrophoric liquid.  Test is not required as the product Velutina contain more than 93% w/w of honey and water, which are inert components, and as the other components are not classified as pyrophoric. Moreover, experience in manufacture and handling shows that the product Velutina does not ignite spontaneously on coming into contact with air at normal temperature. | Acceptable.  The product is not a pyrophoric liquid. |
| Pyrophoric solids | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Self-heating substances and mixtures | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Substances and mixtures which in contact with water emit flammable gases | - | - | - | The product Velutina does not emit flammable gases in contact with water.  Test is not required as the product Velutina contains water (as solvent and as a component of honey) and forms a stable mixture | - |
| Oxidising liquids | - | - | - | Test is not required as the product Velutina contains more than 93% w/w of honey and water, which are inert components and not classified as oxidising. Furthermore, no other component contained in the product is classified as oxidising. mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen. | Acceptable.  The product has no oxidising properties. |
| Oxidising solids | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Organic peroxides | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Corrosive to metals | Statement | - | - | The product Velutina is not corrosive to metals.  Test is not required as the product Velutina does not contain any component classified as corrosive to the metals. It is halogen-free, does not contain any bases and complexing agents and only contains 0.11% of oleic acid. Furthermore, its pH at 20°C is only slightly acid (4.43).  The product will therefore be classified H290 by default. | Acceptable.  The product is classified H290 |
| Auto-ignition temperatures of products (liquids and gases) | Statement | - | - | The product Velutina is not expected to present a significant hazard for auto-flammability.  Test is not required as Velutina contains more than 93% w/w honey and water, which are inert components, and as the other constituents are not considered to be auto-flammable based on available data on their safety data sheets. | Acceptable.  The product has no auto-ignition properties. |
| Relative self-ignition temperature for solids | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |
| Dust explosion hazard | - | - | - | Not required, BP is a ready-to-use liquid formulated as an  AL (other liquid). | - |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is neither flammable nor auto-flammable. It has no explosive properties and oxidising properties.  The product is classified H290: corrosive to metals. |

### Methods for detection and identification

#### Dosage of permethrin

Report: RICAU, 2018, Validation of the analytical method for the determination of permethrin in the product VELUTINA

Report no 17-919062-004

Test facility:

DEFITRACES

Z.A. des Andrés

150, rue Pré-Magne

69126 BRINDAS

FRANCE

Principle of the method:

Permethrin is analysed after extraction from the formulation with methanol and quantified by liquid chromatography using a reverse phase column and a UV detector (λ=225 nm). Permethrin is analysed by Liquid Chromatography by external standard calibration, at retention times of about 11.7 min for trans-permethrin peak and 12.9 min for cis-permethrin peak.

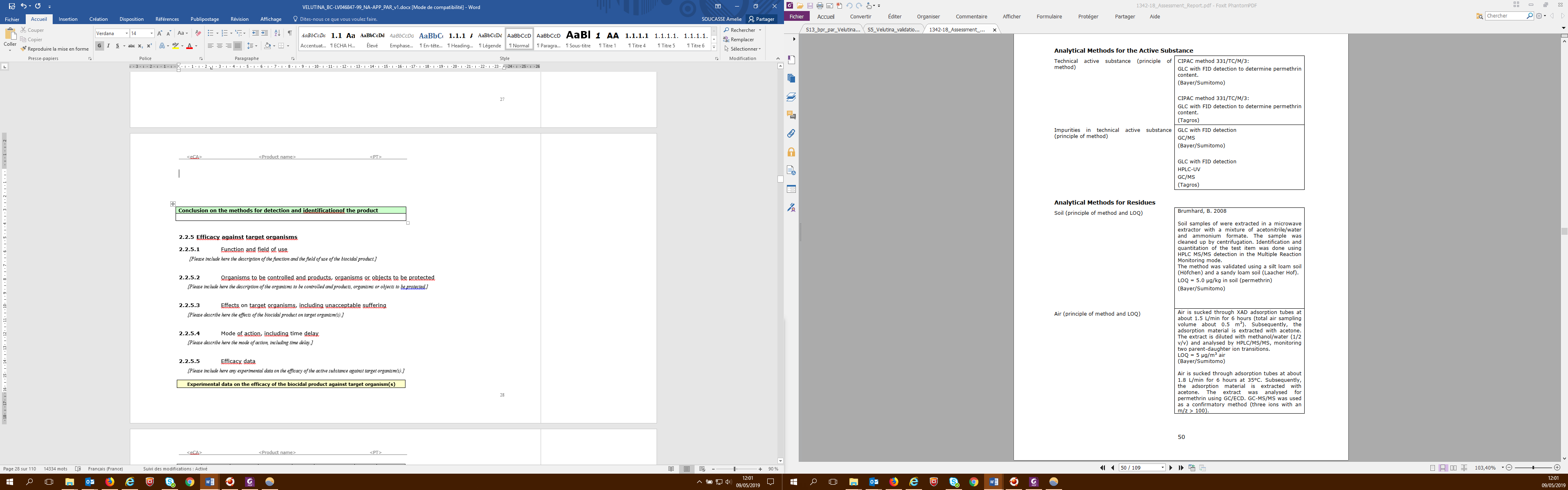
The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

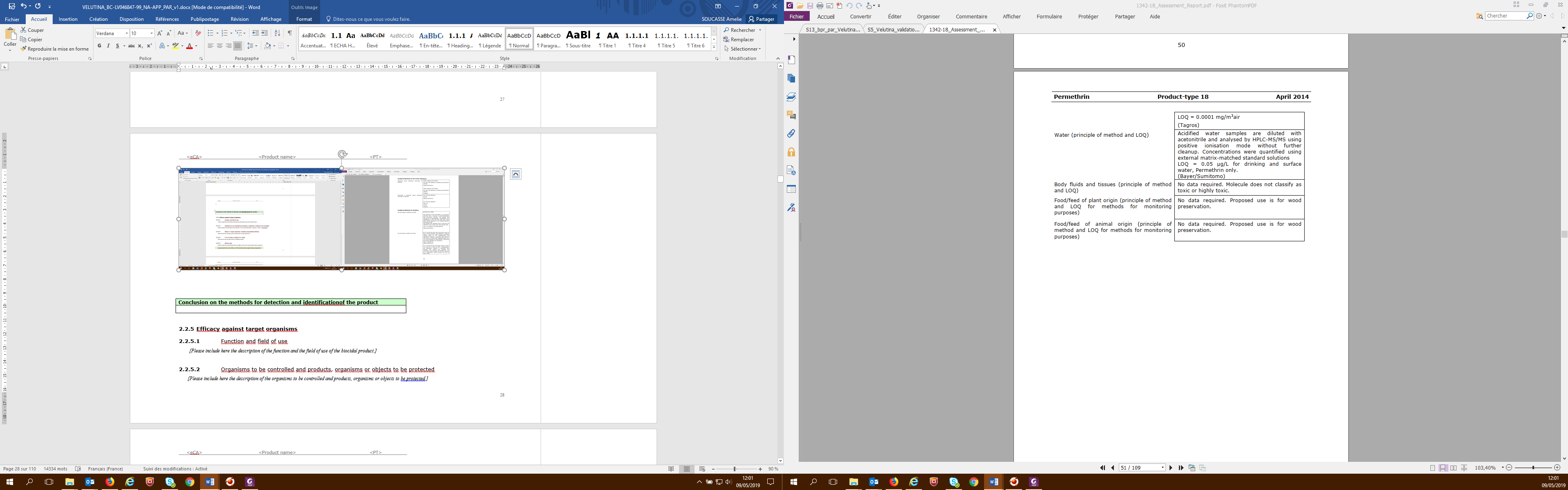
Validation data:

|  |  |
| --- | --- |
|  | Permethrin |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * Reference item of the active substance permethrin * Blank (solvent MeOH) * Formulation blank * Test item of the product |
| Linearity | Linearity was studied by carrying out 5 concentrations between 7.64-23.48 mg permethrin/L.  Calibration curve has been provided with a r2 higher than 0.99. |
| Precision | Precision was evaluated by replicate analyses of the test item (n = 5). The concentration of permethrin in the test item was equal to 0.0765% w/w or 0.765 g/kg. |
| Repeatability (RSD) |
| RSD = 1.21% |
| Accuracy | The accuracy was determined by comparison of the reference items and two reconstituted samples (blank formulation + known amount of reference item). (n = 5) The accuracy results are expressed as the recovery rate.   |  |  |  |  | | --- | --- | --- | --- | | Fortification level mg/L | Recovery rate | Mean recovery rate | n | | 15.30 | 104.3; 104.4 | 104.3 | 2 | | 15.30 | 104.9; 104.0 | 104.5 | 2 | |

The ratio between cis- and trans-permethrin was studied during the precision and reproducibility analysis. The percent area (%) of cis- and trans-permethrin was calculated: 74.8% of trans-permethrin and 25.2% of cis-permethrin.

The analytical method is fully validated for the determination of the active substance permethrin in the product. However, a new analytical method allowing the quantification of each enantiomer should be provided at the renewal of the product.





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| **Conclusion on the methods for detection and identificationof the product** |
| The analytical method is fully validated for the determination of the active substance Permethrin in the product. However, a new analytical method allowing the quantification of each enantiomer should be provided at the renewal of the product.  Analytical methods were provided at EU level for the determination of active substance residue in soil with LOQ = 5.0 µg/kg.  Analytical methods were provided at EU level for the determination of active substance residue in water with LOQ = 0.05 µg/L.  Active substance permethrin is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required.  Analytical method for the determination of permethrin in food/feed of plant and animal origin is not required. |

### Efficacy against target organisms

#### Function and field of use

Main Group 03: Pest Control

Product Type 18: Repellents and attractants

The product Velutina is a ready-to-use insecticide intended to be applied directly on the Asian hornet (or yellow-legged hornet) *Vespa velutina,* with a specific device provided with the product (Pictures are available in Document "Velutina\_Mode d'emploi 1\_1218".).

It is intended to be used outdoors, by professional and non-professional beekeepers only.

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

The product Velutina is used to kill adult Asian hornets, *Vespa velutina*. Killing Asian hornets allows to reduce their predation pressure on apiaries. Nest killing is also claimed.

The organisms to be protected are humans, but also bees.

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

According to the applicant, the product Velutina has the purpose to kill the hornets in their nest. Indeed, each treated hornet is not directly killed, but is a vector for the product to the nest. Back to their nest, the product will diffuse in the nest *via* the vector hornet. By this way, many adults, and possibly including the queen, receive a dose of the biocidal product, and die after a few hours/days.

This allows a reduction of the predation pressure of the hornets on the apiaries and, this can also lead to the complete destruction of the colony. The effect is observed 3-5 days after application on hornets.

