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**



MITE-KILLER

Product type 18

Synthetic amorphous silica (nano)

Case Number NA-APP: BC-LY020656-08

Case Number NA-MAC: BC-SQ060050-33

Evaluating Competent Authority: France

Date: November 2018

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**Note to the reader**

This consolidated PAR for the major change of the product authorisation of MITE KILLER is based on the PAR of the initial assessement of the product MITE KILLER and the subsequent successive assessments (post-authorisation data).

In part 2.1 of this consolidated PAR, the summary of product characteristics is pointed out and corresponds to the decision for the major change application.

In part 2.2 of this consolidated PAR, each section contains the initial assessment and the subsequent successive assessments (major change), the assessments related to the major change of the product are at the end of each section and are highlighted in grey.

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *FR* | BC-LY020656-08 | 01/02/2019 | First authorisation of MITE KILLER |
| NA-ADC | *FR* | BC-SJ019820-35 | 01/07/2019 | Admninistrative change |
| na | *FR* | na | 28/07/2020 | Post-authorisation data received the 02/05/2019 and the 07/08/2019 |
| NA-MAC | *FR* | BC-SQ060050-33 | xxx | Major change assessment :   * Addition of non professional users for bedbugs (use 1) * Addition of an application system. |

# CONCLUSION

The product Mite-Killer containing 1.5% Synthetic amorphous silica pure active substance (1.67 % technical synthetic amorphous silica) is applied indoors only by direct surface spraying for insecticide and acaricide preventive and curative treatments. The product is intended to be applied

* by professionals in bedrooms of private house and hotels against bedbugs in inaccessible locations such as cracks and crevices and on localised surfaces to create barriers,
* by non-professionals in aviaries, dovecotes and poultry houses against poultry red mites on surfaces.

*Physico-chimical properties*

The product Mite-Killer is an off-white liquid formulated as an aerosol. The degazed test item was composed of a homogeneous cloudy liquid lower phase and a colourless limpid liquid upper stage, it has a relative density of 0.723 at 21.5°C. Surface tension data viscosity data were not provided as the product Mite-Killer is biphasic and tests cannot be carried out under agitation condition.

Storage stability tests (8 weeks at 40 ± 2°C, 36 months at 20 ± 2°C and 7 days at 0 ± 2°C) demonstrate the stability of MITE KILLER under tested conditions. However, the spray pattern and particle size distribution after long term storage are still required in post authorization.

The satisfactory operation of the aerosol, the spray volume and spray diameter of the test item Mite-Killer (multi-shot aerosol) were considered to be stable after a storage procedure for 7 days at 0 ± 2°C and 8 weeks at 40°C.

A particle size distribution was performed by laser diffraction on the product Mite-Killer: 2.11% v/v of droplets were inferior of 10 µm and 0.02% v/v were were inferior of 6 µm

Based on its composition, the product Mite-Killer is an extremely flammable aerosol and is classified Flam. Aerosol 1, H222. Testing is considered as unnecessary.

The classification "H229 Pressurised container: May burst if heated." is also justified according to to Regulation 487/2013 (4th Adaptation to Technical and scientific Progress of the CLP), as the preparation is an aerosol. The product must be kept and handled away from heat, hot surfaces, sparks, open flames and other ignition sources. The pressurized container must not be pierced or burnt and must be protected from sunlight.

Experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature.Moreover, according to structural formulas of its ingredients and literature data, the product Mite-Killer is not expected to be oxidising, corrosive to metals or auto-flammable and the product does not react with water.

Biocide product contain more than 10 % formulant classified H304 cat 1. Due to missing value for viscosity, it cannot be assessed if the biocide product is classified H304. Therefore, biocide product is classified H304 cat 1 by default.

An analytical method for determination of silicon dioxide in biocide product was submitted and found validated.

Analytical methods for silicon dioxide residues in soil and water are not required as no exposure of these compartments are expected (indoor use only);

Analytical methods for silicon dioxide residues in air are proposed (NIOSH, 1994, NIOSH Manual of Analytical Methods (NMAM), Fourth Edition Silica, Amorphous Method 7501, Issue 2) and the studies are unprotected;

Analytical methods for silicon dioxide residues in animal and human body fluids and tissues are not required as silicon dioxide is not classified as hazardous.

Analytical methods for silicon dioxide residues in food/feed of animal or plant origin are not required as silicon dioxide under normal conditions of use in the product Mite-Killer will not come in contact with food/feed of animal or plant origin.

Data provided by the applicant to prove the level of *crystalline SiO2* were not acceptable due to deficiencies in the analytical methodology. Consequently, the product can be authorised with a post-authorisation condition to submit analytical data to prove that the percentage crystallinity of the active substance source is below 0.1%.

* **Post-Authorization data assessment – 2020 :**

The provided studies in the frame of post-authorization reiquirement leads to the following conclusions:

* Data regarding the spray pattern and particle size distribution after long term storage are considered acceptable and are therefore no longer requested.
* The NMR analysis demonstrated that the content of crystalline silica is below 0.1%w/w in the product. Moreover, as crystalline silica can only be formed at high temperature (> 1400°C) it cannot be formed during storage of biocide products. Therefore, a fully validated analytical method for the determination of crystalline silica in the product is not requested. Indeed, such analytical method is requested for relevant impurities only when the content increase during storage.
* **Major change application for MITE KILLER – 2021**

Major change has no impact on the physico-chemical section. The new application system was characterised and acceptable.

*Efficacy*

In accordance with the submitted test and the requirements of the TNsG on product evaluation for PT18 (2012), the product Mite-Killer shows sufficient efficacy against bed bugs *Cimex lectularius* (adults, nymphs and eggs) for a curative treatment on porous and non-porous surfaces at the dose of 40 g/m² with the minimum number of application of 3 applications spaced 1 to 4 weeks. The residual effect of 2 weeks in the field was not proved.

For use against poultry red mites *Dermanyssus gallinae* (adults, nymphs and eggs), the product Mite-Killer shows sufficient efficacy on porous and non-porous surfaces for a curative and preventive treatment at the dose of 40 g/m² with a residual effect of 7 weeks.

* **Major change application for MITE KILLER – 2021**

Major change has no impact on the efficacy section.

*Human health*

For professioanl users, the risk is considered acceptable when gloves are worn during the application of the product.

For non professional users, the risk is considered acceptable taking into account appropriate labelling and instructions of use that minimize exposure and health effects.

For secondary exposure of the general public, the risk has been juged acceptable.

For the professionnal and not professional, risk mitigation measures below are proposed to prevent human exposure

* Spray in a well ventilated area.
* Do not use as a space spray.

Risk mitigation measures below are proposed to prevent animal exposure

* Do not spray directly on people and animals.
* **Major change application for MITE KILLER – 2021 :**

The risk assessment for non-professional users has been performed considering the new intended uses claimed by the applicant. No impact of the major change has been observed on the HH risk assessment.

Dietary risk to consommer:

No specific residue data was submitted in the context of this dossier.

Based on its toxicological properties and regulations already in force, silicon dioxyde is unlikely to cause a dietary risk to consumers.

Moreover, as regards the intended use of the product MITE-KILLER against bedbugs, no direct or indirect contamination of food is expected. Nevertheless, to avoid any contamination, the following precautionary statement is proposed:

“ Avoid any direct or indirect contact with food and feed.”

For the application in aviaries, dovecotes and poultry houses by non-professionals, a livestock exposure assessment was provided by the applicant and reviewed by eCA. From this assessment, risk mitigation measures are proposed by the applicant to prevent animal and consumer exposures:

* Take away birds/poultry before treatment
* Remove all feed and drinking water prior to treatment
* Cover all surfaces and facilities likely to be in contact with feed and drinking water.
* **Major change application for MITE KILLER – 2021 :**

No impact of the major change has been observed on the dietary risk to consumer. Only modification of form has been performed in the PAR and is highlighted in grey.

Environmental risk

The product MITE KILLER contains one substance of concern for the environment (Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics).

Following the application of the product MITE-KILLER,

* levels of exposure for non-target species of aquatic (surface water and sediment) and terrestrial compartments are lower than the PNEC of the Substance of concern and the background values of the active substance.
* Concentrations in groundwater related to the use of product MITE-KILLER are also lower than the background values of the active substance or than the benchmark value set by Directive 98/83/EC.

In conclusion, based on the available information related to the use of the product MITE-KILLER, the environmental assessment is acceptable.

* **Major change application for MITE KILLER – 2021 :**

No impact of the major change has been observed on the environmental risk assessment.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### **Identifier of the product / product family**

|  |  |
| --- | --- |
| **Trade name(s)** |  |
|  | France :  MITE-KILLER  FOR BUG PLUS  FOR MITE PLUS  VEXINE  ITEC SPECIAL MITE |

#### **Authorisation holder**

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Denka Registrations B.V. |
| **Address** | Gildeweg 37a  3771 NB  Barneveld  Netherlands |
| **Authorisation number** | FR-2019-0002 | |
| **Date of the authorisation** | 01/02/2019 | |
| **Expiry date of the authorisation** | 31/01/2029 | |

#### **Manufacturer(s) of the products**

|  |  |
| --- | --- |
| **Name of manufacturer** | Denka International B.V. |
| **Address of manufacturer** | Gildeweg 37A,  3771 NB Barneveld  Netherlands |
| **Location of manufacturing sites** | Hanzeweg 1- 3771 NG  Barneveld  Netherlands |

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

|  |  |
| --- | --- |
| **Active substance** | Synthetic amorphous silicon dioxide (nano) |
| **Name of manufacturer** | Rentokil Initial plc |
| **Address of manufacturer** | Foundry Court,  RG13 5PY, Horsham,  United Kingdom |
| **Location of manufacturing sites** | 4 Liverpool Road ;  Warrington WA5 1AB;  United Kingdom |

### 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** |  | Silicon dioxide\* |  |
| **IUPAC or EC name** |  | Silicon dioxide |  |
| **EC number** |  | 231-545-4 |  |
| **CAS number** |  | 112926-00-8 |  |
| **Index number in Annex VI of CLP** |  | - |  |
| **Minimum purity / content** |  | 90% w/w |  |
| **Structural formula** |  |  | O=Si=O |

\* *Synthetic amorphous silica nano*

#### **Candidate(s) for substitution**

Silicon dioxide is not classified.

According to its Assessment Report (2014/03), silicon dioxide does not meet any of the criteria for Persistent, Bioaccumulative and Toxic (PBT) substances or the very Persistent, very Bioaccumulative (vPvB) substances.

Therefore, the active substance does not meet any exclusion criteria listed in Article 5 of Regulation (EU) No.528/2012 (CMR Cat. 1A or 1B, endocrine disruptor, vPvB) or two of the criteria for being PBT in accordance with Annex XIII of Regulation (EC) No.1907/2009, and is not classified as a respiratory sensitizer.

In conclusion, the active substance silicon dioxide contained in the biocidal product Mite-Killer is not a candidate for substitution in accordance with Article 10 of Regulation (EU) No.528/2012

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| Synthetic amorphous silicon dioxide (nano)  (technical)  Synthetic amorphous silicon dioxide (nano) (pure) | Mixture containing minimum 90% w/w silicon dioxide  Silicon dioxide | Active substance | 112926-00-8 | 231-545-4 | 1.67  *1.50* |
| Hydrocarbons, C7, n-alkanes, isoalkanes, cyclics | Hydrocarbons, C7, n-alkanes, isoalkanes, cyclics | Non active substance | - | 927-510-4 | 58.33 |

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

In the CAR of silicon dioxide, the following requirement is given:

“*Given the classification of crystalline silica as carcinogen, it should be checked at the product authorisation stage that no more than 0.1 % of crystalline SiO2 is present as impurity in the technical grade active substance.*”

After discussion and agreement in the Coordination group CG-31 in September 2018, it was concluded that the data provided by the applicant to prove the level of *crystalline SiO2* were not acceptable due to deficiencies in the analytical methodology. Consequently, the product can be authorised with a post-authorisation condition to submit analytical data to prove that the percentage crystallinity of the active substance source is below 0.1%. Data should be submitted to FR CA and results should be considered appropriate by the APCP WG.

* **Post-Authorization data assessment – 2020 :**

Such data were submitted in post authorisation data in 2020: The NMR analysis demonstrated that the content of crystalline silica is below 0.1%w/w in the product. Formation of crystalline silica from amorphous silica can only happen at elevated temperature. (> 1400°C; see details in the CAR). Therefore formation of this impurity during storage stability is not possible. This relevant impurity does not need to be analysed during storage stability tests.

#### **Information on technical equivalence**

Not concerned, the source of active substance is one assessed in the CAR of active substance.

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

|  |  |
| --- | --- |
| IUPAC name or other accepted chemical name | Hydrocarbons, C7, n-alkanes, isoalkanes, cyclics |
| EC number | 927-510-4 |
| CAS number | Not available |
| Concentration (minimum and maximum, g/kg or g/l) | 583.3 g/L |
| Classification and Labelling according to Regulation (EC) No 1272/2008: | Asp Tox 1 – H304  Skin Irrit 2 – H315  STOT SE 3 – H336  Aquatic chronic 2; H411 |
| Relevant toxicological/ecotoxicological information | Asp Tox 1 – H304  Skin Irrit 2 – H315  STOT SE 3 – H336  Aquatic chronic 2; H411 |
| Other grounds for concern | - |

Since Hydrocarbons, C7, n-alkanes, isoalkanes, cyclics leads to the classificarion H336, the substance is considered as SOC. According to the ECHA guidance volume III part B/C, an assessment according BAND A is needed and application of P-statements associated with H statementd is sufficient to manage the risk.

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

According to our assessment, none of the co-formulants contained in the product MITE-KILLER are identified as endocrine disruptors.

Please refer to Confidential Annex.

#### **Type of formulation**

|  |
| --- |
| AE: aerosol |

### Hazard and precautionary statements

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

|  |  |
| --- | --- |
| **Classification** | |
| Hazard categories | Extremely flammable aerosol cat 1  Asp Tox 1  Skin Irrit 2  STOT SE 3  Aquatic Chronic 2 |
| Hazard statements | H222: Extremely flammable aerosol.  H229: Pressurised container: May burst if heated.  H304: May be fatal if swallowed and enters airways.  H315: Causes skin irritation.  H336: May cause drowsiness or dizziness.  H411: Toxic to aquatic life with long lasting effects. |
| Additional hazard statements | None |
|  | |
| **Labelling** | |
| Hazard pictograms | GHS02 GHS07 GHS09 |
| Signal word | DANGER |
| Hazard statements | H222: Extremely flammable aerosol.  H229: Pressurised container: May burst if heated.  H315: Causes skin irritation.  H336: May cause drowsiness or dizziness.  H411: Toxic to aquatic life with long lasting effects. |
| Additional hazard statements | None |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand.  P102: Keep out of reach of children.  P211 Do not spray on an open flame or other ignition source.  P251 Do not pierce or burn, even after use.  P261: Avoid breathing dust/fumes/gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P271: Use only outdoors or in a well-ventilated area  P280: Wear protective gloves/protective clothing/eye protection/face protection  P312: Call a POISON CENTER/ doctor/…/if you feel unwell  P321: Specific treatment (see … on this label).  P302 + P352: IF ON SKIN: Wash with plenty of water/…  P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.  P332 + P313: If skin irritation occurs: Get medical advice/attention  P362 + P364: Take off contaminated clothing and wash it before reuse  P403 +P233: Store in a well ventilated place. Keep container tightly closed.  P405: Store locked up  P273:Avoid release to the environment  P391: Collect spillage  P501: Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified). |

### Authorised use(s)

#### **Use description**

Table 1. Use # 1 – Bedbugs

|  |  |
| --- | --- |
| **Product Type** | PT18 – Insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** | Insecticide. |
| **Target organism (including**  **development stage)** | *Cimex lectularius*  Bedbug  Adults, nymphs and eggs |
| **Field of use** | Indoor use  The product Mite-Killer is a ready-to-use aerosol to be sprayed into cracks and crevices and on surfaces against bedbugs |
| **Application method(s)** | Treatment of porous and non-porous surfaces by spraying  Treatment in crack and crevices by spraying |
| **Application rate(s) and frequency** | 40 g/m2 (9 m2 per can) correspond to 19 seconds of spray/m2*without the blow-pipe and 40 seconds of spray/m² with the blow pipe.*  Minimum number of applications 3 spaced 1 to 4 weeks for curative applications  Repeat if new infestation is monitored or in case of cleaning without exceeding 11 applications per year. |
| **Category(ies) of users** | Professional user  *Non professional user* |
| **Pack sizes and packaging material** | Multi-shot aerosol tin can of 500 mL with an epoxy phenol lacquer.  Removable blow-pipe can be inserted in the spray nozzle. |

***2.1.4.1.1 Use-specific instructions for use***

|  |
| --- |
| * Spray in all the cracks and crevices where the bedbugs can hide. * Create barriers by spraying the bed frames, baseboards (or a 20 cm strip at the bottom of the walls). * Clean carefully the rooms before treatment. * Do not apply on the mattresses. |

***2.1.4.1.2 Use-specific risk mitigation measures***

|  |
| --- |
| * Avoid any direct or indirect contact with food and feed. * For professional user, wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). |

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

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| - |

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

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| --- |
| - |

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

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| --- |
| - |

#### **Use description**

**Table 2. Use # 2 – Poultry red mites**

|  |  |
| --- | --- |
| **Product Type** | PT18 – Insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** | Acaricide. |
| **Target organism (including development stage)** | *Dermanyssus gallinae*  Poultry red mite  Adults, nymphs and eggs |
| **Field of use** | Indoor use  The product Mite-Killer is a ready-to-use aerosol to be sprayed on surfaces against poultry red mites |
| **Application method(s)** | Spraying Surface spraying |
| **Application rate(s) and frequency** | 40 g/m² ( 9 m² per can) correspond to 19 seconds of spray/m2  Minimum 1 application with a residual effect up to 7 weeks  Maximum 5 applications per year |
| **Category(ies) of users** | Non-professional user |
| **Pack sizes and packaging material** | Multi-shot aerosol tin can of 500 mL with an epoxy phenol lacquer |

***2.1.4.2.1.* *Use-specific instructions for use***

|  |
| --- |
| * Spray on the roosts, nesting boxes, under the trays…and in all the corners, cracks and crevices where the mites can hide. * Residual effect until 7 weeks. * Clean carefully the aviaries, dovecotes or poultry houses. |

***2.1 4.2.2 Use-specific risk mitigation measures***

|  |
| --- |
| * Take away birds/poultry before treatment. * Remove all feed and drinking water prior to treatment. * Cover all surfaces and facilities likely to be in contact with feed and drinking water. |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
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| - |

### General directions for use

#### **Instructions for use6**

|  |
| --- |
| * Always read the label or leaflet before use and respect follow all the instructions provided. * Shake the product before the use. * While spraying, hold the aerosol at 30 cm distance from the surfaces. * Repeat in case of new infestation or after cleaning without exceeding the maximum number of treatment authorized per year. |

#### **Risk mitigation measures**

|  |
| --- |
| * Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. * Always wash the hands after handling. * Do not eat, drink or smoke where the product is used. * Do not spray directly on people and animals. * Spray in a well ventilated area. * Do not use as a space spray. |

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

|  |
| --- |
| * Impaired consciousness: do not give fluids or induce vomiting; place in recovery position and seek medical advice immediately. * Inhalation: Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * Mouth contact/Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or in case of mouth contact with large quantities. * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Get medical attention 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. * Keep the container or label available. |

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

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| * Dispose of this material and its container at hazardous or special waste collection point in accordance with local/national regulations. * The disposal of this packaging in the environment will be banned. * Do not empty into drains and streams. |

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

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| --- |
| * Keep away from heat, hot surfaces, sparks, open flames and other ignition sources * No smoking. * Shelf-life: 24 months. * Do not store at a temperature above 40°C. * Keep out of reach of children and pets. |

### Other information

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| * Inform the registration holder if the treatment is ineffective. * The label professional and non professional will be printed separately to avoid potential mis-leading. |

### 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)** |
| Multi-shot aerosol can  *With Removable blow-pipe* | Nominal filling volume: 500 mL  Full capacity: 650 mL | Tin plate with internal coating epoxy phenol lacquer | - | Professional and non- professional | yes |

### Documentation

#### **Data submitted in relation to product application**

Efficacy data: Following laboratory studies and field test have been taken into account for the assessment of the efficacy of the product MITE KILLER:

* Two laboratory tests with the product MITE KILLER (silicon dioxide, 1.5% w/w) on *Cimex lectularius*;
* Laboratory tests with the product MITE KILLER (silicon dioxide, 1.5% w/w) on *Dermanyssus gallinae*;
* Field test with the product MITE KILLER (silicon dioxide, 1.5% w/w) on *Cimex lectularius*.
* Field test with the product MITE KILLER (silicon dioxide, 1.5 % w/w) on *Dermanyssus gallinae.*

**Major change application for MITE KILLER – 2021:** No additional efficacy data have been submitted for the MAC.

Complete physico-chemical properties and toxicology section, refer to list of studies.