The active substance content in the product has been chosen so that the hornets are not knocked-down or even killed too quickly after treatment. According to the applicant, this allows them to fly back to the nest, where they will share the product through trophallaxis. Death of the contaminated hornets is expected to be achieved within the 2-3 days following treatment.

#### Mode of action, including time delay

See permethrin Assessment Report, PT18, April 2014.

Permethrin is a neurotoxin. It is a synthetic pyrethroid acting after ingestion or contact.

The target organisms, hornets inside the nest, are in contact with the product brought back by the treated hornets.

Asian hornets are social Hymenoptera, and as such, trophallaxis is used inside nest, between adults and to feed the larvae (Couto, 2017; Poidatz, 2018). This allows contamination of hornets inside the nest from hornets treated with Velutina.

Once ingested, the product causes convulsions, paralysis and ultimately death in target organisms. Permethrin is a type I axonic poison which exerts its effects by means of hyperexcitation of both the peripheral and central nervous systems of target insects. It binds to a protein in nerves (voltage-gated sodium channel). Normally, this protein opens causing stimulation of the nerve and closes to terminate the nerve signal. Pyrethroids bind to this gate and prevent it from closing normally which results in continuous nerve stimulation. The effects are characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. Permethrin also induces hepatic microsomal enzymes.

#### Efficacy data

Four studies were conducted. The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

Three of these studies were submitted in order to demonstrate the mode of action of the product. But, these studies were not designed to support the claims (reduction of the predation pressure of the hornets on the apiaries and the destruction of the colony).

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| PT18 | Outdoor | Solution containing ethanol (6-8%), water, liquid honey, propolis extract and permethrin.  Permethrin from 0.00 to 0.80% w/w. | Asian hornet  *Vespa velutina* | Screening test to determine the optimal active substance concentration: Captured Asian hornets are treated with a droplet (25 mg) of a solution containing permethrin, and their flying capacity is then evaluated.  The contact time which causes incapacity to fly for hornets is the time interval between treatment and the moment when the hornets do not try anymore to fly. | Test system: once treated, each hornet is released under a 1 L glass jar, placed in the shade. Once under the glass jar, the hornet tries to fly away and buzz at the top of the jar. After a while, corresponding to the measured contact time, the hornet remains on the ground and no longer tries to fly. It hurdles up, and even with the jar open, the hornet is no longer trying to fly.  Replicates:   * in 2016, 4 hornets for each content in permethrin but not replications. * in 2017, 10 hornets for each treatment but no replications.   The product has been applied with the Velutina kit (net + sheet + transparent guide sold with the product). But, the real quantity of product applied during the test has not been measured. | Contact time before incapacity to fly, depending on the permethrin content in the solution:  - 0.00% w/w: > 30 min  - 0.01% w/w: 13.8 min  - 0.02% w/w: 8.3 min  - 0.04% w/w: 7.8 min  **- 0.08% w/w (2016): 6.0 min**  **- 0.08% w/w (2017): > 6.5 min**  - 0.10% w/w: 5.5 min  - 0.12% w/w: 4.6 min  - 0.20% w/w: 4.5min  - 0.40% w/w: 3.3 min  - 0.80% w/w: 1.8 min  The 0.08% w/w content has been chosen for the biocidal product Velutina. After treatment, the hornets can still fly for 6.5 minutes, which could allow them to go back to their nests and exchange with their congeners, according to the applicant.  However, considering the absence of replications and the fact that the exact quantity of product applied is not known, these results are not considered as robust enough to conclude on the contact time before incapacity to fly. | Jaillard B., 2017 S6.7\_01  R = 3  Supportive data |
| PT18 | Outdoor | Velutina containing 0.08% w/w permethrin | *V. velutina* | Determination of the effect of permethrin by contact or by ingestion on the behaviour of Asian hornets (flying capacity, mobility capacity and death). | Velutina is applied either on the head of the captured hornet = contact, or is proposed to the hornet near its mandibles = ingestion. In both cases, only one droplet is used to treat one hornet (exact quantity was not measured).  Controls: same treatment, but with Velutina product without active substance.  Test system: once treated, each hornet is released under a glass jar, placed in the shade. When under the glass jar, three time periods are measured for each hornet:  1) the period during which it tries to fly (flying period),  2) the period during which it moves on the ground (mobility period),  3) the period during which it huddles up before death (death period).  6 hornets were treated for each application method, and for the controls.  No replication | For contact treatment (mean and standard deviation):  - flight period: 7.2 ± 3.0 min  - mobility period: 88 ± 17 min  - death period: 183 ± 32 min  Treated hornets lose their capacity to fly within 7 minutes, their capacity to move within approx. 1.5 hours, and die 3 hours after contact with the product.  For ingestion treatment (mean and standard deviation):  - flight period: 13.8 ± 3.5 min  - mobility period: 140 ± 28 min  - death period: > 240 min  Treated hornets lose their capacity to fly within 14 minutes, their capacity to move within approx. 2.5 hours, and die more than 4 hours after ingestion of the product.  Velutina acts on hornets by contact and also by ingestion.  However this test cannot permit to conclude that the product will be spread through the colony by trophallaxis.  Furthermore, considering the absence of replications and the fact that the exact quantity of product applied is not known, these results are not considered as sufficiently robust. | Jaillard B., 2019  S6.7\_04  RI=3 |
| PT18 | Outdoor | Velutina containing 0.08% w/w permethrin | *V. velutina* | Field study on a nest near a hive.  Determination of the capacity of treated hornets to go back to their nests and precise mode of action of Velutina. | 19 hornets captured near the hive near the hornets' nest have been marked with white paint on 2019/08/20.  To assess the efficacy of the Velutina product on the nest, 10 hornets have been treated with Velutina on 2019/08/22.  Also, 3 hornets have been both treated with Velutina and marked with blue paint on 2019/08/24.  Activity of the nest is assessed by counting hornets entering and leaving the nest during 30 minutes periods at different time of the day. This has been done between 2019/08/08 and 2019/08/24, before destruction of the nest by aspiration on 2019/08/25.  The quantity of product applied during the test is not mentioned in the test report. | From 19 hornets marked: 1 hornet was observed entering in the nest and 5 leaving the nest. However, a decrease of nearly 33% in the activity of hornets can be observed in the results (between 18/08/2020 and 21/08/2020).  There is a decrease of activity (-49%) around the nest one day after treatment. Much less hornets were also observed around the hive near the nest but predation pressure was not measured and reported.  The second treatment of 3 hornets associated with a blue marking had no effect between the morning and the afternoon; the next day the nest was destructed by aspiration and no counting was performed thus the effect of his second treatment on the activity has not been assessed.  At the opening of the nest, 46 hornets were recovered and amongst them 10 (7 white + 3 blue) of 22 (19+3) marked hornets were counted. It can be concluded that 45% of the hornets marked at the apiary belonged to this nest. Cells provided with nymphs and larvae were also observed in this nest, but no cells containing eggs. No queen was recovered. And as the nest was destructed at the end of the test, no conclusion on transmission through trophallaxis can be made.  This study demonstrates that some treated hornets went back to their nest when located around 100 m from an apiary but does not permit to conclude on the transmission of the product through trophallaxis. | Jaillard B., 2019  S6.7\_05  RI=3  Supportive data |

**1) Study by Jaillard B., 2017:**

This study is a screening test, which aimed at choosing the adequate permethrin content for the product Velutina. Indeed, for the whole process to be effective the treated hornets must keep their flight capacity and have sufficient time to go back to their nest and exchange with their congeners before dying. The 0.08% w/w content has been chosen for the biocidal product Velutina. After treatment, the hornets can still fly for 6.5 minutes, which could allow them to go back to their nests, according to the applicant.

However, this test cannot be considered as sufficiently robust (low number of treated hornets, no replication, absence of quantification of the product applied) but can only be considered as supportive data.

**2) Study by Jaillard B., 2019 (S6.7\_04):**

The aim of this study was to determine the effect of permethrin by contact or by ingestion on the behaviour of Asian hornets, in particular its effect on their flying capacity, and maintenance of this capacity. Captured Asian hornets are treated with a droplet of the product Velutina, by contact or by ingestion, and their behaviour (flying capacity, mobility capacity and death) is then evaluated. However, this study does not permit to demonstrate the effect through trophallaxis. Indeed, the treatment per ingestion is not sufficient to demonstrate that the product will be spread through the colony by trophallaxis as it does not assessif a contaminated hornet can transfer the insecticide to hornets that have never been exposed to it before.

Moreover, only 6 hornets per treatment have been tested and no replications have been performed.

Thus, this test cannot be considered as sufficiently robust to conclude on time delay of action (flying capacity, mobility capacity and death) of the product Velutina on a hornet when applied as claimed

**3) Study by Jaillard B., 2019 (S6.7\_05):**

This field study has been performed on one nest and aimed at demonstrating the capacity of treated hornets to go back to their nests and at specifying the mode of action of Velutina.

The activity of the colony was assessed by counting hornets entering and leaving the nest during 30 minutes periods at different time of the day.

An apiary at approx. 100 m served as bait:

1) Day 0: 19 hornets were marked with white paint to see if they returned to the identified nest (next day)

2) Day 2: 10 hornets were then captured and treated with Velutina but not marked and activity of the nest was observed.

3) Day 4: 3 hornets were captured treated and marked with blue paint and activity of the nest was observed.

4) Day 5: destruction of the nest by aspiration and counting of the hornet population.

Following comments can be made on this study:

* From 19 hornets marked: 1 hornet was observed entering in the nest and 5 leaving the nest. This means that some of the hornets marked at the apiary belonged to the nest and returned to it when marked. The test report concludes that "This confirms that even after manipulation and "treatment" according to the Velutina process, hornets keep their normal behaviour, can return to the nest and are still active". However, after the marking of hornets a decrease of nearly 33% in the activity of hornets can be observed in the results (between 18/08/2020 and 21/08/2020). Thus, it cannot be concluded that manipulation or marking has no impact on the activity of the nest.
* The number of treated hornets is low (10) and as these hornets were not marked the proportion of treated hornets going back to the nest is not known. There is a decrease of activity around the nest one day after treatment but as no further study has been performed it cannot be concluded that this variation is really due to the product.
* The second treatment of 3 hornets associated with a blue marking had no effect between the morning and the afternoon; the next day the nest was destructed by aspiration and no counting was performed thus the effect of his second treatment on the activity has not been assessed.
* At the opening of the nest 10 (7 white + 3 blue) out of 22 (19+3) marked hornets were counted. It can be concluded that at least 45% of the hornets marked at the apiary belonged to this nest.
* The test report mentions that the treatment has permitted to reduce the predation pressure at the apiary, however no precise information (no measures) are given on the predation pressure in the test report.
* Regarding the absence of eggs, the applicant concludes that as an egg hatches 3 days after its laying, it can be deduced that the queen has stopped laying 3 days before, so at least 2019/08/22, which is when 10 hornets were treated with Velutina. Thus, the product can stop the laying of the queen. However, it is to be noted that the queen was not recovered at the opening of the nest and that the nest is a primary nest. An hypothesis that can explain the absence of the queen would be that the test was performed at the end of August thus at the period when queens are leaving the primary nest to build another nest at a higher position. Thus, it cannot be concluded that the treatment had an impact on the queen and on its capacity of laying of the eggs.

This study demonstrates that some treated hornets went back to their nest when located around 100 m from an apiary. However, it does not permit to conclude that the product decreases the predation pressure at the apiary as mentioned in the test report. And, this study does also not permit to conclude on the destruction of the nest through trophallaxis as claimed by the applicant. Indeed, the nest has been destructed by aspiration at the end of the test.

The study by Jaillard B. 2018 presented in the table below is a field test that aimed at assessing the efficacy of the Velutina product and process, i.e. the reduction of the predation pressure of the hornets on the apiaries and the destruction of the colony as claimed by the applicant.

The study by Jaillard 2020, allows to demonstrate the weight of a drop of product when applied as claimed and also the remaining quantity of product on a hornet after application.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| PT18 | Outdoor | White paint (like Tipp-Ex) | *V. velutina* | Determination of marking effect: Capture-mark- recapture method.  During a first period, Asian hornets are captured, marked with a droplet of white paint and released. On the following day, same period time, hornets are observed again, and white paint marked hornets are counted.  The objective was to confirm that hornets, even if they are marked, keep a normal behaviour, that is to go back to their nest even if they have been marked, and come back the following day for predation on the hives. | Test system: hornets are captured in front of the assessed hives, marked and released.  3 apiaries, all in the department Hérault (France) have been assessed: one apiary in Les Matelles, in a scrubland area, composed of 4 to 10 hives depending on the season; one urban apiary of one hive in St Gely du Fesc and another urban apiary in Montferrier-le-Lez, composed of 3 hives.  In St Gely du Fesc and Montferrier-le-Lez, 2 assessments have been done, both on two consecutive days (capture and recapture).  In Les Matelles, only one assessment has been done.  Test period: August 2018.  Observations are done between 8.00 and 9.30 am, during approx. 1 hour depending on the number of hornets.  Hornets are captured with the Velutina kit. | On most of the marked hornets, the paint mark has been reduced or thinned, certainly due to the usual intensive grooming of Hymenoptera.  In St Gely du Fesc:   * 1st assessment, mid-August: 10 hornets have been counted and marked. On the following day, 10 hornets have been counted, with 5 marked among them. On the following days, 3 and then 2 marked hornets have been counted. Six days after marking, no more marked hornets have been seen. * 2nd assessment, end of August: 10 hornets have been counted and marked, on the following day 16 have been counted, with 4 marked among them. Only one marked hornet has been seen on the following day, and none after.   In Montferrier-le-Lez:   * 1st assessment, mid-August: 8 hornets have been counted and marked. On the following day, 12 hornets have been counted, with 2 marked among them. Four days later, 21 hornets have been counted, with 1 marked among them. * 2nd assessment, end of August: 9 hornets have been counted and marked, on the following day 5 have been counted, with 2 marked among them. Four days later, 12 hornets have been counted, with 7 marked among them. Two weeks after marking, no more marked hornets have been seen.   In Les Matelles, predation pressure was lower. 6 hornets have been counted and marked. On the following day, 8 hornets have been counted, with 5 marked among them. Four days after marking, no more marked hornets have been seen.  It has to be noted that, on the second day of each assessment, randomly captured hornets (marked or not) have been treated with Velutina (refer to study S6.7\_03), Thus, it is not possible to conclude on the impact of the marking but only to conclude that some of the marked hornets go back to their nests, and continue their predation on the hives on the following days. | Jaillard B., 2018 S6.7\_02  See also efficacy test, S6.7\_03.  Supportive data |
| PT18 | Outdoor | In 2016,  solution similar to Velutina, but containing 0.12% w/w permethrin.  In 2017 and 2018, Velutina, containing 0.08% w/w permethrin. | *V. velutina* | Efficacy test:  Activity of hornets is evaluated (counting) in front of apiaries. Captured Asian hornets are treated with a droplet of the test solution.  Activity of hornets is evaluated again 3 days and 1 week after treatment. | Test system: hornets are captured in front of the assessed hives, treated and released.  Dose of product: one droplet of 25 mg per hornet. But, the quantity of product applied in the test has not been weighed.  Apiaries assessed:   * 5 in 2016 and 2017 : Matelles (10 hives); St Gély-1 (2 hives) and St Gély-2 (1 hive); Cournonsec (3 hives) and Montpellier (10 hives). * 3 in 2018: Matelles (4 hives); St Gély-2 (2 hives); Montferriez-le-Lez (3 hives).   Test period: between July and October.  Assessment: The number of hornets around the hives is counted, during a 15 minutes period, to give an indication of their predation pressure on these hives.  The stress of the hives is also evaluated, and rated from A (normal) to D (extreme stress).  Assessments:  Done before treatment, and then 3 days and 1 week later. | **2016**  The product used was not the product Velutina but a similar product containing 0,12% w/w permethrin thus results of this study are not taken into account.  **2017**  1) Les Matelles: no hornets were observed during the whole season.  2) Montpellier: on August 15, the predation pressure was considerable (> 50 hornets permanently in front of 10 hives). The treatment of > 50 hornets (08/21/2017) had a low impact on the predation pressure (from >100 to >80 hornets / h after 3 days). One week after treatment, the predation pressure had returned to its original state. On August 24, a swarm of bees collapsed, and the hive was taken over by hornets and 3 mL of biocidal solution were placed directly on the top of a frame for 3 consecutive days (not the claimed application method). All the biocidal solution was consumed, and the hornets disappeared from this hive a few days later. The predation pressure decreased for a week, then resumed as before.  The results of this trial demonstrate that the product, when used as claimed, is not sufficiently effective in case of high predation pressure.  3) St Gély 1: The treatment of > 30 hornets had no impact on the predation pressure which stayed between 16-20 hornets/h.  4) St Gély 2: The predation pressure was qualified as moderate (6 hornets/h) and the bees were not stressed (A). The treatment of 27 hornets has lowered the activity to 3 hornets/h 3 days after treatment then, no activity was observed 1 week after treatment.  5) Cournonsec: The predation pressure was of 13 hornets/h and the bees were not stressed (A). The treatment of 17 hornets has lowered the activity to 5 hornets/h 3 days after treatment then, 6 hornets/h were observed 1 week after treatment.  **2018**  1) Les Matelles: The predation pressure was low (9 hornets/h) and late in the season (mid-august) and the bees were not stressed (A). A first treatment of 9 hornets has lowered the activity to 1 hornet/h 3 days after treatment then another treatment of 1 hornet resulted in no observed activity 3 days later.  2) St Gely-2: The apiary was visited from the end of July: A 3-day treatment of 14 (7+5+2) hornets, reduced the predation pressure 3 days later, and cancelled attendance a week later. Predation resumed in mid-August with 11 hornets per hour. A second treatment (9+6+2) reduced the predation pressure 3 days later to 2 hornets per hour. But, predation pressure reached 26 hornets per hour at the end of August: the treatment of 42 hornets in 4 sessions (17 + 9 + 10 + 6) between the end of August and end of September reduced the pressure to 2 hornets per hour.  3) Montferrier-le-Lez: From early August, the activity observed was > 30 hornets per hour (approx. 2 hornets permanently in front of the hives). The swarms of bees were very stressed, and the whereabouts of the bees declined. A massive treatment of 52 (22+21+9) hornets in 2 weeks dropped the predation pressure to 12 to 18 hornets per hour. The treatment was continued regularly until the beginning of September (5 treatments: 9+17+5+7+9 hornets): the result was to reduce the predation pressure to a moderate level (6 hornets / h), without however managing to suppress it. Mid-September, the bees resumed normal activity (stress level A). | Jaillard B., 2018 S6.7\_03  RI=2 |
| PT18 | Outdoor | Velutina containing 0.08% w/w permethrin | *V. velutina* | Study aiming at measuring the weight of a droplet of product and the quantity of product retrieve on a hornet after application. | The weight of whole drops of VELUTINA was determined by weighing using a balance with a precision of 0.0001 g.  Whole, well-formed drops (n=20) fall one by one on a watch glass. Total weight of product was measured after the fall of each new drop. The weight of a drop was deducted by difference.  The exact quantity of VELUTINA deposited on a hornet was determined by double weighing on dead hornets. Hornets were captured, then killed by starvation within 24 hours. Each hornet was placed on a watch glass, then weighed. The watch glass was then removed from the tray of the balance, the hornet was treated with the product following the claimed instructions for uses, and then the watch glass was placed back on the scale, and again weighed. The weight of product deposited on each hornet (n=30) was deducted by difference. | The average weight of a whole well-formed drop of VELUTINA is 24.05 ± 2.4 mg (n = 20).  The average weight of VELUTINA deposited on a hornet is 19.1 ± 4.9 mg (n = 30) on average. | Jaillard B., 2020 S6.7-06\_  Supportive data |

The first part of this study by Jaillard b. 2018 (S6.7\_02) aimed at assessing the behaviour of hornets marked with paint according to the Velutina process. The objective was to confirm that hornets, even if they are marked, keep a normal behaviour, that is to go back to their nest even if they have been marked, and come back the following day for predation on the hives. This part of the study permits to demonstrate that some of the marked hornets went back to their nest and came back the following day for predation on the hives.

In the second part of the study (S6.7\_03), activity of hornets was evaluated by counting in front of several apiaries between 2016 and 2018. Captured Asian hornets were treated with a droplet of the test solution and activity of hornets was evaluated again 3 days and 1 week after treatment.

In 2016 and 2017, efficacy of Velutina was assessed on 5 apiaries (Matelles (10 hives); St Gély-1 (2 hives) and St Gély-2 (1 hive); Cournonsec (3 hives) and Montpellier (10 hives)).

In 2016, the product used was not the product Velutina but a similar product containing 0,12 % w/w permethrin (instead of 0,08%) thus results of this study were not taken into account.

In 2017, insufficient efficacy (no impact on predation pressure) of the product was demonstrated in 2 trials, Montpellier and St Gely-1. In these 2 trials predation pressure was >50 hornets/h and 16-20 hornets/h respectively. In one trial, St Gély-2, the treatment was performed when predation pressure was considered as moderate (6 hornets/h). In this case, the treatment leaded to suppression of the predation pressure one week after treatment. In another trial, Courmonsec, the predation pressure has been lowered from 13 hornets/h to a level that has been considered as acceptable (6 hornets / h) for this apiary one week after treatment.