Residues data

No specific residue data was submitted in the context of this dossier.

#### **Access to documentation**

*The applicant DENKA has a letter of access.*

## Assessment of the biocidal product

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

The product Mite-Killer (containing 1.5% silicon dioxide as active substance) is applied indoors only by direct surface spraying for insecticide and acaricide preventive and curative treatments. The product is intended to be applied by professionals in bedrooms of private house and hotels against bedbugs in inaccessible locations such as cracks and crevices and on localised surfaces to create barriers, and by non-professionals in aviaries, dovecotes and poultry houses against poultry red mites on surfaces.

**Table 2.1.4.1-1. Use 1 – Bedbugs**

|  |  |
| --- | --- |
| **Product Type** | PT18 – Insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** | The product Mite-Killer is a ready-to-use aerosol to be sprayed into cracks and crevices and on surfaces against bedbugs. |
| **Target organism (including**  **development stage)** | *Cimex lectularius* bedbug  Adults, nymphs and eggs |
| **Field of use** | Indoor use |
| **Application method(s)** | Spraying  Cracks and crevices and surface spraying |
| **Application rate(s) and frequency** | 40 g/m2 or 62 mL/m2  Between 1 and 6 weeks interval for curative applications, depending on the level of infestation.  Treatment if new infestation is monitored.  Maximum 11 treatments per year. |
| **Category(ies) of users** | Professional user |
| **Pack sizes and packaging material** | Please see the relevant information in paragraph 2.1.7 of this document and in Section 12.3 of the IUCLID file. |

**Table 2.1.4.1-2. Use 2 – Poultry red mites**

|  |  |
| --- | --- |
| **Product Type** | PT18 – Insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** | The product Mite-Killer is a ready-to-use aerosol to be sprayed on surfaces against poultry red mites. |
| **Target organism (including**  **development stage)** | *Dermanyssus gallinae* poultry red mite  Adults, nymphs and eggs |
| **Field of use** | Indoor use |
| **Application method(s)** | Spraying  Surface spraying |
| **Application rate(s) and frequency** | 40 g/m2 or 62 mL/m2  Minimal 1 week interval for curative treatment.  Up to 6 weeks interval for preventive treatment.  Maximum 5 treatments per year. |
| **Category(ies) of users** | Non-professional user / consumer |
| **Pack sizes and packaging material** | Please see the relevant information in paragraph 2.1.7 of this document and in Section 12.3 of the IUCLID file. |

* **Major change application for MITE KILLER – 2021 :**

|  |  |
| --- | --- |
| **Product Type** | PT18 – Insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** | Insecticide. |
| **Target organism (including**  **development stage)** | *Scientific name: Cimex lectularius*  *Common name: Bed bug*  *Development stage: Adult, nymphs, eggs* |
| **Field of use** | Indoor  Indoor use  The product Mite-Killer is a ready-to-use aerosol to be sprayed into cracks and crevices and on surfaces against bedbugs |
| **Application method(s)** | Spraying  Treatment of porous and non-porous surfaces by spraying  Treatment in crack and crevices by spraying |
| **Application rate(s) and frequency** | 40 g/m2 (9 m2 per can) correspond to 19 seconds of spray/m2 without the blow-pipe and 40 seconds of spray/m² with the blow pipe.  minimum number of applications 3 spaced 1 to 4 weeks apart for curative applications.  Repeat if new infestation is monitored or in case of cleaning without exceeding 11 applications per year. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Multi-shot aerosol tin can of 500 mL with an epoxy phenol lacquer.  Removable blow-pipe |

### Physical, chemical and technical properties

Biocidal product is a ready to use aerosol formulation (GIFAP code AE)

Based on primary particle size (< 25 nm) and specific surface area by volume submitted, active substance is a nanomaterial according to the Commission recommendation on definition of nanomaterial (2011/696/EU) and the Article 3(1)(z) of Regulation EU 528/2012. The data provided in the CAR show that in active substance, primary particles are aggregated in particles of > 1 µm. Aggregate means a particle comprising of strongly bounds or fused particles. Under conditions of normal handling and use, it is considered that aggregates are the smallest stable particles. In this context, data provided by the notifier and literature tend to show that liberation of primary particles and exposure to nano-object (material with one, two or three external dimensions in the nanoscale) is not expected during and after the intended biocidal application considered in this dossier.

Since exposure to nanoscale primary particles was not expected during the specific intended biocidal use, the hazard and risk of the individual particles of silicon dioxide with a nanometric size were not evaluated in this dossier (ie. individual particles not aggregated). This position will be updated with the evolution of knowledge and specific regulations about nanomaterials or with complementary data showing that use of MITE-KILLER leads to exposure to individual particles of silicon dioxide with nanometric size.

A relevant impurity is defined in the CAR of the active substance Synthetic amorphous silica (nano): crystalline silica with a threshold of 0.1%.

Data provided by the applicant to prove the level of *crystalline SiO2* were not acceptable due to deficiencies in the analytical methodology. Consequently, the product can be authorised with a post-authorisation condition to submit analytical data to prove that the percentage crystallinity of the active substance source is below 0.1%.

* **Post-Authorization data assessment – 2020 :**

The NMR analysis demonstrated that the content of crystalline silica is below 0.1%w/w in the product. Formation of crystalline silica from amorphous silica can only happen at elevated temperature. (> 1400°C; see details in the CAR). Therefore formation of this impurity during storage is not possible. This relevant impurity does not need to be analysed during storage stability tests.

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | | **Results** | | **Reference** | **FR evaluation** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20°C and 101.3 kPa | Visual  observation | - | | The degassed test item was composed of a homogeneous cloudy liquid lower phase from 0 to 50-mL graduation and a colourless limpid liquid upper phase from 50- mL to 100-mL graduation. | | DEMANGEL B 2017  study No.15-904017-002 | Acceptable  Due to the biphasic product should be shaken before used. |
| Colour at 20°C and 101.3 kPa | Visual  observation | - | | The degassed test item was composed of a homogeneous cloudy liquid lower phase from 0 to 50-mL graduation and a colourless limpid liquid upper phase from 50-mL to 100-mL graduation. | | DEMANGEL B 2017  study No.15-904017-002 | Acceptable |
| Odour at 20°C and 101.3 kPa | Olfactory test | - | | Characteristic odour | | DEMANGEL B 2017  study No.15-904017-002 | Acceptable |
| Acidity / alkalinity | Not required as Mite-Killer is a non-aqueous product. | | | | | | Acidity /alkalinity could be tested on non aqueous products. However, given the composition of biocide product no acidity or alkalinity is expected. |
| Relative density / bulk density | EC A3 OECD 109 | | - | D (21.5°C / 4°C) = 0.723 ± 0.001. | | DEMANGEL B 2017  Study 15-904017-005 | acceptable |
| Stoge stability test – **accelerated storage** | CIPAC MT46.3  (8 weeks at 40 ± 2°C)  MT used for AS content : ICP –OES validated in analytical part. | | Mite killer | Stability study result in commercial packaging (can with epoxyphenolique coating) after 8 weeks at 40°C   |  |  |  | | --- | --- | --- | |  | Before storage | After storage | | Silice dioxide content %  In degazed BP | 2.7 | 1.34 | | packaging appearance | No sign of corrosion or degradation | | | Packaging weigh | Around 440 g | -0.2% | | Volume / spray of 5s | 12.7 mL | 11.8mL | | Spray diameter | 11 cm | 14 cm |   The variation after 8 weeks *vs.* the value at initial time of silicon dioxide is - 50.4%, the test item was not considered to be stable after 8 weeks of storage.  Explanation submitted about decrease: for the first sampling after storage, an operating mistake was done; no trace of silicon dioxide (SiO2) was found during the analytical quantification, a second sampling was made but the deposit observed during the degassing procedure was not completely recovered; this deviation can explain the decrease of the content of silicon dioxide (SiO2). | | DEMANGEL B 2017  study No.15-904017-002 | Even if the sampling in the study is erroneous, this study demonstrate that spray is stable over time  With study below, it can be assessed the biocide product is stable 8 weeks at 40°C |
| Internal method based on ICP-OES validated and reported in analytical part | |  | Storage study for 8 weeks at 40°C in commercial packaging (can with epoxyphenolique coating).  Silice dioxide content %In gazed BP  Before storage: 1.53 %  After storage: 1.52%  The silicon dioxide content in the product Mite-Killer was considered to be stable after an accelerated storage procedure for 8 weeks at 40°C (- 0.7%). | | B. Meersman 2015  Not GLP | This study is not complete. Only data on content on active substance is available.  With study above, it can be assessed the biocide product is stable 8 weeks at 40°C |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph No.17, 2nd edition, CropLife International (24 months at 20 ± 2°C)  MT used for AS content: ICP –OES validated in analytical part. | | MITE-KILLER batch 250753 | Interim result of long term storage study in commercial packaging (can with epoxyphenolique coating).   |  |  |  | | --- | --- | --- | |  | Before storage | After storage | | Silice dioxide content %  In degazed BP | 2.70 | 2.62 |   Content of silicon dioxide is stable after 6 month storage in commercial packaging. | | Trebert R. 2017 | Final report of shelf life study report, including data on spray pattern and particle size distribution, is required in post registration |
|  | MT used for AS content: ICP –OES validated in analytical part. | | batch (01072014) | Final results of long term storage study in commercial packaging.   |  |  |  | | --- | --- | --- | |  | Before storage | After storage (36 months) | | Silice dioxide content % | 1.53 | 1.51 | | | |  | | --- | | Bart Meersman , 2018 | | The results show that the active substance is stable during the storage. However, the spray pattern and particle size distribution are still required in post authorization |
| Storage stability test – **long term storage at ambient temperature** | The pattern and diameter of the spray of the test item are recorded and measured  after spraying with defined conditions. | | batch 15-240 | Final results of long term storage study in commercial packaging.   |  |  |  | | --- | --- | --- | |  | Before storage | After storage (32 months) | | mean volume of spray after a 5-s spray | No data | 12 mL | | mean spray diameter | No data | 15 cm | | Shape of the spray | No data | circular | | | |  | | --- | |  |   B. Demangel 2019 | **Post-authorization data 2020:** The results show that the active substance is stable during the storage. |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT39.3 | | - | Multi-shot aerosol was tested after 7 days at 0 ± 2°C   |  |  |  | | --- | --- | --- | |  | Before storage | After storage | | Appearance | See above | As initial | |  |  | | | Appearance of packaging | Tin-plate aerosol can, no sign of corrosion or degradation | Tin-plate aerosol can, no sign of corrosion or degradation | | volume of spray after a 5-s spray | 14.4 mL.  no blocking of nozzles was observed. | 15.0 mL.  no blocking of nozzles was observed. | | Spray diameters and patterns | 12 cm.  The shape of the spray on the wetted patch was circular. | 14 cm.  The shape of the spray on the wetted patch was circular. | | |  | Multishot biocide product is stable after 7 days at 0°C. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Not required as the commercial packaging is opaque (tin aerosol can). | | | | | | acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | An accelerated storage study for 8 weeks at 40 ± 2°C according to CIPAC MT46.3 method and a low temperature storage stability study according to CIPAC MT39.3 method with the product Mite-Killer were provided and demonstrate compatibility of product until 40°C. | | | | | | acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Compatibility of biocide product with packaging is demonstrated with accelerated storage test | | | | | | acceptable |
| Wettability | Not applicable. The product is a liquid formulated as an AE (aerosol). | | | | | | acceptable |
| Suspensibility, spontaneity and dispersion stability | Not applicable. The product is a ready-to-use liquid formulated as an AE (aerosol). | | | | | | Biocide product is a suspension, suspensibility would be interesting, regardless of aerosol status.  Due to mitigation measure (should be shake before used) suspensibility is not required. |
| Wet sieve analysis and dry sieve test | Not applicable. The product is a liquid formulated as an AE (aerosol). | | | | | | acceptable |
| Emulsifiability, re-  emulsifiability and emulsion stability | Not applicable. The product is a ready-to-use liquid formulated as an AE (aerosol). | | | | | | acceptable |
| Disintegration time | Not applicable. The product is a ready-to-use liquid formulated as an AE (aerosol). | | | | | | acceptable |
| Particle size distribution, content of dust/fines, attrition, friability | Laser diffraction system | | No data.  Product given as similar to Mite-Killer by applicant | | Particule size distribution of aerosol:  Dv (10%) = 30.65 µm Dv (50%) = 59.35 µm  Dv (90%) = 109.30 µm  0.6050% V < 6 µm  1.293% V < 10 µm | Mo5605 | This test was not performed on actual biocide product.  However, an acceptable study was provided see below. |
| Laser diffraction system | | Product tested:  Mite-Killer (Batch  No.253461) | | Volume Particule size distribution of aerosol:  Dv (10%) = 21 µm  Dv (50%) = 67 µm  Dv (90%) = 203 µm  0.02% V < 6 µm  2.11% V < 10 µm | DEMANGEL B 2017 | Acceptable |
|  | CIPAC MT 187  Laser difraction method | | Mite-killer batch 253461 | | Volume Particule size distribution of aerosol (mean of 3 samples):  Dv (10%) = 19 µm  Dv (50%) = 51 µm  Dv (90%) = 277 µm  3.56% V < 10 µm  49.6% V < 50 µm | N. Rodrigez 2015 | Acceptable |
| Particle size distribution | CIPAC MT 187  Laser difraction method | | Product tested:  Mite-Killer (Batch  No.253461) | | Volume Particule size distribution of aerosol (mean of 3 samples):  Dv (10%) = 19 µm  Dv (50%) = 51 µm  Dv (90%) = 277 µm  3.56% V < 10 µm  49.6% V < 50 µm | N. Rodrigez 2019. | **Post-authorization data 2020 :** Acceptable |
| Persistent foaming | Not applicable. The product is a ready-to-use liquid formulated as an AE (aerosol). | | | | | | acceptable |
| Flowability/Pourability/Dustabi lity | Not applicable. The product is a liquid formulated as an AE (aerosol). | | | | | | acceptable |
| Burning rate — smoke generators | Not applicable. The product is a ready-to-use liquid formulated as an AE (aerosol) and is not intended to be applied as a smoke. | | | | | | acceptable |
| Burning completeness — smoke generators | Not applicable. The product is a ready-to-use liquid formulated as an AE (aerosol) and is not intended to be applied as a smoke. | | | | | | acceptable |
| Composition of smoke — smoke generators | Not applicable. The product is a ready-to-use liquid formulated as an AE (aerosol) and is not intended to be applied as a smoke. | | | | | | acceptable |
| Spraying pattern — aerosols | FEA 644 | | Multi-shot aerosol  Mite-Killer (Batch No.250882) | | The mean volume of spray after a 5-s spray was 14.4 mL.  The nozzles of the aerosols were checked and no blocking was observed. | DEMANGEL B 2017 | acceptable |
| Multi-shot aerosol  Mite-Killer (Batch No.250882) | | The mean spray diameter was 12 cm.  The shape of the spray on the wetted patch was circular. | DEMANGEL B 2017 | acceptable |
| * **Major change application for MITE KILLER – 2021** | | | | | | | |
| Spraying pattern — aerosols |  | | Mite killer aerosol blowpipe  (Batch No.250882) | | The mean volume after 10s spray was measured to be 0.9-1.1 g/s  The spray pattern at 30 cm is a 5x8cm round surface | Van der Werff B. 2020 | acceptable |
| Other technical characteristics | - | | - | |  |  |  |
| Physical compatibility | Not applicable. The product is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical compatibility of Mite-Killer with other biocidal products, chemicals or active substances is required. | | | | | | acceptable |
| Chemical compatibility | Not applicable. The product is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. Hence, no data on the chemical compatibility of Mite-Killer with other biocidal products, chemicals or active substances is required. | | | | | | acceptable |
| Degree of dissolution and dilution stability | Not applicable. The product is a ready-to-use liquid formulated as an AE (aerosol). | | | | | | acceptable |
| Surface tension | EC A5 OECD 115 | | - | | Mite-Killer is biphasic and the test cannot be carried out under agitation condition. |  | Acceptable |
| Viscosity | OECD 114 | | - | | Mite-Killer is biphasic and the test cannot be carried out under agitation condition. |  | No data submitted.  Viscosity could have been tested with stiring.  Therefore biocide product will be classified as H304 cat 1 by default |

**Conclusion on the physical, chemical and technical properties of the product**

The product Mite-Killer is an off-white liquid formulated as an aerosol. The degazed test item was composed of a homogeneous cloudy liquid lower phase and a colourless limpid liquid upper phase, it has a relative density of 0.723 at 21.5°C. Surface tension data viscosity data were not provided as the product Mite-Killer is biphasic and tests cannot be carried out under agitation condition.