In 2018, efficacy of Velutina was assessed on 3 apiaries: Matelles (4 hives), St Gély-2 (1 hive), Montferriez-le-Lez (3 hives).

The first day, captured hornets were marked with a drop of white paint (see S6.7\_02).

From Day 2 of the capture-mark-recapture method, white-tagged hornets and unmarked hornets were counted at the same time as they were captured for processing. All hornets caught (whether marked or not) were treated.

A suppression of the predation pressure was demonstrated in “les Matelles”. In this trial, the predation pressure of 9 hornets/h was considered as low and bees were not stressed.

In St Gely 2, several treatments were needed to lowered and maintain an acceptable level of predation pressure (2 hornets/h) and an acceptable level of stress of the bees.

In Montferrier-le-Lez, several treatments were also needed to reduce the predation pressure to a moderate level (6 hornets/h) and to reduce the stress level of the bees from C (very stressed) to A (not stressed). But the predation pressure achieved at the end in this trial cannot be considered as acceptable as this same level has required a treatment in other trials. Efficacy of the product in case of high infestation or when applied late in the season is not sufficient.

It has to be noted that in one case (Montpellier, 2017) the predation pressure was so high that the biocidal was placed directly on a beehive for 3 consecutive days leading to suppression of the predation pressure. But, this kind of application is not claimed and is considered as a misuse of the product.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| Three studies were submitted in order to demonstrate the mode of action of the product.  The first trial aimed at choosing the permethrin content for the Velutina product, so that the treated hornets still have time (6.5 min) to go back to their nests. The second one, conducted on captured hornets, aimed at demonstrating that after treatment with a droplet of Velutina on the head (contact), the hornets can still fly and go back to their nests and exchange with their congeners, which in turn would be "treated" by ingestion. However, the treatment per ingestion is not sufficient to demonstrate that the product will be spread through the colony by trophallaxis.  These tests have not been considered as sufficiently robust (low number of tested hornets, no replication, and absence of quantification of the product applied).  The third test, which has been conducted on a hornets’ nest, demonstrates that some treated hornets go back to their nest when it is located around 100 m from an apiary. But, it does not permit to conclude on the destruction of the nest through trophallaxis as claimed.  To support the efficacy of the product Velutina against the Asian hornet, a last trial was provided. The criteria used to support the effectiveness is a reduction of the predation pressure in the apiary.  But, as presented above a great variability can be observed among the results obtained in this field trial, and the level of predation pressure considered as acceptable differs among the trials (one explanation could be the size of the apiary).  Despite these variabilities, the product has demonstrated an impact on the predation pressure supporting that the product may have an efficacy early in the season (at the time of primary nests).Several treatments might be necessary to lower the number of hornets and keep the predation pressure to an acceptable level..  However, it can be concluded that in case of high pressure level or when treatment is late in the season the efficacy of the product VELUTINA is not demonstrated. Thus, the product is not to be used in these cases. |

#### Occurrence of resistance and resistance management

Resistance to permethrin has been reported for a number of pests both in agriculture and public health (German cockroach (Atkinson et al., 1991), house fly (Shen and Plapp, 1990), stable fly (Cilek and Greene, 1994), Culex mosquitos (Wan-Norafilack et al., 2013), Aedes mosquitos (Saavedra-Rodriguez et al., 2008), Anopheles mosquitos (Müller et al., 2008), etc.), when permethrin has been used as a general insecticide. In general, pyrethroïd resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms (see permethrin Assessment Report, PT18, April 2014).

However, no specific data has been found in the literature regarding occurrence of resistance to permethrin among hornets or other Vespinae species.

#### Known limitations

The product is more effective when used early in the season, July-August.

The product is not to be used in case of high infestation. According to the applicant, beyond a frequentation of 25 hornets per hour on the whole apiary, VELUTINA loses its effectiveness due to a too populous nest or too many nests. Beyond 50 hornets per hour over the entire apiary, VELUTINA is no longer effective.

As demonstration of the efficacy has been performed in apiaries containing up to 10 hives, it cannot be concluded that the product will be efficacious in apiaries containing more than 10 hives. Thus, the product should only be used in apiaries containing up to 10 hives.

#### Evaluation of the label claims

The label claim of the Velutina product is "reduction of the hornet population to limit predation pressure on apiaries and the complete destruction of the colony.”

FR CA concluded that:

* + - The claim of destruction of the nest is not demonstrated

The product, applied at 25 mg/hornet, has an impact on the predation pressure supporting that the product has an efficacy early in the season (at the time of primary nests); depending on the site, several treatments might be necessary to lower the number of hornets and keep the predation pressure to an acceptable level.

To ensure a satisfactory level of efficacy the recommendations proposed in the SPC have to be implemented.

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

The product Velutina is not intended to be used with another biocidal product.

### Risk assessment for human health

#### Assessment of effects on Human Health

No study was conducted. Classification is determined by using the calculation method described in the Guidance on the Application of the CLP Criteria Version 5.0 (July 2017), based on the available data on each component.

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not irritating to the skin |
| Justification for the value/conclusion | According to the composition, none of the component is toxicologically relevant for skin corrosion and irritation. |
| Classification of the product according to CLP | No classification is required for skin corrosion and irritation to the skin. |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not irritating to the eye |
| Justification for the value/conclusion | Classification is made by calculation method: one component is classified Skin irrit. 2, H319 but ≤10%. |
| Classification of the product according to CLP | No classification for eye irritation is required. |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | The classification has been determined according to the CLP Regulation. |
| Classification of the product according to CLP | No classification is required for respiratory tract irritation. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising to the skin |
| Justification for the value/conclusion | The classification has been determined using the calculation method. Permethrin is classified H317 cat.1 but ≤0.1 |
| Classification of the product according to CLP | No classification for skin sensitisation is required. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitising to the respiratory system. |
| Justification for the value/conclusion | According to the composition, none of the component is toxicologically relevant for respiratory. |
| Classification of the product according to CLP | No classification for respiratory sensitisation is required. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not acutely toxic via the oral route. |
| Justification for the selected value | The classification has been determined using the calculation method. Permethrin is classified acute toxicity (oral) cat. 4, H302 but ≤0.1%. No other of the components is classified for acute oral toxicity. |
| Classification of the product according to CLP | No classification for acute oral toxicity is required. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not acutely toxic via inhalation. |
| Justification for the selected value | The classification has been determined using the calculation method. Permethrin is classified acute toxicity (inhalation) cat. 4, H332 but ≤0.1%. No other of the components is classified for acute inhalation toxicity. |
| Classification of the product according to CLP | No classification for acute inhalation toxicity is required. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not acutely toxic via the dermal route. |
| Justification for the selected value | The classification has been determined using the calculation method. None of the components is classified for acute dermal toxicity. |
| Classification of the product according to CLP | No classification for acute dermal toxicity is required. |

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Permethrin |
| Value(s) | 70% |
| Justification for the selected value(s) | The product is mainly based on honey. According to EFSA guidance on dermal absorption 2017, a default dermal absorption value of 70% may be applied for other types of formulations from organic solvent-based and water-based/dispersed or solid formulations, such as gel for direct application. |

***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, the following co-formulant has been identified as substances of concern:

| **Name and CAS**  **SOC** | **Reason(s) for identification** | **Relation to band** | **Consequences on the Human Risk assessment** |
| --- | --- | --- | --- |
| Propan-2-ol  CAS: 67-63-0 | Biocidal active substance at a concentration > 0.1% | Band C | Quantitative risk assessment for the professional and non-professional when TRVs available |

Considering that the product is applied with a pipette and that the application is outdoor only, inhalation is considered negligible.

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

No data

#### 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 | n.a | No | No | n.a | No | No | No |
| Dermal | n.a | Yes | Yes | n.a | No | No | No |
| Oral | n.a | No | No | n.a | No | No | Yes |

The product Velutina is a ready-to-use insecticide to be applied directly on the Asian hornet (or yellow-legged hornet) *Vespa velutina*: a hornet is captured and immobilised, a droplet of product (25 mg) is put between the head and the thorax, and then the hornet is released. Back at their nest, the product will diffuse in the nest *via* the vector hornet.

*Primary exposure:*

Professionals and non-professionals beekeepers may be exposed during spot application for dermal exposure. Inhalation is considered negligible regarding the low vapour pressure of active substance (2.155 x 10-6 Pa at 20°C) and application method.

*Secondary exposure:*

The product is applied directly on hornets which return to their nest after treatment, therefore no secondary contact with the product is expected.

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Spot application | **Primary exposure – dermal exposure**  The product is applied directly on hornets with a maximum application rate of 2.5 g product/day (for 2 nests). | Professionals beekeepers |
| 2. | Spot application | **Primary exposure – dermal exposure**  The product is applied directly on hornets with a maximum application rate of 2.5 g product/day (for 2 nests). | Non-professionals beekeepers |

***Industrial exposure***

No exposure is foreseen.

***Professional exposure***

*Scenario [1]*

| **Description of Scenario [1]** |
| --- |
| A reverse scenario approach is done to assess the amount of product needed on the skin to reach the AEL for a professional user, with the following parameters for dermal exposure:   |  |  |  | | --- | --- | --- | | **Parameters** | **Value** | **Reference** | | AELlong-term (mg/kg bw/d) | 0.05 | CAR 2016 | | Concentration of permethrin | 0.086 % | Applicant’s data | | Dermal absorption | 70% | Default value (EFSA 2017) | | Adult body weight (kg) | 60 | HEAd Hoc Recommendation no. 14 | |

**Calculations for Scenario [1]**

Maximum quantity to reach the AELlong-term is equal to **5.0** **g** of the product that would be necessary for a professional beekeeper to generate systemic effects due to the dermal primary exposure. This quantity corresponds to twice the maximum application rate of 2.5 g product/day (for 2 nests).

Same calculation is made for Propan-2-ol with the AEL of 17.9 mg/kg bw/d and 0.1263% of concentration: (17.9\*60/70%)/0.1263% = 1215 g of product.

***Non-professional exposure***

*Scenario [2]*

| **Description of Scenario [2]** |
| --- |
| A reverse scenario approach is done to assess the amount of product needed on the skin to reach the AEL for a non-professional user, with the following parameters for dermal exposure:   |  |  |  | | --- | --- | --- | | **Parameters** | **Value** | **Reference** | | AELmedium-term (mg/kg bw/d) | 0.05 | CAR 2016 | | Concentration of permethrin | 0.086 % | Applicant’s data | | Dermal absorption | 70% | Default value (EFSA 2017) | | Adult body weight (kg) | 60 | HEAd Hoc Recommendation no. 14 | |

**Calculations for Scenario [2]**

Maximum quantity to reach the AELmedium-term is equal to **5.0** **g** of the product that would be necessary for a non-professional beekeeper to generate systemic effects due to the dermal primary exposure. This quantity corresponds to twice the maximum application rate of 2.5 g product/day (for 2 nests).

Same calculation is made for Propan-2-ol with the AEL of 10.7 mg/kg bw/d and 0.1263% of concentration: (10.7\*60/70%)/0.1263% = 726 g of product.

***Exposure of the general public***

The product is applied directly on hornets, which return to their nest after treatment, therefore no exposure is expected for general public.

***Monitoring data***

No data.

***Dietary exposure***

Regulation (EU) No.528/2012 specified that biocidal products containing active substances that, as a result of their use, may lead to residues in food shall only be authorized if these residues do not have unacceptable effects on human health.

The product VELUTINA is a ready-to-use insecticide to be applied on hornets.

However, the entry of a treated hornet in a beehive cannot be excluded.

Therefore, a calculation to rule out risk via diet following the consumption of contaminated honey is provided below.

| **Description of Scenario [1]** | | |
| --- | --- | --- |
|  | Parameters1 | Value |
| Tier 1 | Mean of honey produced by a beehive | 10 kg |
| Application rate of 1 drop | 25 mg product/hornet |
| Concentration of permethrin in the product | 0.086% w/w |

1 Include e.g. generic parameters. Use footnotes for references and justifications.

The mean value of 10 kg of honey produced by a beehive was provided by the applicant. Even if the mean of honey produced can be higher, this value is considered as relevant by eCA as the calculation will be a worst case.

Amount of active substance per kilogram of honey:

Application rate of the product \* concentration of the active substance / mean of honey produced by a beehive = 25 mg product \* 0.086% a.s. / 10 kg honey = 0.00215 mg a.s./kg honey

For the consumer exposure, it is considered that 20 g of honey are consumed per person and per day (equivalent to 0.333 g honey/kg bw/d for an adult). This value comes from the food basket reported in the Guideline Veterinary medical products (Volume 8, October 2005, p. 57/78; ECHA, 2017).

Therefore the worst case consumer exposure (WCCE) is

0.00215 mg a.s./kg honey \* 0.02 kg honey/day = 0.000043 mg a.s./day/ person

eCA agreed with this evaluation for the chronic exposure assessment as this default value of 20 g/pers covers the honey consumption reported in PRIMo rev. 3.1 (max 6.17 mg honey/kg bw/d).

For acute exposure assessment, the daily consumption of 20 g does not covered by data reported in PRIMo rev. 3.1. Therefore for acute assessment, PRIMo rev. 3.1 was taken into account by eCA as a worst case.

For honey, the large portion is 90.53 g/adult (i.e. 1.38 g/kg bw) and 36.5 g/child (i.e. 3.58 g/kg bw).

The worst case consumer acute exposure is below 0.01 µg/kg bw (see excel sheet reported in Annexe § 3.4)

Residue definitions

Permethrin (sum of isomers)

*List of scenarios*

| **Summary table of main representative dietary exposure scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Type of use1** | **Description of scenario** | **Subject of exposure2** |
| 1. | General population | **Secondary exposure – oral exposure**  The entry of a treated hornet in a beehive cannot be excluded. Exposure calculation via diet following the consumption of contaminated honey should be assessed. | Honey |

1 e.g. animal husbandry, food industry, professional use, residential use.

2 e.g. chicken, milk, beer

*Information of non-biocidal use of the active substance*

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use1** | **Intended use** | **Residue definition -** |
| 1. | Plant protection product | Not approved | Permethrin (sum of isomers) -MRL (Reg. (EU) 2017/623) |
| 2. | Veterinary use | Antiparasitic agent on bovine | Permethrin (sum of isomers) -MRL (Reg (EU) 37/2010) |

1 e.g. plant protection products, veterinary use, food or feed additives

2 e.g. MRLs. Use footnotes for references.

It should be noted that no MRLs are set in honey commodities in Regulation (EU) 2017/623 and Regulation (EU) 37/2010

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

Not relevant.

*Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)*

Not relevant.

*Estimating transfer of biocidal active substances into foods as a result of non-professional use*

Not relevant.

***Exposure associated with production, formulation and disposal of the biocidal product***

Not relevant.

***Aggregated exposure***

Not performed.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake** |
| 1. | Professionals | 1/no PPE | Maximum quantity to be touched: 5.0 g |
| 2. | Non-professionals | 1/no PPE | Maximum quantity to be touched: 5.0 g |

#### Risk characterisation for human health

Reference values to be used in Risk Characterisation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (mg/kg bw/d)** | **AF1** | **Correction for oral absorption** | **Value (mg/kg bw/d)** |
| AELshort-term | 2-year rat toxicity study | 50 | 100 | No | 0.5 |
| AELmedium-term/long-term | 1-year dog chronic toxicity study | 5 | 100 | No | 0.05 |
| ARfD | 2-year rat toxicity study | 50 | 100 | No | 0.05 |
| ADI | 1-year dog study | 5 | 100 | No | 0.5 |

1 10 x 10 for inter- & intraspecific differences.

Reference values to be used in Risk Characterisation: **Propan-2-ol**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Reference** |  | **Study** | **NOAEL NOAEC** | **AF3** | **Correction for oral absorption** | **Value** |
| AELshort-term, AELmedium-term, AELlong-term | General population | Human volunteer study (neurological effects) | 200 ppm | 6.4 | 100% | 10.7 mg/kg bw/d |
| Professional workers | 3.8 | 100% | 17.9 mg/kg bw/d |
| AECshort-term, AECmedium-term, AEClong-term | General population | 6.4 | - | 31.25 ppm (8h) |
| Professional workers | 3.8 | - | 52.6 ppm (8h) |
| ARfD, ADI | Not necessary, no residues in food expected | | | | | |

3 AF of 3.8 for intraspecies variability within the population (from 5 to 75 years of age). AF of 6.4 for intraspecies variability within the general population (from birth to 75 years of age).

**Maximum residue limits or equivalent**

No MRLs on honey commodities are set in biocides regulation.

Residue definitions

Permethrins (sum of isomers)

**Specific reference value for groundwater**

*[If it is proposed to derive a value according to BPR Annex VI point 68, other than the maximum permissible concentration laid down by Directive 98/83/EC, please include the argumentation and the calculations here. Otherwise, please delete this chapter.]*

***Risk for industrial users***

No exposure is foreseen.

***Risk for professional users***

Maximum quantity to reach the AELlong-term for permethrin is equal to **5.0** **g** of the product that would be necessary for a professional beekeeper to generate systemic effects due to the dermal primary exposure. This quantity corresponds to twice the maximum application rate of 2.5 g product/day (for 2 nests).

Maximum quantity to reach the AELmedium-term for propan-2-ol is equal to **1215** **g** of the product.

**Conclusion**

The exposure to such amount of product is not likely to occur, then the risk for professional users is considered as acceptable without gloves.

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

Maximum quantity to reach the AELmedium-term for permethrin is equal to **5.0** **g** of the product that would be necessary for a non-professional beekeeper to generate systemic effects due to the dermal primary exposure. This quantity corresponds to twice the maximum application rate of 2.5 g product/day (for 2 nests).

Maximum quantity to reach the AELmedium-term for propan-2-ol is equal to **726** **g** of the product.

**Conclusion**

The exposure to such amount of product is not likely to occur, then the risk for non-professional users is considered as acceptable.

***Risk for the general public***

No exposure is foreseen.

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

Taking into account the ADI of 0.05 mg/kg bw/d, the following risk for consumer is reported by the applicant:

* For adults of 60 kg: WCCE \* 100/ (ADI\*bw) = 0.000043 \* 100/(0.05\*60)= 0.00143% of the ADI
* For a child of 15.6 kg: WCCE \* 100/ (ADI\*bw) = 0.000043 \* 100/(0.05\*15.6)= 0.0055% of the ADI

The chronic consumer exposure is below 1% of the ADI. No risk is expected following consumption of contaminated honey and no further assessment is necessary.

eCA agreed with this evaluation.

For acute risk assessment, according to PRIMo rev 3.1. and the ARfD of 0.5 mg/kg bw, the risk is below 1% of the ARfD for adults and children (0.00059% of adults and 0.00154% for child). Results are reported in the Excel sheets presented in Annexe §3.4

The acute exposure is below 1% of the ARfD. No risk is expected following consumption of contaminated honey and no further assessment is necessary.

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

Not applicable

### Risk assessment for animal health

Not relevant. Primary exposure is only for professionals and non-professionals. Secondary exposure is not expected for domestic animals as the product is applied directly on hornets.

### Risk assessment for the environment

The following environmental exposure and risk assessment was conducted for the biocidal product (BP) VELUTINA that is a ready-to-use insecticide to be applied outdoor, directly on the Asian hornet (or yellow-legged hornet) *Vespa velutina* with a specific device provided with the product. The product contains 0.086% w/w technical permethrin (CAS No.52645-53-1), as the active substance with an insecticidal action (product type (PT) 18).

The assessment has been conducted for the active substance and its relevant metabolite only. No substance of concern was defined for the environment.

No additional studies regarding ecotoxicity and environmental fate for the biocidal product have been performed.

#### Effects assessment on the environment

An overview for the PNECs for the active substance permethrin and its relevant metabolites is given in the table below:

|  |  |
| --- | --- |
| **Compartment** | **PNEC (permethrin)** |
| STP microorganisms | 4.95 µg/l |
| Surface water | 0.00047 µg/l |
| Sediment | 0.217 µg/kg wwt |
| Soil | 175 µg/kg wwt (revised in CG22) |
| Birds | 16.7 mg a.s./kg food |
| Mammals | 120 mg a.s./kg food |

|  |  |
| --- | --- |
| **Compartment** | **PNEC (DCVA)** |
| STP microorganisms | Not available |
| Surface water | 15 µg/l |
| Sediment | 12 µg/kg wwt |
| Soil | 4600 µg/kg wwt |

|  |  |
| --- | --- |
| **Compartment** | **PNEC (PBA)** |
| STP microorganisms | Not available |
| Surface water | >10 µg/l |
| Sediment | 9 µg/kg wwt |
| Soil | 1440 µg/kg wwt |

***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***

No new data is available.

|  |  |
| --- | --- |
| **Classification of the Active Substance Permethrin** | |
| Value/conclusion | Very toxic to aquatic life  Very toxic to aquatic life with long-lasting effects |
| Justification for the value/conclusion | Daphnia was the most sensitive aquatic organism with the lowest acute ecotoxicity endpoint (48h): EC50 1.27E-03 mg/L and the lowest chronic ecotoxicity endpoint (21d): NOEC 4.7E-06 mg/L. |
| Classification of the product according to CLP and DSD | The following classification in accordance with the criteria in Regulation (EC) No 1272/2008 is proposed in the AR (2014):  Aquatic Acute 1; H400; M = 100  Aquatic Chronic 1, H410, M = 10000 |

|  |  |
| --- | --- |
| **Classification and labelling of the Product VELUTINA** | |
| Value/conclusion | **Aquatic Chronic Cat 1; H410** |

***Further Ecotoxicological studies***

No new data is available.