Storage stability tests (8 weeks at 40 ± 2°C, 36 months at 20 ± 2°C and 7 days at 0 ± 2°C) demonstrate the stability of MITE KILLER under tested conditions. However, the spray pattern and particle size distribution after long term storage are still required in post authorization.

The satisfactory operation of the aerosol, the spray volume and spray diameter of the test item Mite-Killer (multi-shot aerosol) were considered to be stable after a storage procedure for 7 days at 0 ± 2°C and 8 weeks at 40°C.

A particle size distribution was performed by laser diffraction on the product Mite-Killer: 2.11% v/v of droplets were inferior of 10 µm and 0.02% v/v were were inferior of 6 µm.

* **Post-Authorization data assessment – 2020 :**

Data regarding the spray pattern and particle size distribution after long term storage are considered acceptable and are therefore no longer requested.

* **Major change application for MITE KILLER – 2021**

Data regarding the spray pattern of blow pipe device was submitted and the new device is considered acceptable.

### Physical hazards and respective characteristics

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **Reference** |
| Explosives | Liquid part of the product Mite-Killer contains no ingredient considered to be explosive based on available data found in literature.  The liquid under pressure is not expected to be explosive either. | | | |
| Flammable gases | Not relevant as the product is formulated as an aerosol. | | | |
| Flammable aerosols | The preparation contains 98.33% w/w of highly flammable liquid and vapour and extremely flammable gas.  Data are not available to assess the classification of biocidal product.  Nevertheless, as classification as Flam. Aerosol 1, H222 is proposed by the applicant (the worst classification possible for a flammable aerosol) eCA agree with this classification. | | | |
| Oxidising gases | No component present in formulation is considered as oxysiding. Mite \_killer have no oxisising properties. | | | |
| Gases under pressure | Internal pressure of MITE-KILLER is 3.4 atm at 20 °Cis lower than the threshold for H280 Classification (gaz under pressure).This classification is not needed for this biocide product.  However, classification H229 Pressurised container: May burst if heated." is the hazard statement for the hazard category of an aerosol. | | | |
| Flammable liquids | Not relevant as the product is formulated as an aerosol. | | | |
| Flammable solids | Not relevant as the product is formulated as an aerosol. | | | |
| Self-reactive substances and mixtures | Not required as the liquid part of the product Mite-Killer contains no ingredient considered to be explosive or self-reactive based on available data found in literature. | | | |
| Pyrophoric liquids | Not required as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature. | | | |
| Pyrophoric solids | Not relevant as the product is formulated as an aerosol. | | | |
| Self-heating substances and mixtures | Not relevant as the product is formulated as an aerosol. | | | |
| Substances and mixtures which in contact with water emit flammable gases | Not required as the product Mite-Killer contains no ingredient classified as water-react. 1 or water-react. 2 and as the chemical structures of the ingredients do not contain metals or metalloids. | | | |
| Oxidising liquids | Not required as the product Mite-Killer contains 98.33% w/w of non-oxidising ingredients based on available data found in literature. | | | |
| Oxidising solids | Not relevant as the product is formulated as an aerosol. | | | |
| Organic peroxides | Not required as the product does not contain organic peroxide. | | | |
| Corrosive to metals | Not required as the product Mite-Killer contains no ingredient classified as corrosive to metals. | | | |
| Auto-ignition temperatures of products (liquids and gases) | Not required as the product Mite-Killer contains no ingredient considered to be auto-flammable based on available data found in safety data sheets of the ingredients. | | | |
| Relative self-ignition temperature for solids | Not relevant as the product is formulated as an aerosol. | | | |
| Dust explosion hazard | Not relevant as the product is formulated as an aerosol. | | | |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| Based on its composition, the product Mite-Killer is an extremely flammable aerosol and is classified Flam. Aerosol 1, H222. Testing is considered as unnecessary.  The classification "H229 Pressurised container: May burst if heated." is also justified according to Directive 75/324/EEC and to Regulation 487/2013 (4th Adaptation to Technical and scientific Progress of the CLP), as the preparation is an aerosol. The product must be kept and handled away from heat, hot surfaces, sparks, open flames and other ignition sources. The pressurized container must not be pierced or burnt and must be protected from sunlight.  Experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature.  Moreover, according to structural formulas of its ingredients and literature data, the product Mite-Killer is not expected to be oxidising, corrosive to metals or auto-flammable and the product does not react with water.  Biocide product contain more than 10% formulant classified H304 cat 1. Due to missing value for viscosity, it cannot be assessed if the biocide product is classified H304. Therefore, biocide product is classified H304 cat 1 by default. |

### Methods for detection and identification

Report: Trebert R. 2017 Validation of analytical Method for the determination of silicon dioxide in the liquid part of biocide product “MITE-KILLER"

Report no BPL17-0007

Test facilities: Saint Etienne du Rouvray cedex France

Principle of the method:

After mineralistation of product using hydrofluoric acid and nitric acid and heating for 2 hours at 99°C, silicium residue are analysed by ICP-OES.

Wavelength used 251.611 nm

Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * Blank item * Formulation blank fortified with active substance * Reference item of the active substance   No peak appears in the formulation blank.  Method is specific. | |
| Linearity | Linearity was studied by carrying out 6 concentrations between 50% and 150% of the reference item.  Calibration curve has been provided with a R2 higher than 0.99. | |
| Precision | Repeatability was evaluated by analyzing nine test item solutions. | |
| Compound | Repeatability (RSD) |
| Active substance | RSD = 5.46% |
| Accuracy | Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 100% | 100.3; 98.2; 98.8; 102.6; 107.5 | 101.5% | 4.92 | 5 | | |

Conclusion:

Silicon is determined in MITE KILLER formulation degazed. Conversion to silicon dioxide is performed by calculation.

RSD of precision and accuracy are slightly high compared to horwitz predictions, but analysis of silicon dioxide is known to be difficult, deviation is acceptable

The analytical method is fully validated for the determination of the active substance silicon dioxide in the product.

* **Post-Authorization data assessment – 2020 :**

Report: H. Colaux. 2019 Trace level detection and quantification of crystalline silica in amorphous silica matrix with 29Si NMR.

Report no BPL17-0007

Test facilities: KU Leuven, Center for surface Chemistry and catalysis, Departement of microbial and molecular systems (M2S), Celestijnenlaan 200F, Leuven, Belgium.

Principle of the method: 29Si NMR spectra was acquired on a 500 MHZ spectrometer operating at 99.5MHz. Using the specific properties of crystalline silica relaxation, The system is specific to crystalline silica.

Two test item have been used in this study as amorphous material : Gasil 23D (batch n° : GA16114) and FORM24 which present a different amorphous silica.

These test item have been fortified with standard crystalline silica at 1, 2.5, 5 %w/w and 0.1, 0.6, 1, 2, 5 and 10 %w/w respectively for Gasil 23D and FORM24.

The linear regression (y=a\*x +b) on Gasil 23D results in a = 0.96966 and b = 0.00070806.

The linear regression (y=a\*x +b) on FORM244 results in a = 0.96966 and b = 0.00070806.

Both affine regressions demonstrate a linear correlation (r²>0.99) with intercept closed to 0, indicating the crystalline silica concentration in the blank GASIL 23D sample is lower than 0.1%w/w.

**Conclusion:**

The NMR analysis demonstrated that the content of crystalline silica is below 0.1%w/w in the product. Moreover, as crystalline silica can only be formed at high temperature (> 1000°C[[1]](#footnote-2)) it cannot be formed during storage of biocide products. Therefore, a fully validated analytical method for the determination of crystalline silica in the product is not requested. Indeed, such analytical method is requested for relevant impurities only when the content increase during storage.

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| **Analytical methods for soil** |

For the environmental assessment (presented in the green boxes), the quantity of silicon dioxide released from the product Mite-killer is compared with the silica background in the considered compartment. However, according to the CAR, after the use of the product no emission to the aquatic environment is expected. And, only the quantity of silicon dioxide release into the soil was compared with the background value. Consequently, the use of analytical monitoring methods seem not be relevant to achieving the risk assessment.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for air** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Internationally accepted method: NIOSH, 1994, NIOSH Manual of Analytical Methods (NMAM), Fourth Edition Silica, Amorphous Method 7501, Issue 2 | | | | | | | | | |

|  |
| --- |
| **Analytical methods for water** |

Analytical methods for silicon dioxide residues in water is not required as no exposure of this compartment is expected (indoor use only);

|  |
| --- |
| **Analytical methods for animal and human body fluids and tisues** |

Analytical methods for silicon dioxide residues in animal and human body fluids and tissues are not required as silicon dioxide is not classified as hazardous.

|  |
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| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** |

Analytical methods for silicon dioxide residues in food/feed of animal or plant origin are not required as silicon dioxide under normal conditions of use in the product Mite-Killer will not come in contact with food/feed of animal or plant origin

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| **Conclusion on the methods for detection and identification of the product** |
| * Analytical methods for silicon dioxide residues in soil and water are not required as no exposure of these compartments are expected (indoor use only); * Analytical methods for silicon dioxide residues in air are proposed (NIOSH, 1994, NIOSH Manual of Analytical Methods (NMAM), Fourth Edition Silica, Amorphous Method 7501, Issue 2) and the studies are unprotected; * Analytical methods for silicon dioxide residues in animal and human body fluids and tissues are not required as silicon dioxide is not classified as hazardous. * Analytical methods for silicon dioxide residues in food/feed of animal or plant origin are not required as silicon dioxide under normal conditions of use in the product Mite-Killer will not come in contact with food/feed of animal or plant origin. |

### Efficacy against target organisms

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

*Main Group 03: Pest Control*

*Product Type 18: Insecticides, acaricides and products to control other arthropods*

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

The product Mite-Killer (1.67 % w/w technical silicon dioxide) is a ready-to-use aerosol to be used by professionals against bedbugs (*Cimex lectularius)* and by non-professionals against poultry red mites (*Dermanyssus gallinae)*. It is used indoors only.

The product is sprayed on surfaces and, cracks and crevices. Since the product is formulated as a ready- to-use product, no dilution or other preparations are necessary. The application rate is 40 g/m².

The product Mite-Killer is intended to be used for the curative treatment against bedbugs *Cimex lectularius* (adults, nymphs and eggs) and poultry red mites *Dermanyssus gallinae* (adults, nymphs and eggs). Residual efficacy is claimed for two weeks for bed begs and 6 weeks for poultry red mite.

The product is used for the purpose of the protection of human health.

* **Major change application for MITE KILLER – 2021**

The same target organisms and application rate are claimed as for the first authorisation. The changes claimed are:

* The addition of non professional users for the use against bed bugs
* A removable blow-pipe that can be inserted in the spray nozzle is added in  
  the packaging. It allows more precise application of the product in cracks and  
  crevices, without changing the application rate.

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

As described in the CAR, silicon dioxide acts on harmful organisms by dehydration of the insects. It leads to desiccation and death of the target organism.

#### Mode of action, including time delay

The mode of action of silicon dioxide is currently not clear. One opinion is that this active substance leads to dehydration of the insects most probably through absorption of the lipid layer covering insects' chitin protection, which then leads to desiccation and death of the target organism.

The time delay between exposure and death of the target organisms is within 1 to 3 days.

#### **Efficacy data**

| **Experimental data on the efficacy of the biocidal product Mite-Killer against target organisms** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide | Indoors | Mite-Killer  (silicon dioxide, 1.5% w/w) | *Cimex lectularius* (bedbugs)  20 insects per replicate, adults of mixed sex. | Laboratory insecticidal and residual efficacy test on non porous surfaces (glazed tile) and porous surfaces (wallpaper, mattress fabric). | Application rate: 40.13 g/m², applied only on the whole surfaces.  Surfaces: 225 cm² (15\*15 cm), of glazed tile (non-porous), wallpaper and mattress fabric (porous).  Temperature = 24-25°C  Relative humidity = 65-70 %  Application: spraying.  Exposure: 6 hours of exposure, then transfer in a clean plastic beaker.  Tests: Day 1, the day after application, and 8 and 12 weeks after application.  Mortality evaluated after 1, 2, 3, 5, 7, 10 and 14 days after beginning of exposure.  For each surface and each treatment (test product/untreated control), 3 replicates. | The residual efficacy against bed bugs on partially tiles after 1 day, 8 and 12 weeks of treatment were:  **Glazed tile**  1 day = 100 % within 24 h  8 weeks = 100 % within 48 h  12 weeks = 100 % within 24 h  **Wallpaper**  1 day = 100 % within 24 h  8 weeks = 100 % within 24 h  Aged 12 weeks = 100 % within 24 h  **Mattress fabric**  Aged 1 day = 100 % within 24 h  Aged 8 weeks = 80 % within 14 days  Thus, according to the TNsG requirements for the residual effect ("≥ 95% mortality within 24 hours"), the aerosol Mite-Killer is sufficiently effective against bedbugs, and has a 12 weeks residual efficacy on glazed tiles and wallpaper. | Radecki C., 2015  RI = 2 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Insecticide | Indoors | Mite-Killer  (silicon dioxide, 1.5% w/w) | *Cimex lectularius* (bedbugs)  10 insects per replicate, adults of mixed sex. | Laboratory residual efficacy test on mattress fabric (porous surface) | Application rate: 44.9 g/m²  Surfaces: 144 cm² (12\*12 cm) of mattress fabric (porous surface).  Application: spraying.  Exposure: 6 hours of exposure, then transfer in a clean plastic beaker.  Tests: Day 0, the day of application, and 2, 4 and 6 weeks after application.  Mortality evaluated 5, 15, 30, 45, 60  minutes, and 2, 4, 6, 24, 48 and 72 hours after beginning of the 6 hours exposure.  For each ageing and each treatment (test product/untreated control), 5 replicates. | The assessment 24 hours after beginning of exposure of affected bed bugs on treated surface aged between 0 to 6 weeks (mean values of 5 replicates):  T0 🡪 76 %  2 weeks aged 🡪 80 %  4 weeks aged 🡪 84 %  6 weeks aged 🡪 94 %  Control:  T0 🡪 0.2 %  2 weeks aged 🡪 0 %  4 weeks aged 🡪 0 %  6 weeks aged 🡪 0 %  The product Mite-Killer didn’t show a residual efficacy against bedbugs on porous mattress fabric as mortality on treated fabric surfaces 2, 4, 6 and 8 weeks aged, wasn’t ≥ 95 % within 24 hours according to the criteria of TNsG PT 18  Furthermore, the application rate was higher than the one claimed. | Kinsey R., 2016  RI = 3 |
| Insecticide | Indoors | Mite-Killer  (silicon dioxide, 1.5% w/w) | *Cimex lectularius* (bedbugs) wild  Live bedbugs found before 1st treatment:  Site 1 (total surface = 36.1 m²): 261  Site 2 (total surface = 41.48 m²): 12  Site 3 (total surface = 104.49 m²): 29  Fresh eggs, fresh blood spots and cast skins were also found.  Inhabitants showed signs of bites | Field test | Application rates in the 3 sites treated: Site 1: 36.1 m² => dose applied = 62.24 g/m²  Site 2: 41.48 m² => dose applied = 30.95 g/m²  Site 3 : 104.49 m² => dose applied = 21.5 g/m²  In the first and third site, 7 sprays were used for each treatment, i.e.  2247 g of product (complete product, liquid + propellant) applied each time. In the second site, 4 sprays were used, i.e. 1 284 g of product applied at each treatment.  Application: spraying.  Frequency:  first treatment after the first visual inspection determining the infestation level. Second and third treatment after the inspections: 2 weeks and 6 weeks after initial treatment, respectively.  Assessment: visual observation before each treatment and 8 weeks after initial treatment (Occurrence of fresh eggs, blood spots and cast skins is indicated.).  Percentage efficacy calculated as percentage reduction of live bed bugs compared to pre-treatment levels. | |  |  |  |  | | --- | --- | --- | --- | | site | Assessment week | Dose applied (g/m²) | Efficacy (%) | | 1 | 2  6  8 | 62.24  62.24  62.24 | 59  99.2  100 | | 2 | 2  6  8 | 30.95  30.95  30.95 | 100  75  100 | | 3 | 2  6  8 | 21.5  21.5  21.5 | 86.2  93.1  100 |   The amount of product applied in the site 1 is higher than the dose claimed therefore this site is not taken into account.  The requirements mentioned in the TNsG on Efficacy of PT18 products (2012) for field tests against bedbugs are "after a period of 6-10 weeks, the population reduction exceeds 90% relative to either untreated sites or pre- treatment levels. Treatment repeats usually are necessary in bedbug control. At the end of a treatment, 100 % efficacy should be achieved". This criterion is fulfilled, and the product Mite-Killer is effective against bedbugs.  No residual effect was proven in this field test as results on sites 2 and 3 are not consistent 2 weeks after the application | Foltan P., 2016  RI = 2 |
| Acaricide | Indoors | Mite-Killer  (silicon dioxide, 1.5% w/w) | *Dermanyssus gallinae* (poultry red mites)  20 mites per replicate, adults of mixed sex. | Laboratory residual efficacy test. | Application rate: 40.13 g/m², applied only on one half of the surfaces.  Surfaces: 225 cm² (15\*15 cm), of glazed tile (non-porous), wallpaper and mattress fabric (porous).  Temperature = 24-25°C  Relative humidity = 65-70 %  The untreated part of each surface was covered with a folded paper to serve as harbourage.  Application: spraying.  Exposure: 14 days of exposure, inside a glass ring on the surface. The mites have the choice between the treated and untreated parts of the surface.  Tests: Day 1, the day after application, and 8 and 12 weeks after application.  Mortality evaluated after 1, 2, 3, 5, 7,  10 and 14 days after beginning of exposure.  For each surface and each treatment (test product/untreated control), 3 replicates. | The residual efficacy against red poultry mites on partially tiles after 1 day, 8 and 12 weeks of treatment were:  **Glazed tile**  1 day = 100 % within 24 h  8 weeks = 100 % within 24 h  12 weeks = 100 % within 24 h  **Wallpaper**  1 day = 100 % within 24 h  8 weeks = 100 % within 24 h  12 weeks = 100 % within 48 h  **Mattress fabric**  1 day = 100 % within 24 h  8 weeks = 100 % within 48 h  12 weeks = 73 % within 14 days  Thus, according to the TNsG requirements for this kind of tests ("≥ 90% mortality in 24 hours"), the aerosol Mite-Killer is sufficiently effective against poultry red mites, and has a 12 weeks residual efficacy on glazed tile and wallpaper. | Radecki C., 2015  RI = 2 |
| Acaricide | Indoors | Mite-Killer  (silicon dioxide, 1.5% w/w) | *Dermanyssus gallinae* (poultry red mites) | Field test | Pre-Test Period:  The field test was conducted in cages from the Club poules (VetAgroSup) in Marcy at Lyon (France) infested by red mites.  The henhouse was outside, but not exposed to bad weather because covered, (cages (treated or not) being under a covered structure).  Four to three days before the treatment, 10 scotch tapes were placed in each individual cage (3 cages for the control and 3 treated cages) to look for populations of red mite.  For this, scotch tapes were positioned in the morning and removed the morning after. The trapped red mites were counted to have the estimated population.  Test Period:  At D0, poultry were taken away and individual cages from the test site were treated with the Test Item (treated area) at 0,6 g silicon dioxide /m², as to say 40 g /m² of the whole product.  For the treated area, the Test Item was sprayed on the roosts, nesting boxes, under the trays and in all the corners, cracks and crevices where the mites can hide.  As the treated zone was corresponding to 8.73m², 2 aerosols (the first was emptied and the second was partially emptied) were needed to apply the treatment.  Chickens were reintroduced in cage after liquid has dried up and fresh air has reached the cages. | Pre-Test Period:  Treated area: 371 red mites  Control area: 417 red mites  Treated area:  D8 🡪 4  D15 🡪 0  D22 🡪 0  D36 🡪 0  D50 🡪 2  Control area:  D8 🡪 248  D15 🡪 311  D22 🡪 424  D36 🡪 273  D50 🡪 301  One week after treatment, there were only 4 mites trapped on the scotch tapes in the treated area. And from two weeks after treatment, no mite was trapped, up to 5 weeks after treatment. At the last assessment, 7 weeks after treatment, only 2 mites were trapped. A new infestation is considered only from 5 mites trapped. Thus, from the first treatment, no new infestation occurred within 7 weeks, and no other treatment was applied after the first one. | Guicherd A., 2017  RI = 2 |

* For use against bed bugs *Cimex lectularius,* indoors, by professionals users:

According to the efficacy data submitted, the requirements and criteria of TNsG PT 18 (2012) are fulfilled for curative treatment against bed bugs *Cimex lectularius* (adults, nymphs and eggs). The residual effect of 2 weeks in the field was not proved.

We consider that efficacy against nymphs is demonstrated, as this development stage is heterometabole (nymphs is smaller version of adults), thus we expected that the effect of the product could be the same as for adults.

Regarding the residual effect in laboratory, the data submitted demonstrate that the product has a residual efficacy of 12 weeks on glazed tiles (non-porous surface) and wallpaper (porous surface). Nevertheless, on mattress fabric (porous surface), the results are not compliant with the criteria of TNsG PT 18, as mortality on treated fabric surfaces 2, 4, 6 and 8 weeks aged, wasn’t ≥ 95 %.

* For use against poultry red mites *Dermanyssus gallinae,* indoors, by non-professionals users:

The efficacy data submitted are compliant with the requirements of TNsG PT 18 (2012) as laboratory and field tests were submitted. Therefore, the efficacy of the product Mite-Killer against poultry red mites *Dermanyssus gallinae* according to the claims was proved with a residual effect of 7 weeks.

Regarding the demonstration of efficacy against eggs and nymphs, these development stages were not tested in labotatory. However, field test showed a good growth of population in the control (more than 300 poultry red mites after D50 in untreated site), which means presence of all development stage (including eggs).

Regarding efficacy against nymphs, as this development stage is heterometabole (nymphs is smaller version of adults), thus we expected that the effect of the product could be the same as for adults.

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| --- |
| **Conclusion on the efficacy of the product** |
| In accordance with the submitted test and the requirements of the TNsG on product evaluation for PT18 (2012), the product Mite-Killer shows sufficient efficacy against bed bugs *Cimex lectularius* (adults, nymphs and eggs) for a curative treatment on porous and non-porous surfaces at the dose of 40 g/m² with the minimum number of applications of 3 spaced from 1 to 4 weeks. The residual effect of 2 weeks in the field was not proved.  For use against poultry red mites *Dermanyssus gallinae* (adults, nymphs and eggs) for a curative and preventive treatment, the product Mite-Killer shows sufficient efficacy on porous and non-porous surfaces at the dose of 40 g/m² with a residual effect of 7 weeks. |

* **Major change application for MITE KILLER – 2021**

No additional efficacy data have been submitted for the MAC.

Major change has no impact on the efficacy section.

#### **Occurrence of resistance and resistance management**

It is known that insects with fully developed cuticles are more resistant to the action of silicon dioxide. Nymphs, whose cuticles are not fully developed, are more susceptible. However, resistance per se i.e. the ability of a given population to withstand a poison that was effectively lethal to earlier generations of the species has not been reported for silicon dioxide. This is thought to be due to a combination of reasons, including the fact that sorptive dusts like silicon dioxide work by a combination of physical and chemical means and sorptive dusts do not contain any chemical groups to which target arthropods are known to be resistant or apt to becoming resistant to. Indeed, sorptive dusts like silicon dioxide have been identified in literature reviews as a possible means of controlling insects that are resistant to conventional insecticides.

Given the fact that resistance to silicon dioxide is unlikely to develop, a management strategy for the control of the development of resistance to silicon dioxide has not been proposed.

The users should inform if the treatment is ineffective and report straightforward to the registration holder.

#### **Known limitations**

No limitation has been observed according to the current uses.

#### **Evaluation of the label claims**

French competent authorities (FR CA) assessed that the product Mite-Killer has shown a sufficient efficacy, for the following use claimed:

* *Cimex lectularius* (adults, nymphs and eggs) for a curative treatment, indoor, by professional users. The residual effect of 2 weeks in the field was not proved.
* *Dermanyssus gallinae* (adults, nymphs and eggs) for a curative and preventive treatment, indoor (birds and poultry houses/ shelters as aviaries, coops, small hen houses) by non-professionals users with a residual effect of 7 weeks.

The application rate validated is the following:

* *Cimex lectularius* (adults, nymphs and eggs) for a curative treatment at the dose of 40 g/m² with the minimum number of applications of 3 spaced 1 to 4 weeks.
* *Dermanyssus gallinae* (adults, nymphs and eggs) for a curative and preventive treatmentat the dose of40 g/m² with a residual effect of 7 weeks.

To ensure a satisfactory level of efficacy, the following recommendations have to be implemented:

* Always read the label or leaflet before use and respect follow all the instructions provided.
* Inform the registration holder if the treatment is ineffective.
* Retreat in case of new infestation or in case of cleaning without exceeding the maximum number of treatment authorized per year,

Using against bedbugs:

* Clean carefully the rooms before treatment,
* Spray in all the cracks and crevices where the bedbugs can hide,
* Create barriers by spraying the bed frames, baseboards (or a 20 cm strip at the bottom of the walls), behind the frames on walls,…

Using against poultry red mites:

* Clean carefully the aviaries, dovecotes or poultry houses,
* Spray on the roosts, nesting boxes, under the trays…and in all the corners, cracks and crevices where the mites can hide,
* Residual effect until 7 weeks
* **Major change application for MITE KILLER – 2021**

Major change has no impact on the efficacy section

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

### Risk assessment for human health

#### **Assessment of effects on Human Health**

No toxicological study has been submitted for the product MITE KILLER.

The classification of the product has been set according to the calculation rules presented in the CLP regulation.

Given the content of active substances and co-formulants, the following classification is required:

* **Asp Tox 1 – H304**;
* **Skin Irrit 2 – H315;**
* **STOT SE 3 – H336**

***Skin corrosion and irritation***

No data submitted.

***Eye irritation***

No data submitted.

***Respiratory tract irritation***

No data submitted.

***Skin sensitization***

No data submitted.

***Respiratory sensitization (ADS)***

No data submitted.

***Acute toxicity***

No data submitted.

***Information on dermal absorption***

No systemic effect has been observed with silicon dioxide; no dermal absorption value is necessary.

Only local effects are taken into account in the risk assessment.

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

Due to the proposed classifcation including in the submitted MSDS and its impact on the classification of the product, the solvent Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (EC number 927-510-4) has been identified as a substance of concern.

This substance leads to a classification **Asp Tox 1 – H304; Skin Irrit 2 – H315 and STOT SE 3 – H336** of the product. Therefore, according to the BPR Guidance Volume III Human health – Part B Risk Assessment, the BAND A evaluation scheme is applied. In this context, a qualitative risk assessment associated with the application of P and H statements is performed.

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

No data available.

***Other***

No data available.

* **Major change application for MITE KILLER – 2021 :**

No impact of the major change.

#### **Exposure assessment**

The product MIT-KILLER is a ready-to-use aerosol to be used by professionals against bedbugs and by non-professionals against poultry red mites. It is used indoors only.

The product is sprayed on surfaces, cracks and crevices. Since the product is formulated as a ready-to­use product, no dilution or other preparations are necessary.

The application rate is 40 g/m2, corresponding to 55.6 mL/m2 (considering a product density of 0.72).

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

According to the intended uses of the product MITE KILLER (surface spraying and crack and crevices), primary exposure is intended *via* inhalation and dermal routes.

Secondary exposure is intended for bystanders/residents (adult and children) *via* inhalation route following exposure of volatilised residues, dermal route following contact with the surfaces, and/or oral route following hand-to-mouth behaviour.

| **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** |
| Inhalation | No | Yes | Yes | No | No | Yes |
| Dermal | No | Yes | Yes | No | No | Yes |
| Oral | No | Yes | Yes | No | No | Yes |

Professionals and non-professionals are expected to be exposed to Silicon dioxide for which physico-chemical and toxicological data are summarized in the following table (source: Assessment Report, March 2014):

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Active Substance** | **Concentration**  **(% w/w)** | **Molecular weight**  **(g/mol)** | **Vapor Pressure**  **(Pa)** | **Log Pow** | **Inhalation absorption** | **Dermal absorption** | **Oral absorption** |
| **SiO2** | 1.67 | 60.08 | n.a | n.a | 100% | n.a | n.a |

No local effect after acute dermal exposure and no systemic effect by oral route are observed for the active substance SiO2. Moreover the active substance is assumed to have a very limited dermal penetration potential. Therefore, these exposure paths are not considered in the assessment of the product.

Exposure of professionals and non-professionals is mainly *via* inhalation; therefore, a quantitative risk assessment will be performed. Dermal exposure to MITE KILLER will be assessed in a qualitative way.

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Spraying surface, cracks and crevices  (indoors) | **Primary exposure, inhalation and dermal**  The product is sprayed onto surfaces or cracks and crevices of bedrooms against bedbugs. | Professionnals |
| 2. | Spraying surface  (indoors) | **Primary exposure, inhalation and dermal**  The product is sprayed onto surfaces of aviaries, dovecotes and poultry house against red mites. | Non-professionals |
| 3 | Inhalation of product residus during cleaning with vacuum cleaner | **Secondary exposure, inhalation**  The product is sprayed onto surfaces of bedrooms and adults are exposed during the cleaning of the room with a vacuum cleaner. | General public |

***Industrial exposure***

The product MITE KILLER is intended to be used by professional and non-professionals only. Therefore, industrial users are not expected to be exposed to the product and no exposure assessment is deemed necessary.

***Professional exposure***

*Scenario [1]: Primary exposure – Spraying by professionals*

| **Description of Scenario [1] Primary exposure – Spraying by professionals** | | | | |
| --- | --- | --- | --- | --- |
| The product MITE KILLER is a ready-for-use insecticide aerosol for direct surface treatment against bedbugs. The product is applied by spray application on surfaces or cracks and crevices in bedrooms. The application rate is 40 g aerosol/m², corresponding to 55.6 mL/m2.  During the spray application, exposure occurs *via* dermal and inhalation routes.  The Pest Control Fact sheet (surface application with aerosol can), updated with the New default values for the spray model (2010) has been used in ConsExpo web to estimate exposure during application of the product.  According to the applicant’s data, the maximal content of the aerosol can is 650 ml, corresponding to 500 mL of product.  Considering a relative density of 0.72 and a mass generation of 2.2 g/s, a spray duration of 164 s (2.7 min) for the use of one aerosol can is calculated.  The maximal treated surface for one aerosol device can be calculated as follow:  Content (500 ml) x density (0.72 g/ml) / efficacy dose (40 g p.b./m²) = 9 m²  A spray duration of 10 minutes is considered, corresponding to emptying more than 3 aerosols and a surface of treatment of more than 27 m2 per event. | | | | |
|  | **Parameters1** | **Value** | **Unit** | **Reference** |
| **Tier 1** | Weight fraction SiO2 | 2.78 | % | Applicant’s data corresponding to SiO2 fraction in the formulation without propellent gas. |
| Frequency | 6 | per day | Default value from ConsExpo |
| Spray duration | 10 | min | Applicant’s data |
| Exposure duration | 240 | min | Default value from ConsExpo |
| Room volume | 20 | m3 | Default value from ConsExpo for unspecified room |
| Room height | 2.5 | m | Default value from ConsExpo |
| Ventilation rate | 0.5 | per hour | Default value from ConsExpo |
| Inhalation rate | 1.25 | m3/h | HEEG opinion no 17 |
| Mass generation rate | 2.2 | g/s | Applicant’s data |
| Airborne fraction | 0.2 | - | Default value from ConsExpo |
| Density non volatile | 0.72 | g/cm3 | Applicant’s data |
| Inhalation cut off diameter | 10 | µm | Default value from ConsExpo |
| Median diameter | 67 | µm | Applicant’s data |
| Inhalation absorption value | 100 | % | - |
| Body weight (adult) | 60 | kg | HEEG opinion no 17 |

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**Calculations for Scenario [1]**

The mean exposure on day of exposure is 5.8 x 10-3 mg/m3, corresponding to a pulmonary burden of 0.174 mg s.a (taking into account an inhalation rate of 1.25 m3/h and 24h exposure duration).

Furthermore, considering an inhalation rate of 1.25 m3/h and a 8-hour daily occupational exposure duration, it is assumed the operator will inhale 8 x 1.25 = 10 m3/day. The 8h-Time Weighted Average (TWA) concentration leading to an exposure of 0.175 mg/day is: 0.175 (mg) / 10 (m3) = **0.0175 mg/m3**.

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/m3)** | **Estimated total uptake**  **(mg/m3)** |
| Scenario [1] | 1/no PPE | 0.0175 | 0.0175 |

**Further information and considerations on scenario [1]**

The product is classified Skin Irrit. 2 – H315.

A qualitative RA is necessary. The hazard categories are determined according to the hazard descriptions (classification) and criteria defined in the ECHA Guidance: Classification Skin Irrit. 2, H315 belongs to the Low hazard category.

*Combined scenarios*

Not expected

***Non-professional exposure***

*Scenario [2]: Primary exposure – Spraying by non-professionals*

| **Description of Scenario [2] Primary exposure – Spraying by non-professionals** | | | | |
| --- | --- | --- | --- | --- |
| The product MITE KILLER is a ready-for-use insecticide aerosol for direct surface treatment against red mites. The product is applied by spray application on surfaces in aviaries, dovecotes and poultry houses. The application rate is 40 g aerosol/m², corresponding to 55.6 mL/m2.  During the spray application, exposure occurs *via* dermal and inhalation routes.  The Pest Control Fact sheet (surface application with aerosol can), updated with the New default values for the spray model (2010) has been used in ConsExpo web to estimate exposure during application of the product.  According to the applicant’s data, the maximal content of the aerosol can is 650 ml, corresponding to 500 mL of product.  Considering a relative density of 0.72 and a mass generation of 2.2 g/s, a spray duration of 164 s (2.7 min) for the use of one aerosol can is calculated. The default value proposed by ConsExpo web is 10 min, but it has been considered that the use of the realistic spray duration was more appropriate.  The maximal treated surface for one aerosol device can be calculated as follow:  Content (500 ml) x density (0.72 g/ml) / efficacy dose (40 g p.b./m²) = 9 m² | | | | |
|  | **Parameters1** | **Value** | **Unit** | **Reference** |
| **Tier 1** | Weight fraction SiO2 | 2.78 | % | Applicant’s data corresponding to SiO2 fraction in the formulation without propellent gas. |
| Frequency | 9 | per year | Default value from ConsExpo |
| Spray duration | 164 | s | Applicant’s data |
| Exposure duration | 240 | min | Default value from ConsExpo |
| Room volume | 58 | m3 | Default value from ConsExpo |
| Room height | 2.5 | m | Default value from ConsExpo |
| Ventilation rate | 0.5 | per hour | Default value from ConsExpo |
| Inhalation rate | 1.25 | m3/h | HEEG opinion no 17 |
| Mass generation rate | 2.2 | g/s | Applicant’s data |
| Airborne fraction | 0.2 | - | Default value from ConsExpo |
| Density non volatile | 0.72 | g/cm3 | Applicant’s data |
| Inhalation cut off diameter | 10 | µm | Default value from ConsExpo |
| Median diameter | 67 | µm | Applicant’s data |
| Inhalation absorption value | 100 | % | - |
| Body weight (adult) | 60 | kg | HEEG opinion no 17 |

**Calculations for Scenario [2]**

The mean exposure on day of exposure is 9.2 x 10-5 mg/m3, corresponding to a pulmonary burden of 0.003 mg s.a (taking into account an inhalation rate of 1.25 m3/h and 24h exposure duration).

Furthermore, considering an inhalation rate of 1.25 m3/h and a 8-hour daily occupational exposure duration, it is assumed the operator will inhale 8 x 1.25 = 10 m3/day. The 8h-Time Weighted Average (TWA) concentration leading to an exposure of 0.003 mg/day is: 0.003 (mg) / 10 (m3) = **0.0003 mg/m3**.

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/m3)** | **Estimated total uptake**  **(mg/m3)** |
| Scenario [1] | 1/no PPE | 0.0003 | 0.0003 |

* **Major change application for MITE KILLER – 2021 :**

The major change request consists in the addition of the non professional users for the use of the product against bed bugs. The claimed application rate being the same that the one used for the initial risk assessment (use agains poultry red mites), no impact is expected on HH risk assessment.