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

No new data is available.

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

No new data is available.

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

No new data is available.

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

No new data is available.

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

The product VELUTINA is a ready-to-use insecticide to be applied outdoor, directly on the *Vespa velutina*, with a specific device provided with the product. The product can be used by professional and non-professional beekeepers only.

Emissions during application

According to the intended use as a spot application directly on the target organisms, local releases directly to soil are taken into account. The soil is therefore the main receiving compartment following the use of the product VELUTINA. A risk assessment for this compartment is provided for direct releases due to the application of the product on the back of the target organisms. It considers the active substance and its metabolites. Nevertheless, please note that a protective floor mat is provided in the sold kit, in order to prevent direct releases towards the soil when the treatment is applied.

Emissions during “service-life”

A direct release can also occur during the “service life” of the product when the hornet is released into the environment after the treatment. An accidental emission to the aquatic and terrestrial compartments can occur if the hornet dies before arriving to its nest.

Releases to rainwater to sewer system in urban situation are not considered to be significant as the product VELUTINA is intended to be used in rural areas. It is also specified that catching devices must be cleaned with disposable absorbent paper to avoid discards to the STP due to washing. Thus, no contamination either directly or indirectly of the STP is expected when using the product VELUTINA.

The volatilisation of permethrin is considered to be negligible based on its vapour pressure (2.155\*10-6 Pa at 20°C) and Henry’s law constant (4.6\*10-3 to 4.5\*10-2 Pa.m3/mol). In addition, as permethrin is rapidly degraded in the air, it would not be transported over large distances in the atmosphere. Therefore, the risk of contamination of air can be considered as negligible and this route of entry in the environment is not of concern.

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

No new data is available.

***Leaching behaviour (ADS)***

No new data is available.

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

No new data is available

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

No new data is available.

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

No new 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)***

No new data is available. The product VELUTINA is a ready-to-use insecticide directly applied on a limited number of targets, at a local scale.

***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)***

The biocidal product is a ready to use gel bait applied as spot on a limited number of targets. A risk assessment for spray application is therefore deemed not appropriate.

The product VELUTINA contains the active substance permethrin known to be toxic to bees (LD50oral = 0.163 µg/bee and LD50contact = 0.0235 µg/bee) and therefore a risk for bees cannot be excluded.

#### Exposure assessment

General information

|  |  |
| --- | --- |
| Assessed PT | PT18 |
| Assessed scenarios | No harmonised scenario available for the claimed use. |
| ESD(s) used | Homemade scenarios for this specific use.  The proposed exposure scenarios are extrapolations based on default values from the scenario “spot application” in the guidance ESD PT18 (2008) and from the scenario “bridge over pond” in the guidance ESD PT08 (2013). |
| Approach | Consumption based - Outdoor spot application, direct release |
| Distribution in the environment | Calculated based on ECHA Guidance on the BPR Vol IV Part B (2017) |
| Groundwater simulation | No – calculated according to ECHA Guidance on the BPR Vol IV Part B ; 2017 |
| Confidential Annexes | No |
| Life cycle steps assessed | Releases to the environment can take place from the following steps:   * Application step   During the application, a part of permethrin can be released to the adjacent soil (bare soil)   * Service life step   Direct release to the environment via hornet can occur on soil or water bodies.  To conclude, 2 scenarios are proposed for the environmental risk assessment:  Scenario 1a: release during the application step of the product on hornets  Scenario 1b: : release to the environment during the way back of hornets to the nest |
| Remarks | / |

***Emission estimation***

The product VELUTINA is ready-to-use, thus no release following mixing and/or loading step is taken into account.

The product is applied outdoor by beekeepers, directly on hornets, with a specific device provided with the product. Please note that in this assessment, there is no difference of emission between professional and non-professional uses for the emission towards the environmental compartments according to the claimed application rate. Only users able to apply this product (*i.e.* able to catch hornets to apply the droplet) are the relevant users.

According to the intended use, no emission is expected. Nevertheless, due to the outdoor use of the product, the toxicity of permethrin, the mode of application of the product on living targets, a risk assessment is conducted in case of ‘accidental’ releases of the product in the environment.

Two cases of accidental releases are identified:

* accidental release during the treatment of hornets (Scenario 1a)
* accidental release during the way back of hornets to the nest (Scenario 1b)

For the first case (scenario 1a), as no harmonized scenario is available for the claimed use, a worst-case approach is conducted according to default values from the scenario “spot application” proposed in the guidance ESD PT18 for household and professional uses (2008) on bare soil. According to this approach, only the risk assessment for the soil is relevant.

For the second case (scenario 1b), as no harmonized scenario is available for the claimed use, a worst-case approach was conducted assuming an accidental situation where a treated target would fall into the aquatic compartment, using default values of “bridge over pond” scenario (PT08). An accidental release of the hornet on the floor is considered covered by scenario 1a.

Justification of the parameters used for both scenarios:

- **Number of treated hornets (scenario 1a and 1b):** a maximum amount of 50 hornets treated per nest is claimed by the applicant to provide high season efficacy as a conservative approach. According to the instruction of use (2.1.5.1), it is also the maximum of hornets that can be treated per apiary per day (Tier 1). A refinement is also proposed for only one treated hornet, which better reflects accidental emissions, especially when the hornet flies back to its nest (scenario 1b - Tier 2).

- **Fraction emitted to soil during application (scenario 1a)**: as a worst case, it is considered that 100% of the applied product will fall on the bare soil during the application of the product.

**- Volume of exposed soil (scenario 1a)**: as a worst case, the volume of soil exposed is based on the default value of the scenario “spot application” from the ESD PT18. Indeed, the soil contaminated during the application is supposed to be the same. But during the application or due to the fly of the hornets the exposure of the soil does not occur at the same place. The releases due to the flight back of the hornets are much more diluted in the environment. The scenario 1a for the application is therefore considered to cover releases to soil for scenario 1b.

**- Volume of exposed water (scenario 1b):** as a worst case, the volume of water exposed is based on the default value of the scenario “bridge over pond” from the ESD PT08.

**Scenario [1a]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario1a:Outdoor spot application on hornet, accidental release during **the treatment of hornets** on the bare soil | | | |
| Application rate of biocidal product | 0.025 | g/point | One point per hornet as intended by the applicant |
| Concentration of active substance in the product | 0.086 | % | Technical concentration |
| Amount of active substance per point | 2.15E-05 | g a.s./point | *-* |
| Number of application | 50 | [-] | One nest, *i.e.* 50 hornets (worst-case approach proposed by the applicant, as the number of targets needed to reduce hornet predation pressure during high season) |
| Volume of soil exposed | 0.125 | m3 | Default value – ESD PT18 considering an exposed cube of 50 cm edge |
| Density of exposed soil RHO | 1700 | Kg/m3 | Default value |
| Fraction emitted to soil during outdoor application on hornet | 1 |  | Worst-case approach in case of release on **bare soil** |

Calculations for Scenario [*1a*]

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Soil | 1.08E-06 | 50 treated hornets in the same soil area |

**Scenario [1b]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario1b:Outdoor spot application on hornet, accidental release during the **way back of hornets to the nest** | | | |
| Application rate of biocidal product | 0.025 | g/point | One point per hornet |
| Concentration of active substance in the product | 0.086 | % | Technical concentration |
| Amount of active substance per point | 2.15E-05 | g a.s./point |  |
| Number of application | Tier 1: 50  Tier 2: 1 | [-] | Tier 1: One nest (worst-case approach)  Tier 2: One hornet |
| Volume of water exposed | 1000 | m3 | Default value (ESD PT08) |

Calculations for Scenario [*1b*]

| **Resulting local emission to relevant environmental compartments** | | | |
| --- | --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | Tier 1: 1.08E-06  Tier 2: 2.15E-08 | 50 hornets (worst-case approach)  One hornet |

***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 | Ground-water | Other |
| Scenario 1 | yes | yes | no | no | no | no | yes | yes | no |

|  |  |  |
| --- | --- | --- |
| **Input parameters used in the environmental exposure assessments according to the CAR (April, 2014)** | | |
| **Inputs** | **Value** | **Unit** |
| **Permethrin** | | |
| CAS number | 52645-53-1 | - |
| Molecular weight | 391.29 | g.mol-1 |
| Vapour pressure (at 20°C) | 2.16E-06 | Pa |
| Water solubility (at 20°C) | 4.95E-03 | mg.L-1 |
| Partition coefficient (log POW) (pH 7) | 4.67 | Log 10 |
| Biodegradability | Not Readily biodegradable |  |
| Degradation in soil (DT50) (at 12°C) | 106 | days |
| Adsorption / desorption Koc | 26930 | L.kg-1 |
| BCF fish | 570 | L.kg-1 |
| BMF fish | 1 | - |
| BCF earthworms | 15108 | L.kg-1 |
| **Metabolites** | | |
| **DCVA** | | |
| Molecular weight | 209.07 | g.mol-1 |
| Degradation in soil (DT50) (at 12°C) | 174.8 | days |
| Max. % occurrence water | 62.6 | % |
| Max. % occurrence sediment | 21.7 | % |
| Max. % occurrence soil | 11.3 | % |
| Koc | 188.53 | L.kg-1 |
| Ksoil-water (worst case considering complete miscibility and negligible vapour pressure) | 5.86 | [m3.m-3] |
| **PBA** | | |
| Molecular weight | 214.22 | g.mol-1 |
| Degradation in soil (DT50) (at 12°C) | 148\* | days |
| Max. % occurrence water | 28.8 | % |
| Max. % occurrence sediment | 16.4 | % |
| Max. % occurrence soil | 15 | % |
| Koc | 37.55 | L.kg-1 |
| Ksoil-water (worst case considering complete miscibility and negligible vapour pressure) | 1.33 | [m3.m-3] |

\* harmonized value from the pyrethroid metabolites LoEP (2020)

**Calculation method of metabolites emissions**

To estimate PEC in the environmental compartments for the metabolites DCVA and PBA, their own Koc value has been considered. PECs were further estimated considering the molecular mass fraction and the metabolite formation fraction (max. % occurrence) in each exposed compartment.