A removable blow-pipe that can be inserted on the spray nozzle is added in the packaging for the use against bed bugs. This device leads to the modification of the spray parametrs:

* A new mass generation rate of 1 g/s (instead of 2.2 g/s) can be calculated considering an application rate of 40 g/m2 and 40 s spray/m2 (applicant’s data);
* a total spray duration of 360 s (6 min) is therefore calculated (taking into account a volume of 500 mL of product in aerosol can, a density value of 0.72 and a mass generation rate of 1 g/s).

The application rate (40 g/m2) and the exposure duration (a default value of 240 min from ConsExpo) remain unchanged.

Despite the modifictaion of the spray paramaters, no impact is expected on the resuslts of the exposure assessment. The spray duration is increased compared to the intital assessment but the mass generation is lower with the blow-pipe.

A mean concentration on the day of exposure of **1.0 x 10-4 mg/m3** is observed after modelisation with ConsExpo web and considering the new parameters (see excel data sheet in section 3.7).

The conclusion set during the initial assessment are therefore considered extrapolable and the risk is deemed acceptable for the use of MITE KILLER by non professionals against bed bugs with or without blow-pipe.

**Further information and considerations on scenario [2]**

The product is classified Skin Irrit. 2 – H315.

According to recommendations from the ECHA Guidance for Human Health Risk Assessment, a qualitative risk assessment has to be performed since there is no basis for setting an AEL, AEC or DMEL for the identified endpoint. This qualitative risk assessment concerns consumer when applying the product MITE-KILLER by spraying.

The hazard categories are determined according to the hazard descriptions (classification) and criteria defined in the ECHA Guidance: Classification Skin Irrit. 2, H315 belongs to the Low hazard category.

*Combined scenarios*

Not considered.

***Exposure of the general public***

*Scenario [3]: Secondary exposure – Exposure to product residues during the use of vacuum cleaner*

| **Description of Scenario [3] Secondary exposure – Exposure to product residues during the use of vacuum cleaner** | | | | |
| --- | --- | --- | --- | --- |
| Secondary exposure to MITE KILLER may be negligible but it cannot be fully excluded. The exposure scenario of cleaning up dust with vacuum cleaner is considered.  Indicative values are taken from '*Consumer spraying and dusting Model 2, vacuuming after dusting application, non-cyclone vacuum cleaner*' in TNsG for human exposure assessment (TNsG part 2 p.200).  The inhalation exposure value from the model is 0.8 mg/m3.  A task duration is necessay to use this exposure model.  The maximal task duration (Tmax) has been calculated taking into account the acute term AEC value as the limit concentration not to be exceeded.  The pulmonary burden corresponding to the acute AEC can be calculated as follows:  AECacute term (mg/m3) x 1.25 m3/h x 8h = 2 mg (corresponding to the pulmonary burden not to be exceeded).  Therefore, Tmax can be calculated as follows:  Exposure value (mg/m3) x 1.25 m3/h x Tmax (h) = maximal pulmonary burden (mg)  0.8 (mg/m3) x 1.25 (m3/h) x Tmax = 2 (mg)  Tmax= 2 / (0.8 \*1.25)  Tmax = 2h | | | | |
|  | **Parameters1** | **Value** | **Unit** | **Reference** |
| **Tier 1** | Weight fraction SiO2 | 100 | % | Assumption linked to the evaporation of the solvent and the mode of application[[2]](#footnote-3) |
| Exposure value | 0.8 | mg/m3 | Value from TNsG |
| Exposure duration | 2 | h | Maximal exposure duration to not exceed AEC value |
| Inhalation rate | 1.25 | m3/h | HEEG opinion no 17 |
| Inhalation absorption value | 100 | % | - |

**Calculations for Scenario [3]**

Cf. Excel data sheet ”MITE KILLER\_Expo HH”.

The potential inhaled active substance is 2.0 mg.

Furthermore, considering an inhalation rate of 1.25 m3/h and a 8-hour daily occupational exposure duration, it is assumed the operator will inhale 8 x 1.25 = 10 m3/day. The 8h-Time Weighted Average (TWA) concentration leading to an exposure of 2 mg/day is: 2 (mg) / 10 (m3) = 0.2 mg/m3

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/m3)** | **Estimated total uptake**  **(mg/m3)** |
| Scenario [3] secondary exposure | 1/no PPE | 0.2 | 0.2 |

**Further information and considerations on scenario [3]**

None

*Remark:* Only local reference values for inhalation were derived in the active substance dossier. SiO2 is not volatile ( no P vapour was determined as melting point >300˚C). Therefore, exposure of toddler when he enters in a treated room is not expected.

*Combined scenarios*

Not considered.

***Monitoring data***

No data submitted.

***Dietary exposure***

No specific residue data was submitted in the context of this dossier.

As mentioned in the Assessment Report of silicon dioxide (Product-type 18, March 2014 – RMS: France), it should be noted that:

- Silicon, in the form of silicon dioxide and silicates, occurs ubiquitously in the environment: silicon dioxide and silicates are present in almost all plants, animals and in natural waters. According to the Joint FAO/ WHO Expert Committee on Food Additives, very small amounts of silica are normally present in all body tissues and there is no evidence that they play any physiological role[[3]](#footnote-4).

- Synthetic amorphous silica are used in a wide variety of application, including consumer products: they are used in ointments, thicken pastes, and are present in cosmetics, pharmaceuticals, food[[4]](#footnote-5) and feed[[5]](#footnote-6).

- Silicon dioxide is an approved food additive: silicone dioxide (E551) is used as an anti-caking agent[[6]](#footnote-7) in dry powdered foodstuffs (including sugars) at the maximum level of 10 g/kg. It is approved for use in plastic material coming into contact with food, without hazard to public health.

The US Food and Drug Administration (FDA) has classified silicon dioxide as Generally Recognized as Safe (GRAS) and has approved its use as a dietary food additive at levels of up to 2% by weight in food. Moreover, UK food supplements contain up to 500 mg silicon[[7]](#footnote-8). In agreement with the review by the US Environmental Protection Agency (EPA), the FDA considered that exposure to amorphous silicon dioxide in food does not pose any risk for Human. Besides, the Acceptable Daily Intake (ADI) for silicon dioxide and certain silicates was qualified as “not specified” by the JECFA during its 29th meeting (1985) (Assessment Report, 2014).

Based on its toxicological properties and regulations already in force, silicon dioxyde is unlikely to cause a dietary risk to consumers.

In addition, as regards the intended use of the product MITE KILLER by professionals, no direct or indirect contamination of food is expected. Nevertheless, to avoid any contamination, the following precautionary statement is proposed:

“ Avoid any direct or indirect contact with food and feed.”

For the application in aviaries, dovecotes and poultry houses by ~~non-professional~~ against bedbugs, a livestock exposure assessment was provided by the applicant and reviewed by eCA. From this assessment, risk mitigation measures are proposed by the applicant to prevent animal and consumer exposures:

- Take away birds/poultry before treatment

- Remove all feed and drinking water prior to treatment

- Cover all surfaces and facilities likely to be in contact with feed and drinking water

*List of scenarios*

| **Summary table of main representative dietary exposure scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Type of use1** | **Description of scenario** | **Subject of exposure2** |
| 1. | Animal husbandry (Birds and poultry houses/shleters: aviaries, coops, small hen houses) | Use against poulty red mite by spraying in aviaries, dovecotes and poultry houses by non-professionals. | Poultry |

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** | **Reference value(s) 2** |
| 1.kieselgur (diatomaceous earth) (CAS number: 61790-53-2) | Plant Protection Products use[[8]](#footnote-9) | - Applications by mixing with stored grain as insecticide/acaricide for the control of insects and mites in stored products  - Applications by electrostatic dusters or hand applicators in empty rooms against stored product insects and mites and amateur soil treatment applications against insects | No MRL required (substance temporarily included in Annex IV)[[9]](#footnote-10) |
| 2. Silicon dioxyde (CAS N° 7631-86-9) | Food additives | Silicon dioxide (E551) is used as an anti-caking agent only in foods in dried form (i.e foods dried during  the production process, and mixtures thereof) with maximum level of 10 g/kg[[10]](#footnote-11).  Silicon dioxide is also an  additive authorized in feed[[11]](#footnote-12). | No MRL required |

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

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

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

Scenario 1

For non-professional applications, residues in food can be expected through exposure of poultry. Therefore, the potential for indirect exposure via food arises from consumption of food of animal origin (poultry) contaminated with synthetic amorphous silica residues. According to the European draft guidance document (2014)[[12]](#footnote-13) : “*In the stepwise approach, exposure estimates are performed successively in different tiers. If the pre-defined threshold of concern (trigger value = 0.004 mg a.s/kg animal bw/day) is exceeded, exposure estimation moves to the next tier. If the trigger value is not exceeded, no significant residues are expected in food of animal origin and dietary risk assessment is stopped [secondary exposure to the general public is not considered relevant] unless the substance is exceptionally toxic*”.

If trigger value of 0.004 mg a.s/ kg b.w./d is exceeded then secondary exposure to general public via ingestion of food and product of animal origin should be assessed.

According to European draft guidance document (2014), external exposure assessment encompasses a worst-case exposure estimated based on information on the intended uses and on a set of default values. Exposure estimation can be divided into a screening step and a realistic worst-case estimate step.

Exposure calculations and default values for livestock are detailed in European draft guidance document (2014). Only treatment of chickens and hens housing are intended in the frame of this dossier. Exposure results are detailed below for both screening and realistic worst-case estimate steps .

For the screening step, it is assumed that the entire amount of biocidal product applied is taken up by animals. Therefore, following calculation are made for a spray treatment:

Livestock exposure = [Application rate (mg as/m2) x Area treated (m2)] / [number of

animals per stable x livestock body weight (kg)]

The realistic worst-case estimate takes into account additional parameters for refinement or risk mitigations measures.

According to European draft guidance document (2014), poultry (broiler chickens and laying hens) can be exposed to the biocidal product via different routes of exposure: oral intake, dermal intake and inhalation.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Exposure** | | | | | |
| **Oral** | | | **Dermal** | | **Inhalation\*\*\*\*\*** |
| **Licking wall\*** | **Fly ingestion \*\*** | **Contaminated feed\*\*\*** | **Rubbing\*\*\*\*** | **Spray contact\*\*\*\*** |
| **Poultry** | NR | NR | NR | NR | NR | NR |

R: Relevant – NR: Not Relevant

\* Poultry is not subject to this kind of behaviour

\*\* Poultry seek out dead insects intentionally and MITE KILLER is an insecticide. However, this product has shown to be effective against bedbugs and red mites only. The product is not expected to kill flies, especially as it is applied on small surfaces and does not contain any attractant. At a concentration of 1.5% w/w SiO2, the product is also not expected to kill other insects. Therefore, the oral exposure via insect ingestion is considered as negligible.

\*\*\* It is assumed that poultry houses are cleaned and emptied before treatment and that all the feeding and drinking containers are covered during the product application.

\*\*\*\* Poultry does not rub against walls. In addition, these animals are not allowed into the housing during the product application. Therefore, no dermal exposure can occur from spray hitting them during treatment.

\*\*\*\*\* The poultry are not allowed into the housing during the product application. They are expected to return into the housing only when the dust particles have completely settled down onto the surfaces. Therefore, no inhalation exposure is expected.

Based on considerations detailed in table above, exposure of poultry to MITE KILLER can be considered as negligible.

| **Description of Scenario [1]** | | |
| --- | --- | --- |
| MITE KILLER is applied by spraying on the surfaces of the poultry houses. Concentration in the biocidal product MITE KILLER of silicon dioxyde is 1.67 % (w/w). A quantity of 40 g of product is used per square meter which represents 668 mg a.s./m2. The scenario used for assessment is: Surface treatment of animal housing (floor and wall of stable without partitions) | | |
|  | Parameters | Value |
| Screening step | Maximal application rate of active substance | 668 mg/m2 |
| Area treated (wall + floor area per stable) | European draft guidance document (2014)10 (See Appendix 3.4) |
| Number of animal per stable |
| Body weight of animals |
| Realistic worst-case estimate | Risk mitigations measures proposed by the applicant to prevent poultry exposure:  ” - Take away birds/poultry before treatment  - Remove all feed and drinking water prior to treatment  - Cover all surfaces and facilities likely to be in contact with feed and drinking water.” | - |

**Calculations for estimating livestock exposure for Scenario [n]**

| **Internal dose received by the animal (mg as/kg bw/d)** | | | | | |
| --- | --- | --- | --- | --- | --- |
| DRAWG (2014): Dietary Risk Assessment Working Group (now ARTFood) « Guidance on estimating livestock exposure to biocidal active substances” – draft not yet published. A draft was publicly available in 2010. | | | | | |
|  | Species | Inhalation exposure | Dermal exposure | Oral exposure | Total exposure |
| Screening Step | Broiler chickens | NC | NC | NC | 33.7 |
| Laying hens | NC | NC | NC | 71.4 |
| Realistic worst-case estimate | Broiler chickens | NR | NR | NR | NR |
| Laying hens | NR | NR | NR | NR |

NC: Not calculated - NR: Not Relevant

**During commenting period,** 2 MS raised concerns about the applicability of RMM for poultry. Therefore, to answer this concern, FR provided hereafter an exposure estimation for poultry in the case where RMM are not applied. First of all, exposure to silicon dioxide through oral and dermal paths is considered negligible because oral and dermal absorptions are really limited (See § 2.2.6.2 Exposure Assessment - Identification of main paths of human exposure towards active substance(s))). Poultry might only be exposed through inhalation. Based on scenario 2 performed in toxicological section – primary exposure – spraying by non professional, the mean exposure on day of exposure was calculated to be around 9.2 x 10-5 mg AS/m3. Taking into account an alveolar ventilation rate of 0.2 m3/d for both broiler and laying hens and a body weight of 1.7 kg and 1.9 kg respectively (default values detailed in ARTFood15 : Guidance on estimating livestock exposure to biocidal active substances), inhalation exposure was estimated to be around 1.08 x 10-6 and 9.7 x 10-6 mg AS/kg bw/d respectively for broiler and laying hens. Estimated exposures are below the trigger value of 0.004 mg/kg bw/d. Therefore, after application of MITE KILLER, exposure of poultry is expected to be negligible and there is no need to assess indirect exposure to general public via ingestion of food and product of animal origin.

**Conclusion**

In screening step assessment, the trigger value of 0.004 mg a.s./kg b.w./day is largely exceeded. According to livestock exposure assessment performed by the applicant (based on European draft guidance document (2014) draft guidance) and reviewed by eCA, realistic worst case livestock exposure exceed the trigger value of 0.004 mg a.s./kg b.w./d without risk mitigations measures. Therefore, risk mitigation measures are proposed by the applicant to prevent animal and consumer exposures:

* + - Take away birds/poultry before treatment
    - Remove all feed and drinking water prior to treatment
    - Cover all surfaces and facilities likely to be in contact with feed and drinking water.

Based on these RMMs,exposure of poultry is expected to be negligible. There is no need to assess indirect exposure to general public via ingestion of food and product of animal origin (poultry).

*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*

As regards non professional uses, only estimation of food of animal origin has been performed (See paragraph ” *Estimating Livestock Exposure to Active Substances used in Biocidal Products*”).

* **Major change application for MITE KILLER – 2021 :**

No impact of the major change has been observed on the dietary risk to consumer. Only modification of form has been performed in the PAR and is highlighted in grey.

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

Not applicable.

***Aggregated exposure***

Not applicable.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake**  **(mg/m3)** |
| 1. | Professionals | Tier 1/No PPE | 0.0175 |
| 2. | Non professionals | Tier 1/No PPE | 0.0003 |
| 3 | General public | Tier 1/No PPE | 0.2 |

#### **Risk characterisation for human health**

**Reference values to be used in Risk Characterisation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEC** | **AF** | **Correction for oral absorption** | **Value** |
| AEC short-term | 5-day inhalation rat study | 5 mg/m3 | 25 | n.a | 0.2 mg/m3 |
| AEC medium-term | 5-day inhalation rat study | 5 mg/m3 | 25 | n.a | 0.2 mg/m3 |
| AEC long-term | 5-day inhalation rat study | 5 mg/m3 | 50 | n.a | 0.1 mg/m3 |
| ARfD | n.a | | | | |
| ADI |

***Risk for industrial users***

Not appicable.

***Risk for professional users***

**Systemic effects**

Not applicable

**Combined scenarios**

Not applicable

**Local effects**

Quantitative Risk assessement (inhalation route)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **NOAEC**  **mg/m3** | **AEC**  **mg/m3** | **Estimated uptake**  **mg/m3** | **Estimated uptake/ AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| [1] Spray application | 1 | 5 | 0.1 | 0.0175 | 17 | Yes |

Qualitative Risk assessement (dermal route)

According to the Guidance on the BPR Volume III Human Health – Part B Risk Assessment, the measures to conclude on acceptability for professional exposure are as follows:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hazard | | | Exposure | | | | | | | Risk |
| Hazard Category | Effects in terms of C&L | Additional relevant hazard information | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant RMM & PPE | Conclusion on risk |
| Low | Skin Irrit 2 – H315 | - | 18 | **Professional** | Spraying application | Dermal | Less than few minutes | Sources for dermal contamination being from:  - direct spraying of the product;  - direct contact with treated surface during application | Since professional will be exposed more than one hour per day, wear of gloves is required. | Acceptable |

**Conclusion**

For the inhalation route, the risk is deemed acceptable for professionals without PPE;

For the dermal route, gloves are required.

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

**Systemic effects**

Not applicable

**Combined scenarios**

Not applicable

**Local effects**

Quantitative Risk assessement (inhalation route)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **NOAEC**  **mg/m3** | **AEC**  **mg/m3** | **Estimated uptake**  **mg/m3** | **Estimated uptake/ AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| [2] Spray application | 1 | 5 | 0.1 | 0.0003 | 0.3 | Yes |

* **Major change application for MITE KILLER – 2021 :**

The conclusion set during the initial assessment are therefore considered extrapolable and the risk is deemed acceptable for the use of MITE KILLER by non professionals against bed bugs with or without blow-pipe.

Qualitative Risk assessement (dermal route)

According to the Guidance on the BPR Volume III Human Health – Part B Risk Assessment, the measures to conclude on acceptability for non professional exposure are as follows:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hazard | | | Exposure | | | | | | | Risk |
| Hazard Category | Effects in terms of C&L | Additional relevant hazard information | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant RMM & PPE | Conclusion on risk |
| Low | Skin Irrit 2 – H315 | - | 18 | **Non Professional** | Spraying application | Dermal | Less than one hour per day | Sources for dermal contamination being from:  - direct spraying of the product;  - direct contact with treated surface during application | Labelling, instructions for use that minimise exposure or possible health effects | - Low volume of spray application;  - Low frequency of use;  - Reversible toxicological effects  Considering this, the risk is deemed acceptable |

**Conclusion**

For the inhalation route, the risk is deemed acceptable for non professional users.

For the dermal route, due to the low hazrad category of the product, the risk is considered acceptable taking into account appropriate labelling and instructions of use that minimize exposure and health effects.

* **Major change application for MITE KILLER – 2021 :**

The conclusion set during the initial assessment are therefore considered extrapolable and the risk is deemed acceptable for the use of MITE KILLER by non professionals against bed bugs with or without blow-pipe.

***Risk for the general public***

**Systemic effects**

Not applicable

**Combined scenarios**

Not applicable

**Local effects**

Quantitative Risk assessement (inhalation route)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **NOAEC**  **mg/m3** | **AEC**  **mg/m3** | **Estimated uptake**  **mg/m3** | **Estimated uptake/ AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| [3] | 1 | 5 | 0.2 | 0.2 | 100 | Yes |

**Conclusion**

For secondary exposure of general public, %AEC is equal to 100%, meaning that the risk should be considered unacceptable.

However, this conclusion is based on very conservative assumptions.

The indicative value proposed by the model *'Consumer spraying and dusting Model 2, vacuuming after dusting application, non-cyclone vacuum cleaner*' (from TNsG, part. 2, p 200) is based on experimental studies where SiO2 powder (100% SiO2) is applied at doses up to 60 g a.s/m2.

MITE KILLER is intended to be used at an application rate of 40 g product/m2. After application of the product, the concentration of SiO2 on treated surface is considered 100% since it can be assumed that the solvent is evaporated. So only 1.1 g a.s/m2 remain on the treated surface which is much lower than the 60g of dust /m² in the study. It is therefore considered that the indicative value from the TNsG model is a very conservative and worst-case value compared to the application rate claimed for MITE KILLER. It can therefore be assumed that the inhalation intake during the cleaning with vacuum cleaner is lower than 0.2 mg/m3 leading to a %AEC lower than 100%.

The risk is therefore considered acceptable.

* **Major change application for MITE KILLER – 2021 :**

No impact of the major change.

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

**Maximum residue limits or equivalent**

Not relevant

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

Based on the intended uses and the proposed risk mitigation measures, the acute and chronic exposure to residues resulting from the intended use is unlikely to cause a dietary risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

* **Major change application for MITE KILLER – 2021 :**

No impact of the major change has been observed on the dietary risk to consumer. Only modification of form has been performed in the PAR and is highlighted in grey.

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

Not applicable. The product contains only one active substance.

### Risk assessment for animal health

Not relevant.

Risk mitigation measures below are proposed to prevent animal exposure

* Do not spray directly on people and animals.

### Risk assessment for the environment

|  |
| --- |
| Please notice that the risk assessment for the environment (section 2.2.8) is reported as provided by the applicant. The FR CA position is presented in **green evaluation boxes.** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 1 - FR CA position:  The risk assessment of the product MITE-KILLER is based on the information provided in the Assessment Report of Synthetic amorphous silicon dioxide PT18 (March 2014) and on the REACH registration dossiers available on the ECHA website concerning the co-formulant named ‘hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics’ (heptane isomer) which is identified as a substance of concern.  The co-formulant ‘hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics’ (heptane isomer) is classified as Aquatic chronic 2, H411 and it is present at a relatively high concentration (58.33%) in the product MITE-KILLER. According to the appendix 1 of the Transitional Guidance on mixture toxicity assessment for biocidal products for the environment, the calculation of the relative toxic units of compounds shows that the toxicity of product is principally linked (more than 99%) to the toxicity of the hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics’ (heptane isomer).   |  |  |  | | --- | --- | --- | | **Summary of relative toxic units (TU)** | | | |  | Silicon dioxide | Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics | | Content in the product [w/w %] | 1.67 | 58.33 | | Aquatic compartment | | | | Fish | 0.35 | 99.65 | | Invertebrates | 0.53 | 99.47 | | Algae and cyanobacteria | 0.1 | 99.9 |   The calculation of relative TU are based on the following endpoints for silicon dioxide:  - Fish: L(E)C50 and NOEC>110 mg/L  - Invertebrates: L(E)C50 and NOEC>86 mg/L  - Algae: ErC50 and EbC50 >54 mg/L  The endpoints used for hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics’ (heptane isomer) are below:  - Fish: L(E)C50 =13.4 mg/L and NOELR = 1.534 mg/L.  - Invertebrates: L(E)C50 = 3 mg/L and NOEC= 0.17 mg/L  - Algae: EL50 (24h) = 10 mg/L and EL50 (4 days)= 3.7 mg/L  For the Silicon dioxide, data on algae has not been considered as relevant for risk assessment. However this value was presented in the doc IIA of the CAR. Nevertheless, it should be noted that whatever the retained value for silicon dioxide, the toxicity of the product is mainly driven by the Hydrocarbons, C7, n-alkanes, isoalkanes, cyclics and this substance can be considered as a SoC.  Therefore, the co-formulant ‘Hydrocarbons, C7, n-alkanes, isoalkanes, cyclics is considered as a substance of concern based on its content in the product in comparison to the content in silicon dioxide and based on the aquatic ecotoxicity data from the REACH registration dossiers available on the ECHA website. It is therefore taken into account in the mixture toxicity assessment of the product MITE-KILLER.  There are no indications for synergistic effects for the active substance and the coformulants in the literature.  Conclusion: the environmental risk assessment of the product MITE-KILLER is based on the active substance silicon dioxide, and also on ‘hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics’ (heptane isomer). |

#### **Effects assessment on the environment**

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| Infobox 2 - FR CA position:  **PNEC derivation- Active substance**  PNEC values were proposed in the Assessment Report of Synthetic amorphous silicon dioxide PT18.   |  |  | | --- | --- | | **Summary table on PNEC for Synthetic amorphous silicon dioxide** | | | **Environmental compartment** | **PNEC value** | | PNEC STP | 100 mg.L-1 | | Surface water | 8.6E-02 mg.L-1 | | Freshwater sediment \* | 2.19 mg.kgwwt-1\* | | Soil \* | 706 g.kg dwt-1 = 625 g.kgwwt-1\* |   \* According to the CAR, the PNEC cannot be calculated with the partitioning method from PNEC water. Therefore, as agreed during TMIII10, PNEC is replaced by silica background in the considered compartment.  As explained in the Assessment Report of Synthetic amorphous silicon dioxide PT18, It is not necessary to perform an assessment of secondary poisoning.  **PNEC derivation- Substance of Concern**  Endpoint values were calculed from available ecotoxicity data on SoC Hydrocarbons, C7, n-alkanes, isoalkanes, cyclics. So, the lowest endpoint for the substance of concern is NOEC (21days) =170µg/L (for the aquatic invertebrates). Only one long term study is available leading to an AF=100.  For the STP compartment, value obtained with *Tetrahymena pyriformis* is EL50 (48h)= 26.81 mg/L according to the Echa disseminated website. An AF=10 according to the table 19 p.137 in the BPR vol.IV part B+C is used to derive a PNECstp.   |  |  | | --- | --- | | **Summary table on PNEC for the SoC**  **Hydrocarbons, C7, n-alkanes, isoalkanes, cyclics** | | | **Environmental compartment** | **PNEC value** | | Surface water | 1.70E-03 mg.L-1 | | Freshwater sediment (EPM) | 4.10E-01 mg.kgwwt-1 | | Soil (EPM) | 3.42E-01 mg.kgwwt-1 | | STP | 2.681 mg.L-1 |   No ecotoxicological data are available to set a PNEC value for the Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (heptane isomer) for secondary poisoning. Indeed, according to the BPR vol IV part B+C (2017) (p.159) : “ Secondary poisoning effects on bird and mammal populations rarely become manifested in short-term studies. Therefore, results from long-term studies are strongly preferred, such as NOECs for mortality, reproduction or growth. If no adequate toxicity data for mammals or birds are available, an assessment of secondary poisoning cannot be made.” If EC50 is used, only EC50 data from repeated-dose toxicity tests should be used to assess secondary poisoning effects according to the Guidance document. So, as no long term data or EC50 based on repeated dose toxicity are available on ECHA disseminated website for this SoC, the risk for secondary poisoning cannot be made. |

The product MITE-KILLER is a ready-to-use aerosol insecticide and acaricide containing 1.5% w/w silicon dioxide as active substance. Beside the active substance, the co-formulant heptane isomers leading the product Mite Killer to be classified for the environment has been identified as a substance of concern (see section 2.2.8.3.7 on mixture toxicity).

A summary of the available ecotoxicity data on the active substance silicon dioxide and on the heptane isomers is presented below. All the data on silicon dioxide are coming from the Assessment Report of the active substance (see Assessment Report of silicon dioxide, PT18, 2014/03). Data on the heptane isomers are coming from the SDS of heptane isomers and from the REACh registration dossier available on the ECHA website.

**Table 2.2.8.1-1: Available ecotoxicity data on silicon dioxide**

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| --- | --- | --- | --- |
| **Species** | **Time scale** | **Endpoint** | **Toxicity** |
| **Aquatic organisms** | | | |
| *Oncorhynchus mykiss* | 96 h | LC50 (mortality) | > 110 mg a.s./L |
| *Daphnia magna* | 48 h | LC50 (mortality) | > 86 mg a.s./L (measured concentration) |
| *Selenastrum capricornutum* | 72 h | ErC50 | Several deficiencies led to consider the study as not reliable. Nevertheless, considering the mode of action of the compound, no toxicity to algae was expected. |
| Heterogeneous sample of bacteria, found naturally in domestic sewage | 3 h | NOEC | 1000 mg a.s./L |

**Table 2.2.8.1-2: Available ecotoxicity data on heptane isomers**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Time scale** | **Endpoint** | **Toxicity** | **Source** |
| *Pseudokirchneriella subcapitata* | 72 h | EC50 | 10 – 30 mg/L | SDS of 11/07/2013 Reach registration dossier |
| *Daphnia magna* | 48 h | EC50 | 3 mg/L | SDS of 11/07/2013 |
| *Daphnia magna* | 21 d | NOEC | 0.17 mg/L | SDS of 11/07/2013 |
| *Oncorhynchus mykiss* | 96 h | LC50 | > 13.4 mg/L | SDS of 11/07/2013 Reach registration dossier |
| *Freshwater fish (QSAR modelling)* | 28 d | NOELR (growth) | 1.534 mg/L | Reach registration dossier |
| *Tetrahymena pyriformis (QSAR modelling)* | 48 h | EL50 | 26.81 mg/L | Reach registration dossier |

The PNECs available in the Assessment Report of silicon dioxide are summarised in the following table:

**Table 2.2.8.1-3: Summary of PNEC of the active substance silicon dioxide**

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| --- | --- | --- |
| **Compartment** | **PNEC** | **Remarks** |
| Freshwater | 0.086 mg a.s./L | It has to be pointed out that the calculated PNEC is lower than the background levels of dissolved silica found in the natural aquatic compartments, reported to be from 0.4 to 26  mg/L. The calculated PNEC value can therefore be considered as a conservative value. |
| Freshwater sediment | 2.19 mg Si/kgwwt | PNECsediment is replaced by silica background in sediment, which varies in a range from 2.19 to 16.48 mg Si/kgwwt. The value of 2.19 mg Si/kgwwt is used for the assessment. |
| Soil | 706 g Si/kgdwt | PNECsoil is replaced by silica background in soil, which is about 706 g/kgdwt |
| STP | 100 mg a.s./L | An assessment factor of 10 is applied to derive the PNECmicroorganisms. |

***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***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Infobox 3 - FR CA position:   |  |  | | --- | --- | | **Classification of the Active Substance** | | | Value/conclusion | Active substance - Synthetic amorphous silicon dioxide: not classified | | Justification for the value/conclusion | Daphnia was the most sensitive aquatic organism with the lowest LC**50** >86 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: not classified |  |  |  | | --- | --- | | **Classification of the SoC** | | | Value/conclusion | Substance of concern - Hydrocarbons, C7, n-alkanes, isoalkanes, cyclics: H411- Toxic to aquatic life with long-lasting effects | | Justification for the value/conclusion | Daphnia was the most sensitive aquatic organism with the lowest NOEC=0.17 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:   * Aquatic chronic 2; H411. |  |  |  | | --- | --- | | **Classification of the Product MITE-KILLER** | | | Value/conclusion | **Aquatic Chronic 2** | |

There is no ecotoxicological data available for the product MITE-KILLER. The classification of the product is therefore based on data on the active substance and co-formulants.

Several aquatic ecotoxicological data on the active substance are available and are presented in the table 2.2.8.1-1 above. Based on these data, the active substance silicon dioxide is not classified for the environment according to Regulation (EC) No.1272/2008 (CLP) (see Assessment Report of silicon dioxide, PT18, 2014/03).

According to the SDS (see Section 13 of the IUCLID file), one component of the product MITE-KILLER other than the active substance is classified for the environment according to Regulation (EC) 1272/2008 (CLP) and has the following classification:

- "Heptane isomers": Aquatic Chronic 2, H411 with a content > 50% w/w in the product

No other component of the product MITE-KILLER is classified for the environment. Therefore, it is not suspected that the composition of the product would influence the ecotoxicological properties of the heptane isomers in a way that may considerably alter the conclusions of the classification. The detailed composition is given in Section 2 of the IUCLID file and in the confidential annex in Section 13 of the IUCLID file (see document "A3.6\_Confidential\_composition\_ MITE-KILLER \_151029").

Based on the above data, the product MITE-KILLER is classified according to Regulation (EC) No.1272/2008 (CLP) as following:

- Aquatic chronic 2, H411: Toxic to aquatic life with long lasting effects.

The classification of the product is presented in IUCLID, Section 12 Classification & labelling.

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| **Information relating to the ecotoxicity of the biocidal product** | |
| Justification | The product MITE-KILLER is classified for the environment as aquatic chronic 2, H411, based on the active substance and components data, according to the rules laid down in Regulation 1272/2008 (CLP).  No further aquatic ecotoxicity data on the product MITE-KILLER is deemed necessary. |

***Further Ecotoxicological studies***

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| Infobox 4 - FR CA position:  No data is available. |

No data is available.

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| **Data waiving** | |
| Information requirement | Further ecotoxicological studies. |
| Justification | The product MITE-KILLER is a ready-to-use aerosol insecticide and acaricide for direct surface treatment containing 1.5% w/w silicon dioxide as active substance.  The product is applied by spray application at the dose of 40 g aerosol/m2  It is used indoors:  - by professionals in bedrooms of private houses and hotels against bedbugs in inaccessible locations such as cracks and crevices and on localised surfaces to create barriers.  - by non-professionals in aviaries, dovecotes and poultry houses against red mites on surfaces.  As the product is for indoor use only, it is not expected that the environment will be contaminated directly. Surface water including sediment may be contaminated only via the Sewage Treatment Plant (STP) effluent and the soil may be contaminated only via sewage sludge application. Therefore the risk of exposure of non-target organisms is very limited when using the product according to label recommendations.  Aquatic ecotoxicological data on the active substance silicon dioxide are available showing that a low toxicity to aquatic organisms is expected.  Moreover silicon, in the form of silicon dioxide and silicates, occurs ubiquitously in the environment: silicon dioxide and silicates correspond to about 25% of the earth’s crust.  Silicon dioxide and silicates are present in practically all plants, animals and in natural waters. Furthermore, although silicon dioxide is obtained from chemical synthesis, the produced substance is chemically equivalent to the natural silicon dioxide.  As indicated by the vapour pressure of 6 kPa, heptane isomers is a very volatile substance. This is confirmed by the simulation with the Petrorisk model (version 5.2, see REACh registration dossier) which indicates that 96% of the heptane isomers is distributed in the air at a regional scale. Therefore, it can be reasonably predicted that almost all the heptane isomers is volatilised very rapidly after the application step and thus long before the cleaning step (which could occur at a later date) allowing to conclude that emissions of heptane isomers into the environment are negligible.  Thus no additional aquatic or terrestrial ecotoxicological study with the product was conducted. |

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

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| Infobox 5 - FR CA position:  No data is available. |

No data is available.

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| **Data waiving** | |
| Information requirement | Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk. |
| Justification | Based on the intended uses of the product MITE-KILLER and the ecotoxicological properties of the active substance silicon dioxide and the heptane isomers, there is no concern regarding other specific non-target organisms like for instance, sediment dwelling organisms, aquatic macrophytes or brackish, estuarine or marine organisms.  Indeed, as explained under Point 2.2.8.1.2, exposure of the environment is very limited and may occur only indirectly via the STP.  Aquatic ecotoxicological data on the active substance silicon dioxide are available showing that no toxicity to aquatic organisms is expected.  Moreover silicon, in the form of silicon dioxide and silicates, occurs ubiquitously in the environment: silicon dioxide and silicates correspond to about 25% of the earth’s crust. Silicon dioxide and silicates are present in practically all plants, animals and in natural waters. Furthermore, although silicon dioxide is obtained from chemical synthesis, the produced substance is chemically equivalent to the natural silicon dioxide.  As indicated by the vapour pressure of 6 kPa, heptane isomers is a very volatile substance. This is confirmed by the simulation with the Petrorisk model (version 5.2, see REACh registration dossier) which indicates that 96% of the heptane isomers is distributed in the air at a regional scale. Therefore, it can be reasonably predicted that almost all the heptane isomers is volatilised very rapidly after the application step and thus long before the cleaning step (which could occur at a later date) allowing to conclude that emissions of heptane isomers into the environment are negligible.  Thus no additional aquatic or terrestrial ecotoxicological study with the product was conducted. |

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

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| --- |
| Infobox 6 - FR CA position:  No data is available. |

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Supervised trials to assess risks to non-target organisms under field conditions. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. The product MITE-KILLER is an aerosol. The product is not in the form of bait or granules. Therefore no additional study is deemed necessary to address this point. |

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

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| --- |
| Infobox 7 - FR CA position:  No data is available. |

No data is available.

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| --- | --- |
| **Data waiving** | |
| Information requirement | Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. The product MITE-KILLER is an aerosol. The product is not in the form of bait or granules. Therefore no additional study is deemed necessary to address this point. |

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

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| Infobox 8 - FR CA position:  No data is available. |

No data is available.