***Calculated PEC values***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values - Permethrin** | | | | |
|  | **PECwater** | **PECsed** | **PECsoil**  **Initial concentration without degradation** | **PECGW** |
| [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |
| Scenario 1a - application | Not relevant | Not relevant | 5.06E-03 | 1.06E-02 |
| Scenario 1b - way back of hornets to the nest | Tier 1: 1.08E-06  Tier 2: 2.15E-08 | Tier 1: 6.29E-04  Tier 2: 1.26E-05 | (covered by Scenario 1a) | (covered by Scenario 1a) |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values - DCVA** | | | | |
|  | **PECwater** | **PECsed** | **PECsoil**  **Initial concentration without degradation** | **PECGW** |
| [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |
| Scenario 1a - application | - | - | 3.05E-04 | 8.87E-02 |
| Scenario 1b - way back of hornets to the nest | Tier 1: 3.60E-07  Tier 2: 7.19E-09 | Tier 1: 7.30E-05  Tier 2: 1.46E-06 | (covered by Scenario 1a) | (covered by Scenario 1a) |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values - PBA** | | | | |
|  | **PECwater** | **PECsed** | **PECsoil**  **Initial concentration without degradation** | **PECGW** |
| [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |
| Scenario 1a - application | - | - | 4.15E-04 | **5.32E-01** |
| Scenario 1b - way back of hornets to the nest | Tier 1: 1.65E-07  Tier 2: 3.31E-09 | Tier 1: 5.52E-05  Tier 2: 1.10E-06 | (covered by Scenario 1a) | (covered by Scenario 1a) |

Concerning the calculated value of 0.53 µg/L for PBA in groundwater, please note that the scenario 1a is a very worst-case approach given the number of treated hornets, the restricted area of soil and the fraction emitted to soil. Indeed, this worst case emission to soil is very concentrated in a small volume of soil. This kind of emission can occur at a very local scale and does not reflect what can happen to groundwater compartment on a larger scale, as in the case of sewage sludge spreading. It is therefore considered that contamination of groundwater can be excluded. Moreover, as proposed by the applicant, the application is conducted on a floor mat to collect all the product waste.

***Primary and secondary poisoning***

Primary poisoning

**Insectivorous (birds and mammals):**

The product is applied on the back of hornets that may be potential targets for insectivorous birds or mammals.

Tier 1 approach:

2.15\*10-5 g of active substance on one hornet, considering an average weight of 0.3 g per target[[2]](#footnote-2), results in 71.7 mg of permethrin per kg food. It is above the PNECoral, birds (16.7 mg as/kgfood), which are the most-sensitive organisms to permethrin. Nevertheless, this tier 1 approach considers that 100% of the diet for birds is based on treated hornets, which is an unrealistic worst-case approach.

Tier 2 approach:

The parameters used for the primary poisoning refinement (avoidance factor, fraction of diet obtained from treated area, composition of diet obtained from treated area) are not available for this type of scenario. Thus, no harmonized evaluation is possible.

Nevertheless, in the Assessment Report of permethrin, it has to be noted that permethrin is of low toxicity for birds (DL50-oral > 3000 mg/kgbw). Moreover, only a small fraction of the population of a nest is treated (from 1/10th to 1/20th), which reduces the exposure of birds to permethrin by at least a factor of 10. Also considering that treated hornets will be scattered into the environment before arriving to their nest, the most relevant scenario is the predation of a small number of hornets by predators. Thus, no risk is expected for primary poisoning.

However, it has to be noted that in France, some beekeepers use chickens to fight against predation pressure from the Asian Hornet. For that reason, a risk mitigation measure is added to prevent the use of the product close to a henhouse:

* **“Do not use near poultry houses”.**

**Bees assessment:**

The product VELUTINA (in gel form) contains the active substance permethrin known to be toxic to bees (LD50oral = 0.163 µg/bee and LD50contact = 0.0235 µg/bee) and therefore a risk for bees cannot be excluded.

Furthermore, VELUTINA is formulated with more than 90% of attractant for hornets (in order to contaminate the nest), that can also be attractive for bees. Considering the concentration of permethrin in VELUTINA product (0.086% w/w), one drop of 25 mg is sufficient to kill a bee.

Nevertheless, the applicant argued that the product is used exclusively by beekeepers so the effects on bees are directly under surveillance. The product is not relevant if a negative effect is observed on bees. For these reasons, no risk is identified for bees when the product is used by beekeepers according to the labelling.

Taking into account this argumentation, the justification provided by the applicant was considered as acceptable by FR CA.

Nevertheless, as the product is intended to be used near beehives, as a precautionary measure and for consumer information, the following information should be added on the label:

* **“Hazardous to bees”.**

Secondary poisoning

The active substance permethrin has a log Kow > 3 (log Kow = 4.67) and a BCF > 100 (mean BCF in fish = 570 L.kg-1, BMF = 1 and BCF in earthworm = 15108 L.kg-1). According to the scenarios, secondary poisoning may occur via the aquatic food chain and/or via the terrestrial food chain. The concentration of permethrin in food (*i.e.* in fish and in earthworm) of fish-eating and worm-eating predators (birds or mammals) has been calculated.

The results for each scenario are summarised in the following table.

|  |  |  |
| --- | --- | --- |
| **Summary table on estimated theoretical exposition for the permethrin** | | |
|  | **PEC in fish** | **PEC in earthworm** |
| [mg.kg wet fish-1] | [mg.kg wet earthworm-1] |
| Scenario 1a - application | - | 7.25E-02 |
| Scenario 1b - way back of hornets to the nest | Tier 1: 3.06E-04  Tier 2: 6.13E-06 |  |

#### Risk characterisation

***Atmosphere***

Significant exposure of the environment via the atmosphere is not expected whatever the considered use. According to the CAR, volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155×10-6 Pa at 20°C) and Henry constant (4.5×10-2 Pa.m3.mole-1). Permethrin would not be transported over large distances in the atmosphere in gaseous phase.

**Conclusion:**Emissions and PECs in air are considered as negligible. It can be concluded that the use of the product VELUTINA will not pose a significant risk to the atmospheric compartment.

***Sewage treatment plant (STP)***

Considering the specific instructions of use

* **“Capture and processing accessories** (**net, floor mat, etc) must be cleaned with disposable absorbent paper towels and not with water.”**

Significant exposure of the environment via STP is not expected whatever the considered emission pathway

Conclusion: Emissions and PECs in STP are considered as negligible. It can be concluded that the use of the product VELUTINA will not pose a significant risk to the STP compartment.

***Aquatic compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values- Permethrin** | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** |
| Scenario 1a - application | - | - |
| Scenario 1b - way back of hornets to the nest | Tier 1: **2.29E+00**  Tier 2: 4.57E-02 | Tier 1: **2.90E+00**  Tier 2: 5.80E-02 |

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values- DCVA** | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** |
| Scenario 1a - application | - | - |
| Scenario 1b - way back of hornets to the nest | Tier 1: 2.40E-05  Tier 2: 4.79E-07 | Tier 1: 6.08E-03  Tier 2: 1.22E-04 |

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values- PBA** | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** |
| Scenario 1a - application | - | - |
| Scenario 1b - way back of hornets to the nest | Tier 1: 1.65E-05  Tier 2: 3.31E-07 | Tier 1: 6.13E-03  Tier 2: 1.23E-04 |

Conclusion on the risk to the aquatic compartment (only relevant for the scenario 1b, when the hornets are on their way back to their nest and fall accidentally in a pond): The PEC/PNEC ratios are below the trigger value of 1 for the active substance permethrin as well as for the metabolites DCVA and PBA, except for the scenario 1b- Tier 1. Nevertheless, this is a worst-case approach considering that none of the 50 treated hornets will go back to the nest and all will fall down in the same water body. If it is the case, this should no longer be considered as an accidental release but as a sign that the product is misused or ineffective.

If one hornet falls in the water compartment, the risk is considered as acceptable (Tier 2). A reverse calculation was done to calculate the number of treated hornets that can fall in the same pond without leading to unacceptable risk for the aquatic compartment. Using a volume of 1000 m3, up to 17 treated hornets that fall in the same pond results in acceptable risk for the aquatic compartment (*i.e.* up to more than one third of the treated hornets in case of high infestation).

To conclude, in order to prevent this kind of accidental situation, risk mitigation measures are added:

- “**Do not use near an aquatic environment”**

- **“When possible, remove the empty hornet nest at the end of the treatment”**

***Terrestrial compartment***

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values - Permethrin** | |
|  | **PEC/PNECsoil** |
| Scenario 1a - application | 2.89E-02 |
| Scenario 1b - way back of hornets to the nest | (covered by Scenario 1a) |

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values - DCVA** | |
|  | **PEC/PNECsoil** |
| Scenario 1a - application | 6.64E-05 |
| Scenario 1b - way back of hornets to the nest | (covered by Scenario 1a) |

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values - PBA** | |
|  | **PEC/PNECsoil** |
| Scenario 1a - application | 2.88E-04 |
| Scenario 1b - way back of hornets to the nest | (covered by Scenario 1a) |

Conclusion: The PEC/PNEC ratios are below the trigger value of 1 for the active substance permethrin as well as for the metabolites DCVA and PBA. Therefore, direct release into local soil due to the use of VELUTINA results in acceptable risk for soil.

***Groundwater***

As shown in the “Summary table on calculated PEC values” the trigger value of 0.1 µg/L was not exceeded in the assessed scenarios, excepted for the PBA metabolite in case of direct release to bare soil after the treatment of 50 hornets on the same restricted area of 0.25 m2. Nevertheless, the applied scenario is a very worst-case approach given the number of treated hornets, the restricted area of soil and the fraction emitted to soil. Indeed, this worst case emission to soil is very concentrated in a small volume of soil. This kind of emission can occur at a very local scale and does not reflect what can happen to groundwater compartment on a larger scale, as in the case of sewage sludge spreading. Moreover, in case of the hornet falls to the ground on his way back to his nest, it is very unlikely that all 50 treated hornets fall in the same restricted area of 0.25m2. In addition, a risk management measure requiring the use of a protective floor mat for the area where treatment of target organisms takes place is included in the instructions for use in order to avoid contamination of the terrestrial compartment and thus groundwater. This is why the risk is considered acceptable for groundwater.

Conclusion: Considering the specific instruction of use the risk is considered acceptable for groundwater :

* **The treatment must be carried out with the floor mat supplied with the product**

***Primary and secondary poisoning***

Primary poisoning

**Insectivorous (birds and mammals):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on secondary poisoning** | | | | |
| **Scenario** | **PECoral predator** [mg.kg-1food] | **PEC/PNECbirds** | **PEC/PNECmammals** | **Remarks** |
| **1a/1b**  **(Tier 1)** | 71.7 | **4.29E+00** | 5.97E-01 | Diet=100% of treated hornets |
| **1a/1b**  **(Tier 2)** | 7.17 | 4.29E-01 | 5.97E-02 | Diet=1/10 of treated hornets |

No risk is expected for primary poisoning if treated hornets constitute 1/10 of predator food, which is considered as a worst case regarding the specific use of the product.