The product MITE-KILLER is a ready-to-use aerosol insecticide and acaricide for indoor surface treatment in bedrooms of private houses and hotels against bedbugs and, in aviaries, dovecotes and poultry houses against red mites.

As the product is for indoor use only, it is not intended to be applied directly in a specific habitat such as water body, wetland, forest or field. No large proportion of specific habitat type is treated with the product MITE-KILLER and it can be concluded that no secondary ecological effect is expected when using the product MITE-KILLER according to label recommendations.

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

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| Infobox 9 - FR CA position:  No data is available. |

The foreseeable routes of entry in the environment are based on the use envisaged and the behaviour of the product is extrapolated from the information on the active substance silicon dioxide and on the substance of concern heptane isomers.

The product MITE-KILLER is a ready-to-use aerosol insecticide and acaricide for direct surface treatment

containing 1.5% w/w silicon dioxide as active substance.

The product is applied by spray application at the dose of 40 g aerosol/m2

It is used indoors:

- by professionals in bedrooms of private houses and hotels against bedbugs in inaccessible locations

such as cracks and crevices and on localised surfaces to create barriers,

- by non-professionals in aviaries, dovecotes and poultry houses against red mites on surfaces.

According to the intended uses, the Sewage Treatment Plant (STP) is considered as the main receiving compartment following wet cleaning events. Then, the final environmental compartment will be surface water, including sediment (through STP effluent), the soil and the groundwater (from sludge application) and the outdoor air.

Please see section Fate and distribution in exposed environmental compartments for more information regarding silicon dioxide and heptane isomers fate and distribution in the environment.

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

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| Infobox 10 - FR CA position:  No data is available. |

No data is available.

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| --- | --- |
| **Data waiving** | |
| Information requirement | Further studies on fate and behaviour in the environment. |
| Justification | As explained above, the expected concentrations of the product in the environment are rather low as the product is only used indoor. Environment may be contaminated indirectly only via the STP effluent and sewage sludge applications.  Therefore, it can be concluded that there is no need to conduct additional environmental studies with the product MITE-KILLER. |

***Leaching behaviour (ADS)***

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| Infobox 11 - FR CA position:  No data is available. |

The product MITE-KILLER is an aerosol for indoor surface treatment in bedrooms of private houses and hotels and, on surfaces in aviaries, dovecotes and poultry houses.

It is not intended to be used for the treatment of surfaces exposed to weathering. Leaching is not relevant for the product MITE-KILLER.

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

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| Infobox 12 - FR CA position:  No data is available. |

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| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in soil. |
| Justification | Exposure of the environment will be very limited because the product MITE-KILLER is for indoor use only.  Moreover, data are available on the active substance silicon dioxide, which occurs ubiquitously in the environment.  Due to its limited water solubility in natural conditions and extremely low vapour pressure, silicon dioxide is expected to be distributed mainly into soils and sediments, weakly into water and probably not at all in the air. This compound is expected to combine indistinguishably with the soil layer and sediment due to its chemical identity with inorganic soil matter.  Based on the physico-chemical nature of silicon dioxide (inorganic structure, chemical stability, i.e. high stability of the Si-O bond), it was not scientifically founded to determine the rate and the route of biodegradation in the different compartments of the environment, as the process applies only to organic compounds.  Regarding the heptane isomers, a distribution modelling using the Petrorisk model version 5.2 was performed for the REACh registration. Results are available on the ECHA website. Based on the regional scale exposure assessment, the distribution of the substance in the soil is 0.55%.  Based on this assessment, there is no need to conduct additional studies on distribution and dissipation in soil with the product MITE-KILLER. |

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

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| Infobox 13 - FR CA position:  No data is available. |

No data is available.

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| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in water and sediment. |
| Justification | Exposure of the environment will be very limited because the product MITE-KILLER is for indoor use only.  Moreover, data are available on the active substance silicon dioxide, which occurs ubiquitously in the environment. Due to its limited water solubility in natural conditions and extremely low vapour pressure, silicon dioxide is expected to be distributed mainly into soils and sediments, weakly into water and probably not at all in the air. This compound is expected to combine indistinguishably with the soil layer and sediment due to its chemical identity with inorganic soil matter. Based on the physico-chemical nature of silicon dioxide (inorganic structure, chemical stability, i.e. high stability of the Si-O bond), it was not scientifically founded to determine the rate and the route of biodegradation in the different compartments of the environment, as the process applies only to organic compounds.  Regarding the heptane isomers, a distribution modelling using the Petrorisk model version 5.2 was performed for the REACh registration. Results are available on the ECHA website. Based on the regional scale exposure assessment, the distribution of the substance in water and sediment is 1.4% and 1.8% respectively. Based on this assessment, there is no need to conduct additional studies on distribution and dissipation in water and sediment with the product MITE-KILLER. |

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

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| Infobox 14 - FR CA position:  No data is available. |

No data is available.

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| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in air. |
| Justification | Exposure of the environment will be very limited because the product MITE-KILLER is for indoor use only. Moreover, data are available on the active substance silicon dioxide, which occurs ubiquitously in the environment. Silicon dioxide is not volatile, and therefore exposure via the atmospheric compartment is not considered relevant. Based on the physico-chemical nature of silicon dioxide (inorganic structure, chemical stability, i.e. high stability of the Si-O bond), it was not scientifically founded to determine the rate and the route of biodegradation in the different compartments of the environment, as the process applies only to organic compounds. Regarding the heptane isomers, a distribution modelling using the Petrorisk model version 5.2 was performed for the REACh registration. Results are available on the ECHA website. Based on the regional scale exposure assessment, the distribution of the substance in the air is 96%. Based on this assessment, there is no need to conduct additional studies on distribution and dissipation in air with the product MITE-KILLER. |

***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)***

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| Infobox 15 - FR CA position:  No data is available. |

No data is available.

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| **Data waiving** | |
| Information requirement | Overspray study to assess risks to aquatic organisms or plants under field conditions. |
| Justification | The product MITE-KILLER is an aerosol for indoor surface treatment in bedrooms of private houses and hotels and, on surfaces in aviaries, dovecotes and poultry houses. It is therefore not intended to be sprayed in or near surface water. Therefore no overspray is foreseen. Based on this assessment an overspray study is not required for the product MITE-KILLER. |

***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)***

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| --- |
| Infobox 16 - FR CA position:  Not relevant. |

No data is available.

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| --- | --- |
| **Data waiving** | |
| Information requirement | Data on overspray behaviour to assess risks to bees and non-target arthropods under field conditions. |
| Justification | The product MITE-KILLER is an aerosol for indoor surface treatment in bedrooms of private houses and hotels and, on surfaces in aviaries, dovecotes and poultry houses. The product is not intended to be sprayed into the outdoor environment and it has no potential for large scale formation of dust. Therefore there is no risk of exposure of honeybees and non-target arthropods. Based on this assessment, no additional study with the product MITE-KILLER was conducted to address this point. |

#### **Exposure assessment**

The environmental exposure assessment has been performed in accordance with the emission scenario document for insecticides, acaricides and products to control arthropods for household and professional use (ESD for PT18, 17/07/2008). In addition, recent agreements published in the Technical agreements of Biocides (TAB, June 2016) were also taken into account to calculate emission values.

The product MITE-KILLER is an aerosol insecticide and acaricide for direct surface treatment containing 1.5% w/w silicon dioxide as active substance.

The product is applied by spray application at the dose of 40 g aerosol/m2.

It is used indoors:

- by professionals in bedrooms of private houses and hotels against bedbugs in inaccessible locations such as cracks and crevices (scenario 1),

- by professionals in bedrooms of private houses and hotels against bedbugs on localised surfaces to create barriers (scenario 2),

- by non-professionals in aviaries, dovecotes and poultry houses against red mites on surfaces (scenario 3).

Environmental release pathways are described for these two scenarios:

Scenarios 1 and 2: spray application by professionals in bedrooms of private houses and hotels against bedbugs

The product MITE-KILLER is a ready-to-use product. Therefore, no emission is calculated for the mixing/loading step.

When applied indoors by professionals against bedbugs, the product MITE-KILLER can reach the targeted surfaces (cracks and crevices) and also the floor, the applicator clothes and the indoor air. The product does not reach directly the environmental compartments during the application.

Nevertheless, surfaces and applicator clothes can be cleaned. Therefore the cleaning step leads to releases either to wastes (through dry cleaning methods) or to waste water (through wet cleaning methods). For the product MITE-KILLER, both methods are possible. As a worst case, the wet cleaning method is considered. Therefore, the STP is considered as the main receiving compartment following wet cleaning events.

Then, surface water, including sediment (through STP effluent), soil and groundwater (from sludge application) are the environmental compartments which can be contaminated indirectly when using the product MITE-KILLER.

Scenario 3: spray application by non-professionals in aviaries, dovecotes and poultry houses against red mites

The product MITE-KILLER is a ready-to use product. Therefore, no emission is calculated for the mixing/loading step.

The product is applied indoors by non-professionals in aviaries, dovecotes or poultry houses on roosts, nesting boxes, under the trays and in all the corners, cracks and crevices where the mites can hide. As the application occurs indoors, the product does not reach the environmental compartments during this step. Moreover, aviaries, dovecotes and poultry houses are not intended to be cleaned. Indeed, according to the label recommendations, the birds must be reintroduced only when the product is dry, and no washing of aviaries, dovecotes and poultry houses is recommended after the treatment. Therefore, no indirect emissions into the environment via the STP will occur.

Then, when using the product MITE-KILLER according to label recommendations in aviaries, dovecotes and poultry houses, there is no direct or indirect exposure of the aquatic or terrestrial compartments. Therefore this scenario will not be further taken into account in the assessment.

|  |
| --- |
| Infobox 17 - FR CA position:  Please note that for the exposure assessment of scenario 3, the applicant argued that the product would be applied indoors and no cleaning takes place afterwards, so there would be no exposure of any environmental compartment. This is not supported by FR CA (cf infobox 19): it was considered that the main use claimed to treat bed bug infestations by professional covers the minor use to treat poultry red mites infestations, and that the barrier scenario can cover global emissions from both uses. For this assessment a cleaning step is considered.  In fact, targeted aviaries, dovecotes or poultry houses are supposed to be reduced surface areas which are managed by non professional users (surface below 10 m2 supported by the package size). In this context, even if a cleaning step occurs the risk is covered by scenario 1 and 2. |

**Table 2.2.8.2-1: General information on exposure assessment**

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | Scenario 1: indoor spray application in inaccessible locations such as cracks and crevices  Scenario 2 : indoor spray application on localised surfaces to create barriers |
| ESD(s) used | Emission Scenario Document for insecticides, acaricides and products to control arthropods for household and professional uses, 2008 |
| Approach | Scenarios 1 and 2: Average consumption |
| Distribution in the environment | Calculated based on TGD 2003, included in EUSES v.2.1.2. |
| Groundwater simulation | Scenarios 1 and 2: No simulation for leaching to groundwater using a higher tier model (e.g. FOCUS models) was performed. |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenarios 1 and 2: Production: No Formulation No Use: Yes  Service life: No |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 17 - FR CA position:  **General information**   |  |  | | --- | --- | | Assessed PT | PT 18 | | Assessed scenarios | MITE-KILLER is a ready-for-use insecticide and acaricide aerosol for direct surface treatment containing 1.67% w/w silicon dioxide (tech.) as active substance. The product is used indoor and applied by spray application at the dose of 40 g /m2.  Scenario:   * MITE-KILLER is used by professionals in bedrooms of private houses and hotels against bedbugs on localised surfaces to create barriers. A use as spot applications in cracks and crevices is covered by the barrier treatment scenario. * On the other hand, MITE-KILLER is also used by non-professionals in aviaries, dovecotes and poultry houses against red mites on surfaces. Emissions related to this non-professional use are covered by the scenario proposed for the professional use. | | ESD(s) used | Emission scenario document for insecticides, acaricides and products to control arthropods for household and professional uses (ESD n°18, OECD, 17/07/2008) | | Approach | Scenario : Average consumption | | Distribution in the environment | Calculated based on ECHA Guidance on the BPR Vol IV Part B ; April 2015 | | Groundwater simulation | A higher tier model (FOCUS model) wasn’t performed | | Confidential Annexes | No | | Life cycle steps assessed | Application step  During the indoor application in bedrooms, the product MITE-KILLER can reach directly the targeted surfaces and also the adjacent floor by spray drift, the applicator clothes and the indoor air. A scenario for a barrier treatment is applied.  Cleaning step  Cleaning events result only in emission to wastewater in considering that the floor and clothes of the applicator are washable. | | Remarks |  | |

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

**Table 2.2.8.2.2-1: Identification of relevant receiving compartments based on the exposure pathway**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh- water | Freshwater sediment | Sea- water | Seawater sediment | STP | Air | Soil | Groundwater |
| Scenario 1 | Yes | Yes | No | No | Yes | No | Yes | Yes |
| Scenario 2 | Yes | Yes | No | No | Yes | No | Yes | Yes |
| Scenario 3 | No | No | No | No | No | No | No | No |

For the scenarios 1 and 2, sewage treatment plants are the primary compartment for emissions. Surface water bodies (including sediment) and soil compartment (including groundwater) are secondary exposed compartments respectively via sewage treatment plant effluents and sewage sludge applications. Exposure of atmosphere can be expected considering the mode of application by spraying of the product MITE-KILLER, resulting in direct emission to air. However, based on the indoor application of the product it is likely that emissions to the atmosphere will be negligible.

Regarding the scenario 3, applications are made indoors only for the treatment of aviaries, dovecotes and poultry houses that are not intended to be cleaned after application. Therefore, no direct or indirect emissions into the environment via the STP are foreseen.

The available data on fate and behaviour from Assessment Report of silicon dioxide are summarized in the following table.

**Table 2.2.8.2.2-2: Available fate and distribution data for the active substance silicon dioxide**

|  |  |  |
| --- | --- | --- |
| Input | Value | Unit |
| Molecular weight | 60.08 | g/mol |
| Melting point | 1710 | °C |
| Boiling point | *Ca.* 2230 | °C |
| Vapour pressure (at 25°C) | Not applicable as melting point > 300°C(1) | Pa |
| Water solubility (at 25°C) | Not soluble(1) | mg/L |
| Log Octanol/water partition coefficient | Not applicable for inorganic substance | Log 10 |
| Organic carbon/water partition coefficient (Koc) | Not applicable for inorganic substance | L/kg |
| Henry’s Law Constant | Not applicable as melting point > 300°C | Pa.m3/mol |
| Biodegradability | Not readily biodegradable |  |
| Rate constant for STP | Not applicable for inorganic substance | h-1 |
| DT50 for biodegradation in surface water | Not applicable for inorganic substance | d (at 12ºC) |
| DT50 for hydrolysis in surface water | Study of the hydrolysis as a function of pH is technically not feasible for silicon dioxide. Moreover, due to its limited water solubility in natural conditions, the transformation in silicic acid from dissolution by water would be negligible | d (at 12ºC) |
| DT50 for photolysis in surface water | Silicon dioxide is not expected to degrade photolytically | d or h |
| DT50 for degradation in soil | Not applicable for inorganic substance | d (at 12ºC) |
| DT50 for degradation in air | Not determined as the silicon dioxide is not volatile, and therefore exposure *via* the atmospheric compartment is not considered relevant | d |

(1) This data is a required data in EUSES. As no value is available for this endpoint, the value is set to the minimum in EUSES.

Silicon dioxide is an inorganic chemical, with the molecular formula O=Si=O. Based on the physico-chemical nature of this compound (inorganic structure, chemical stability, i.e. high stability of the Si-O bond), it is not scientifically founded to determine the rate and the route of biodegradation in the different compartments of the environment, as the process applies only to organic compounds. Also, it is not possible to calculate the distribution in the exposed environmental compartments.

Due to its limited water solubility in natural conditions and extremely low vapour pressure, silicon dioxide is expected to be distributed mainly into soils/sediments, weakly into water and probably not at all in the air. This compound is expected to combine indistinguishably with the soil layer and sediment due to its chemical identity with inorganic soil matter. Whatever its origin, man-made or natural (mostly as sand or quartz), and whatever its structure, crystalline or amorphous silica, once released and dissolved into the environment, no distinction can be made between the initial forms of silica.

The available data on fate and behaviour from the SDS and the REACh registration dossier of heptane isomers are summarized in the following table. As the heptane isomers is an UVCB (Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials), most of the endpoints can’t be defined for the substance as a whole and are therefore not available.