However, it has to be noted that in France, some beekeepers use chickens to fight against predation pressure from the Asian Hornet. For that reason, a risk mitigation measure is added to prevent the use of the product close to a henhouse:

* **“Do not use near poultry houses”.**

**Bees assessment:**

The product VELUTINA (in gel form) contains the active substance permethrin known to be toxic to bees (LD50oral = 0.163 µg/bee and LD50contact = 0.0235 µg/bee) and therefore a risk for bees cannot be excluded.

Furthermore, VELUTINA is formulated with more than 80% of attractant for hornets (in order to contaminate the nest), that can also be attractive for bees. Considering the concentration of permethrin in VELUTINA product (0.086% w/w), one drop of 25 mg is sufficient to kill a bee.

Nevertheless, the applicant argued that the product is used exclusively by beekeepers so the effects on bees are directly under surveillance. The product is not relevant if a negative effect is observed on bees. For these reasons, no risk is identified for bees when the product is used by beekeepers according to the labelling.

Taking into account this argumentation, the justification provided by the applicant was considered as acceptable by FR CA.

Nevertheless, as the product is intended to be used near the hives, as a precautionary measure and for a better consumer information, the following RMM has been added by the FR CA:

* **“Hazardous to bees”.**

Secondary poisoning

Birds (PNEC oral bird≥16.7 mg.kg-1 food ) are more sensitive species than mammals (PNEC oral small mammals =120 mg.kg-1 food). Thus, only the most conservative ratio PEC/PNECbirds are presented.

The results for each scenario are summarised in the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on table on secondary poisoning for permethrin** | | | | |
|  | **PECoral predator**  [mg.kg wet fish-1] | **PEC/PNECbirds** | **PEC oral predator**  [mg.kg wet earthworm-1] | **PEC/PNECbirds** |
| Scenario 1a - application | - | - | 7.25E-02 | 4.34E-03 |
| Scenario 1b - way back of hornets to the nest | Tier 1: 3.06E-04  Tier 2: 6.13E-06 | Tier 1: 1.83E-05  Tier 2: 3.67E-07 | - | - |

Conclusion: All secondary poisoning assessment presents RCRs values below 1 for birds (and small mammals) in the aquatic and/or the terrestrial food chains.

The risk of secondary poisoning is acceptable when using the product VELUTINA.

***Mixture toxicity***

The environmental risk assessment of the product VELUTINA is based on the active substance (and its relevant metabolite). No substance of concern has been identified; a mixture assessment is not deemed necessary.

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

The use of the product VELUTINA is very localised and specific. It is not a wide dispersive use. In this dossier, there is only one product for this specific use. The aggregated exposure is not relevant in this dossier.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| According to the intended use, no emission is expected. Nevertheless, due to the outdoor use of the product, the toxicity of permethrin, the mode of application of the product on living targets, a risk assessment is conducted in case of accidental release of the product in the environment. Accidental emissions during the treatment of the hornet are considered at a very small local scale but are in reality much more diluted in the environment, especially when the hornet flies back to its nest.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Scenario | Surface water | Sediment | Soil | Groundwater | Primary Poisoning | Secondary Poisoning | | Scenario 1a - application | nc | nc | Acceptable | Acceptable\* | Unacceptable (Tier 1) Acceptable  (Tier 2) | Acceptable | | Scenario 1b - way back of hornets to the nest | Unacceptable (Tier 1) Acceptable  (Tier 2) | Unacceptable (Tier 1) Acceptable  (Tier 2) | Acceptable | Acceptable | Unacceptable (Tier 1) Acceptable  (Tier 2) | Acceptable |   \*Unacceptable for metabolite PBA for 50 treated hornets, nevertheless this condition was considered highly unrealistic for GW  First of all, significant exposure of the environment via the STP is not expected whatever the considered emission pathway, considering the specific instruction of use:   * “**Capture and processing accessories must be cleaned with disposable absorbent paper towels and not with water”**   For the water compartment, in a first and worst-case approach, the risk is considered as unacceptable, considering that none of the 50 treated hornets will go back to the nest and all will fall down in the same water body (Tier 1), that is considered highly unrealistic. If one hornet fall in the water compartment, the risk is considered as acceptable (Tier 2). However, in order to prevent this kind of accidental situation, risk mitigation measures are added:   * **- “Do not use near an aquatic environment”** * **- “When possible, remove the empty hornet nest at the end of the treatment”**   For terrestrial compartment, the risk is considered as acceptable in both scenarios, considering the specific instruction of use:   * **“The treatment must be carried out with the floor mat supplied with the product”.**   In case of accidental release to bare soil after the treatment of 50 hornets on the same restricted area, the risk is acceptable for the soil and groundwater, except for the PBA metabolite in groundwater. Nevertheless, this scenario is a worst-case approach and very unrealistic as this kind of emission occurs at local scale and does not reflect what can happen to groundwater compartment on a larger scale.  Unacceptable risks are identified for primary poisoning of birds in both scenarios (application and “service life”) with a worst-case approach considering that 100% of the bird diet consists of treated hornets. However, only a part of the hornet colony is treated (5 to 10 % depending on seasonal variations), it is very unlikely that there is an unacceptable risk to birds.  However, it has to be noted that in France, some beekeepers use chickens to fight against predation pressure from the Asian Hornet. For that reason, a risk mitigation measure is added to prevent the use of the product close to a henhouse:   * **“Do not use near poultry houses”.**   Moreover, the product is formulated with more than 80% of attractants and contains the active substance permethrin known to be toxic to bees (LD50oral = 0.163 µg/bee and LD50contact = 0.0235 µg/bee) and therefore a risk for bees cannot be excluded. Nevertheless, as the product is applied by beekeepers, the risk can be considered under control.  For these reasons, as the product is intended to be used near the hives, the following RMM has been added by the FR CA:   * **“Hazardous to bees”.**   The risk is considered as acceptable for secondary poisoning in all scenarios.  To conclude, risks for environmental compartments are acceptable with all the precautionary measures proposed above, in addition to more general measures as :   * **- “Prevent any release to the environment during the product application phase”** |

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

Please see the relevant section.

### Assessment of a combination of biocidal products

Not relevant.

### Comparative assessment

Not relevant.

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

## List of studies for the biocidal product

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of access** | | **Data protection claimed** | |
| **Physico-chemistry** | |  |  |  |  | **Yes** | **No** | **Yes** | **No** |
| S3.1, S3.2, S3.4.1 |  | Demangel B. | 2018 | Physico-chemical tests and chemical analyses before and after an accelerated storage procedure for 14 days at 54 ± 2°C on the product VELUTINA | Spring |  | **X** | **X** |  |
| S3.1, S3.3, S3.4.1, S3.5, S3.8, S3.9 |  | Demangel B. | 2018 | Physico-chemical tests on the product Velutina | Spring |  | **X** | **X** |  |
| S3.4.1 |  | Demangel B. | 2017 | Physico-chemical tests and chemical stability after a storage procedure for 48 months at 20 ± 2°C on the product VELUTINA | Spring |  | **X** | **X** |  |
| **Method validation** | |  |  |  |  | **Yes** | **No** | **Yes** | **No** |
| S5.1 |  | Ricau H. | 2018 | Validation of the analytical method for the determination of permethrin in the product VELUTINA - in compliance with SANCO/3030/99 rev.4 from 11/07/00 | Spring |  | **X** | **X** |  |
| **Efficacy** |  |  |  |  |  | **Yes** | **No** | **Yes** | **No** |
| S6.7\_01 |  | Jaillard B. | 2017 | Effet de la perméthrine sur la capacité d'envol de Vespa velutina. | Spring |  | **X** | **X** |  |
| S6.7\_02  S6.7\_03 |  | Jaillard B. | 2018 | Essais de capture-marquage-recapture de Vespa velutina et d’efficacité du procédé Velutina sur la fréquentation de Vespa velutina au rucher. | Spring |  | **X** | **X** |  |
| S6.7\_04 |  | Jaillard B. | 2019 | Effet du produit biocide Velutina sur Vespa venutina | Spring |  | **X** | **X** |  |
| S6.7\_05 |  | Jaillard B. | 2019 | Expérimentation sur un nid de Vespa velutina | Spring |  | **X** | **X** |  |
| S6.7\_06 |  | Jaillard B. | 2020 | Poids d'une goutte de produit Velutina | Spring |  | **X** | **X** |  |
| S6 |  | Couto A. | 2016 | Étude neurophysiologique et comportementale du frelon asiatique Vespa velutina. Neurobiologie. Université Paris-Saclay. | Public |  | **X** |  | **X** |
| S6 |  | Poidatz | 2017 | De la biologie des reproducteurs au comportement d’approvisionnement du nid, vers des pistes de biocontrôle du frelon asiatique Vespa velutina en France. Ecologie, Environnmeen, Université de Bordeaux. | Public |  | **X** |  | **X** |
| S6 |  | Atkinson et al. | 1991 | Pyrethroid resistance and synergism in a field strain of the German cockroach (Dictyoptera: Blattellidae). J. Econ. Entomol. 84:1247-2150 | Public |  | **X** |  | **X** |
| S6 |  | Shen and Plapp | 1990 | Cyromazine resistance in the house ﬂy (Diptera: Muscidae): genetics and cross-resistance to diﬂubenzuron. J. Econ.Entomol. 83: 1689–1697 | Public |  | **X** |  | **X** |
| S6 |  | Cilek and Greene | 1994 | Stable ﬂy (Diptera: Muscidae) insecticide resistance in Kansas cattle feedlots. J. Econ. Entomol. 87: 275–279. | Public |  | **X** |  | **X** |
| S6 |  | Wan-Norafilack et al. | 2013 | Development of permethrin resistance in Culex quinquefasciatus Say in Kuala Lumpru, Mlalaysia. Saudi J. Biol. Sci. 20(3): 241-250 | Public |  | **X** |  | **X** |
| S6 |  | Saavedra-Rodriguez et al. | 2008 | Quantitative Trait Loci mapping of genome regions controlling permethrin resistance in the mosquito Aedes aegypti. Genetics 180:1137–1152. | Public |  | **X** |  | **X** |
| S6 |  | Muller et al. | 2008 | Field-caught permethrin-resistant Anopheles gambiae overexpress CYP6P3, a P450 that metabolises pyrethroids. PLoS Genet 4(11) | Public |  | **X** |  | **X** |

## Output tables from exposure assessment tools

## New information on the active substance

Not relevant.

## Residue behaviour

Exceel sheet of PRIMo Rev. 3.1 for acute consumer risk assessment.



## Summaries of the efficacy studies (B.5.10.1-xx)

## Confidential annex

Please refer to the confidential annex document.

## Other

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)
2. https://inpn.mnhn.fr/espece/cd\_nom/433589/tab/fiche [↑](#footnote-ref-2)
3. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-3)