**Table 2.2.8.2.2-3: Available fate and distribution data for heptane isomers**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Source** |
| **Active substance** | | | |
| Molecular weight | Can’t be determined for an UVCB substance | g/mol | - |
| Melting point | - 91 | °C | SDS of 11/07/2013 |
| Boiling point (at 1013 hPa) | 79 – 105 | °C | SDS of 11/07/2013 |
| Vapour pressure (at 20 °C) | 6 - 8 | kPa | SDS of 11/07/2013 |
| Water solubility | 2.6 | mg/L | SDS of 11/07/2013 |
| Log octanol/water partition coefficient | Can’t be determined for an UVCB substance | Log 10 | - |
| Organic carbon/water partition coefficient (Koc) | Can’t be determined for an UVCB substance | L/kg | - |
| Biodegradability | Readily biodegradable |  | SDS of 11/07/2013 REACh registration dossier |
| Rate constant for STP | 1 | h-1 | Extrapolated from the biodegradation screening test according to table 6 of the BPR guidance volume IV, part B, April 2015 |
| DT50 for biodegradation in surface water | 15 | d | Extrapolated from the biodegradation screening test according to table 7 of the BPR guidance volume IV, part B, April 2015 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 18 - FR CA position:   | **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | --- | --- | --- | --- | --- | --- | --- | |  | Freshwater | Freshwater sediment | STP | Air | Soil | Groundwater | | Scenario1 | yes | yes | yes | No (except for the substance of concern: heptane isomer) | yes | yes |   **Active substance: Synthetic amorphous silicon dioxide**   |  |  |  | | --- | --- | --- | | **Input parameters used in the environmental exposure assessments according to the CAR (March, 2014)** | | | | Input | Value | Unit | | CAS number | 112926-00-8 | - | | Molecular weight | 60.08 | g.mol-1 | | Vapour pressure | Not applicable as melting point>300°C | Pa | | Water solubility (at 21°C) | Not soluble | mg.L-1 | | Partition coefficient (log POW) (pH 7) | Not applicable | Log 10 | | Biodegradability | Not biodegradable |  | | Degradation in water/sediment (DT50) (at 12°C) | Not relevant | days | | Degradation in soil (DT50) (at 12°C) | Not relevant | days | | Adsorption / desorption Koc | Not relevant | L.kg-1 | | Henry’s Law Constant (at 20°C) | Not applicable | Pa.m-3.mol-1 | | Photo-oxidative degradation in air (DT50) | Not relevant | h | | Total rate constant for removal from top soil (kTOT) | 6.93E-07 (No degradation) | days-1 | | BCF fish | Not expected to have an intrinsic potential for bioconcentration | L.kg-1 | | BMF fish | - | | BCF earthworms | L.kg-1 |  |  |  | | --- | --- | | **Calculated fate and distribution of Synthetic amorphous silicon dioxide in the STP** | | | Compartment | Percentage [%] | | Air | 0 | | Water | 0 | | Sludge | 100 | | Degraded in STP | 0 |   It should be noted that for the synthetic amorphous silicon dioxide, when it released into the environment, these forms are expected to combin with soil or sediment organic matter and adopt the same behavior as natural silica. Therefore, it is not expected that the nanoform of this substance remains in the environment.  **Substance of concern: hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (heptane isomer)**  Regarding the data gap on the substance of concerned , the environmental assessment focused on heptane values and not on other compounds of the UVCB substance. It was decided to choose n-heptane as the representative substitution of the product since n-heptane has the worst Koc and Kow values (see attached file below). Using endpoints of n-heptane is a worst-case approach for STP fraction to sludge and therefore for PECsoil (a change in the Koc value has a higher impact on fraction to sludge compared to fraction to water on which a Koc modification has only a very slight impact).   |  |  |  | | --- | --- | --- | | **Input parameters used in the environmental exposure assessments according to the REACH registration dossiers (04/2017) and SDS (update 07/2013).** | | | | Input | Value | Unit | | CAS number | 64742-49-0 | - | | Molecular weight | 100.21 | g.mol-1 | | Vapour pressure (at 25°C) | 6000 | Pa | | Water solubility (at 25°C) | 2.6 | mg.L-1 | | Partition coefficient log octanol/water (log POW) | 4.5 | Log 10 | | Biodegradability | Readily biodegradable |  | | Degradation in soil (DT50) (at 12°C) | - | days | | Adsorption / desorption Koc | 11070 | L.kg-1 | | Henry’s Law Constant (at environmental temperature 12°C) | 1.11E+05 | Pa.m-3.mol-1 | | Photo-oxidative degradation in air (DT50) | - | h | | Total rate constant for removal from agricultural top soil (kTOT) | 2.81E-02 | days-1 | | BCF fish | - | L.kg-1 | | BCF earthworms | - | L.kg-1 |  |  |  | | --- | --- | | **Calculated fate and distribution in the STP (EUSES model 2.1)** | | | Compartment | Percentage [%] | | Air | 39.5 | | Water | 2.64 | | Sludge | 40.7 | | Degraded in STP | 17.2 |   The compounds described in the UVCB (May 2017 version) are CxHx carbon chains ranging from 6 to 7 carbons and from 6 to 16 hydrogens. The UVCB mixture contains individual compounds with very similar individual structures and very similar physico-chemical properties (see attached file below). This is why Ref-MS FR states that, in view of the high vapour pressure (6000 Pa), the SoC (hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics) can be assessed the same way as Propan-2-ol that has the same range of volatility (5780 Pa).    According to the Propan-2-ol CAR, the main emission pathway during application step of the product will be via air, because the substance evaporates completely within a short time due to the relatively high vapour pressure. Therefore, nearly the whole amount of substance applied is released to indoor air and then, this air is emitted to the local outside air without indoor deposition. Moreover, as it was stated in WG that for small scale applications of alcohol based products as propanol and considering the small treated areas at the local scale with Mite Killer product, the exposure via the atmosphere could be considered negligible. Moreover, for PT18 substances and products, there is normally no assessment of this pathway in air.  For these reasons, it was considered acceptable to only conduct the assessment for the emissions via the STP as it was in line with the EU conclusions.  The exact distribution between air and waste water is not known, but as a reasonable worst-case it is assumed that 90 % of substance is emitted to air and 10 % to waste water. Thus, it is stated that only 10% of the hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (heptane isomer) is released to STP. Consequently, in the following assessment, it is take into account only 5.833% (10% of the product concentration) of the substance of concern as quantity emitted to relevant environmental compartments. |

***Emission estimation***

Local emissions into the primary receiving compartment (i.e. the STP) are calculated in EUSES v2.1.2, based on the scenarios for indoor, spray application presented in the ESD for PT18.

Local emissions are calculated for the active substance silicon dioxide and also for the substance of concern heptane isomers.

However, one must be careful when analysing emissions calculated for the heptane isomers. Indeed, as indicated by the vapour pressure of 6 kPa, heptane isomers is a very volatile substance. This is confirmed by the simulation with the Petrorisk model (see REACh registration dossier) which indicates that 96% of the heptane isomers is distributed in the air at a regional scale. Therefore, it can be reasonably predicted that almost all the heptane isomers is volatilised very rapidly after the application step and thus long before the cleaning step. Emissions calculated below are based on the worst case assumptions that 10% of heptane isomers is not volatilised and remains on the surfaces that will be cleaned. This assumption may not be realistic.

*Scenario 1: indoor spray application by professionals in bedrooms of private houses and hotels against bedbugs in inaccessible locations such as cracks and crevices*

During the application by spraying in cracks and crevices, the product will reach the treated surfaces and also the applicator clothes, the floor and the indoor air. Fractions of emission are set for each of these receiving materials.

Regarding the cleaning step, two cases are considered in the ESD for PT18:

- cleaning events result only in emission to wastes: 100% of the surfaces are cleaned by vacuum/broom and the clothes of the applicator are disposable,

- cleaning events result only in emission to wastewater: 100% of the surfaces are washable and the clothes of the applicator are washed.

For the product MITE-KILLER, the two methods are possible. Therefore, as a worst case, the wet cleaning method is considered for the calculation of emissions into the STP.

To take into account the diffuse character of emissions, it is considered that releases from houses and larger buildings are collected into one STP, which acts as a unique point source. Therefore, calculations are made in two steps. In a first step, emissions following wet cleaning are calculated for one house and for one larger building. Then, in order to take into account the simultaneity of the treatment, emission rates from one house and from one larger building are multiplied by:

- the number of houses and larger building connected to the STP: Nhouse = 4000 and Nlarger building = 300 - the simultaneity factor: according to the ESD, Fsimultaneity = 5.5% for indoor treatment.

All parameters used for emission calculation are summarised in the following table:

**Table 2.2.8.2.1-1: Input parameters for calculating the local emission – scenario 1**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input** | | **Value** | **Unit** | **Remarks** |
| ***Scenario 1: indoor spray application by professionals in cracks and crevices***  ***Input parameters relating to the application step*** | | | | |
| Fraction of substance in the product | Silicon dioxide | 1.5 | % w/w |  |
| Heptane isomers | 58.33 |
| Surface or air space treatment | | Surface treatment (area) | |  |
| Application scope | | Targeted spot  application | |  |
| Quantity of product applied | | 40 | g/m2 |  |
| Area treated with the product - private houses | | 2 | m2 | Default value for targeted spot or cracks and crevices applications in private house indicated in the ESD for PT18 and in the TAB. |
| Area treated with the product - larger buildings (hotels) | | 9.3 | m2 | Default value for targeted spot or cracks and crevices applications in larger building indicated in the TAB. |
| Number of applications per day per building (private house and hotel) | | 1 | /d | The application frequency is between 1 and 6  weeks interval for curative applications, depending on the level of infestation, with a maximum of 5 applications per year. Then, it is considered in the assessment that there is only one application per day. |
| Fraction of product emitted to air during application | | 0.02 | - | Default value for all applications by spraying. |
| Fraction of product emitted to the applicator during application | | 0.004 | - | The product MITE-KILLER is dedicated to a unique mode of application (*i.e.* by aerosol dispenser). Therefore the specific value for self-pressurised aerosol dispenser (0.004) from Table 3.3-1 of the ESD for PT18 is used for the fraction emitted to applicator. |
| Fraction of product emitted to floor during application | | 0.126 | - | The product MITE-KILLER is dedicated to a  unique mode of application (*i.e*. by aerosol dispenser). Therefore the specific value for  self-pressurised aerosol dispenser (0.126) from Table 3.3-3 of the ESD for PT18 is used for the fraction emitted to floor. |
| Fraction of product emitted to treated surfaces during application | | 0.85 | - | Taking into account emission factors of 0.02 for the air, 0.004 for the applicator and 0.126 for the floor, the emission factor to treated surfaces is therefore of 0.85 :  (1 – (0.02 + 0.004 + 0.126)). |
| **Input parameters relating to the cleaning step** | | | | |
| Fraction emitted to waste water from applicator (washable coveralls) | | 1 | - | It is assumed as a worst case that 100% of the applicator clothes are washable. |
| Fraction emitted to waste water from surfaces (treated surfaces and floor) | | 1 | - | It assumed as a worst case that 100% of the surfaces (treated surfaces and floor) are cleaned with water. |
| Fraction of heptane isomers remaining on surfaces after volatilisation | | 0.1 |  | The heptane isomers is a high volatile substance. It is assumed as a worst case that 10% of the substance is not volatilised and remains on the surfaces. |
| Cleaning efficiency | | 0.03 | - | Specific value for cleaning efficiency following applications with ready-to-use aerosols in cracks and crevices from Table 3.3-8 of the ESD for PT18. |
| **Input** | | **Value** | **Unit** | **Remarks** |
| ***Scenario 1: indoor spray application by professionals in cracks and crevices***  ***Input parameters relating to the application step*** | | | | |
| Number of private houses connected to a STP | | 4000 | - | Default value proposed in the ESD for PT18 and in the TAB. |
| Number of larger buildings (including hotels) connected to a STP | | 300 | - | Default value proposed in the TAB. |
| Simultaneity factor | | 5.5 | % | Default value for indoor applications proposed in the ESD for PT18. |

*Calculations for Scenario 1*

Calculations of emissions are made in EUSES, v2.1.2, using the scenario [18] Insecticide, [18.2.1] Indoor spray application and the parameters reported in the table 2.2.8.2.1-1 as input data. The results are reported in the following table.

**Table 2.2.8.2.1-2: Resulting local emission to relevant environmental compartments – scenario 1**

|  |  |  |  |
| --- | --- | --- | --- |
| **Compartment** | **Substance** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | Silicon dioxide | 0.0119 kg/d | Total emission to waste water following the cleaning step from one house = 0.0399 g/d  Total emission to waste water following the cleaning step from one larger building = 0.186 g/d |
| Heptane isomers | 0.0959 kg/d | Total emission to waste water following the cleaning step from one house = 0.323 g/d  Total emission to waste water following the cleaning step from one larger building = 1.50 g/d |

*Scenario 2: indoor spray application by professionals in bedrooms of private houses and hotels against bedbugs on surfaces to create barriers.*

During the application by spraying on surfaces to create barriers, the product will reach the treated surfaces and also the applicator clothes, the floor and the indoor air. Fractions of emission are set for each of these receiving materials.

As for the scenario 1, cleaning events resulting only in emission to waste water are taken into account. All parameters used for emission calculation are summarised in the following table:

**Table 2.2.8.2.1-3: Input parameters for calculating the local emission – scenario 2**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input** | | **Value** | **Unit** | **Remarks** |
| ***Scenario 2: indoor spray application by professionals on surfaces to create barriers Input parameters relating to the application step*** | | | | |
| Fraction of substance in the product | Silicon dioxide | 1.5 | % w/w |  |
| Heptane isomers | 58.33 |
| Surface or air space treatment | | Surface treatment (area) | |  |
| Application scope | | Targeted spot application | |  |
| Quantity of product applied | | 40 | g/m2 |  |
| Area treated with the product - private houses | | 20 | m2 | Default value for barrier treatment in private house indicated in the TAB. |
| Area treated with the product - larger buildings (hotels) | | 93 | m2 | Default value for barrier treatment in larger building indicated in the TAB. |
| Number of applications per day per building (private house and hotel) | | 1 | /d | The application frequency is minimal 1 week interval for curative treatment, up to 3 weeks for preventive treatment, with a maximum of 5 applications per year. Then, it is considered in the assessment that there is only one application per day. |
| Fraction of product emitted to air during application | | 0.02 | - | Default value for all applications by spraying. |
| Fraction of product emitted to the applicator during application | | 0.004 | - | The product MITE-KILLER is dedicated to a unique mode of application (*i.e.* by aerosol dispenser). Therefore the specific value for self-pressurised aerosol dispenser (0.004) from Table 3.3-1 of the ESD for PT18 is used for the fraction emitted to applicator. |
| Fraction of product emitted to floor during application | | 0.126 | - | The product MITE-KILLER is dedicated to a unique mode of application (*i.e*. by aerosol dispenser). Therefore the specific value for self-pressurised  aerosol dispenser (0.126) from Table 3.3-3 of the ESD for PT18 is used for the fraction emitted to floor. |
| Fraction of product emitted to treated surfaces during application | | 0.85 | - | Taking into account emission factors of 0.02 for the air, 0.004 for the applicator and 0.126 for the floor, the emission factor to treated surfaces is therefore of 0.85 : (1 – (0.02 + 0.004 + 0.126)). |
| **Input parameters relating to the cleaning step** | | | | |
| Fraction emitted to waste water from applicator (washable coveralls) | | 1 | - | It is assumed as a worst case that 100% of the applicator clothes are washable. |
| Wet cleaning zone - private houses | | 5.9 | m2 | Default value for the wet cleaning zone in private houses indicated in the TAB. |
| Wet cleaning zone  - larger buildings (hotels) | | 27 | m2 | Default value for the wet cleaning zone in private houses indicated in the TAB. |
| Fraction of heptane isomers remaining on surfaces after volatilisation | | 0.1 |  | The heptane isomers is a high volatile substance. It is assumed as a worst case that 10% of the substance is not volatilised and remains on the surfaces. |
| Cleaning efficiency | | 0.2 | - | Specific value for cleaning  efficiency following applications on surfaces with ready-to-use aerosols from Table 3.3-8 of the ESD for PT18. |
| Number of private houses connected to a STP | | 4000 | - | Default value proposed in the ESD for PT18 and in the TAB. |
| Number of larger buildings (including hotels) connected to a STP | | 300 | - | Default value proposed in the TAB. |
| Simultaneity factor | | 5.5 | % | Default value for indoor applications proposed in the ESD for PT18. |

*Calculations for Scenario 2*

Calculations of emissions are made in EUSES, v2.1.2, using the scenario [18] Insecticide, [18.2.1] Indoor spray application and the parameters reported in the table 2.2.8.2.1-3 as input data. The results are reported in the following table.

**Table 2.2.8.2.1-4: Resulting local emission to relevant environmental compartments – scenario 2**

|  |  |  |  |
| --- | --- | --- | --- |
| **Compartment** | **Substance** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | Silicon dioxide | 0.208 kg/d | Total emission to waste water following the  cleaning step from one house = 0.705 g/d  Total emission to waste water following the  cleaning step from one larger building = 3.23 g/d |
| Heptane isomers | 0.957 kg/d | Total emission to waste water following the  cleaning step from one house = 3.24 g/d  Total emission to waste water following the  cleaning step from one larger building = 14.8 g/d |

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| Infobox 19 - FR CA position:  To cover the main use of the product MITE-KILLER to treat bed bug infestations in domestic and public areas by professional as detailed in the SPC, the barrier scenario is applied. This scenario covers also spot applications in cracks and crevices.  The second use of the product MITE-KILLER in aviaries, coops and small hen houses claims in the SPC by the applicant to treat poultry red mite infestations does not correspond to industrial farming uses. Targeted aviaries, dovecotes or poultry houses are supposed to be reduced surface areas which are managed by non professional users. The treatment is intended to take place on the roosts, nesting boxes, under the trays, in all the corners and cracks and crevices where the mites can hide. Furthermore, the packaging of the product MITE-KILLER, a 500 mL aerosol allows to treat only a surface below 10 m2 .  In this context, considering that the main use claimed to treat bed bug infestations by professional presents the same application rates and frequencies that the minor use to treat poultry red mites infestations, the barrier scenario with a worst case of 3-11 applications per year (Fsimultaneity of 0.815%) can cover global emissions from both uses.  The table below presents input parameters needed to calculate the local emission for the barrier scenario   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for calculating the local emission** | | | | | | **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** | | **Mite - Killer is used by professionals in bedrooms of private houses and hotels against bedbugs on localised surfaces to create barriers.** | | | | | | **INPUTS** | | | | | | **Fraction of active substance (Synthetic amorphous silicon dioxide) in the product (tech)** | **FAI** | **1.67** | **[% w/w]** | Synthetic amorphous silicon dioxide  (sum of all isomers) | | **Fraction of substance of concern in the product remaining on surfaces after volatilisation (10% of the initial concentration) see infobox 18** | **FAI** | **5.833** | **[% w/w]** | hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics’ (heptane isomer) (sum of all isomers) | | **Surface or air space treatment** | **Surface treatment (area)** | | | - | | Application scope | Barrier application | | | - | | Quantity of product applied | **Q prod** | 40 | [g.m-2] | - | | Area treated per house | AREA **treated** | 20 | [m2] | Default value for barrier treatment – Technical Agreements for Biocides (2017) | | Area treated per larger building (hotel) | AREA **treated** | 93 | [m2] | Default value for barrier treatment – Technical Agreements for Biocides (2017) | | Area wet cleaned per house | AREA **wet cleaned** | 5.9 | [m2] | Default value for barrier treatment – Technical Agreements for Biocides (2017) | | Area wet cleaned per larger building (hotel) | AREA **wet cleaned** | 27 | [m2] | Default value for barrier treatment – Technical Agreements for Biocides (2017) | | Fraction emitted to air during application step | **F** air | 0.02 | [-] | Default value - ESD PT18 | | Fraction emitted to applicator during application step | **F** applicator | 0.004 | [-] | Table 3.3-1 - ESD PT18  (self-pressurised aerosol dispenser for surface treatment) | | Fraction emitted to floor during application step | **F** floor | 0.126 | [-] | Table 3.3-3 - ESD PT18  (self-pressurised aerosol dispenser for surface treatment) | | Fraction emitted to treated area during application step | **F** treated | 0.85 | [-] | (1 – (0.02 + 0.004 + 0.126)) | | Fraction emitted to wastewater during cleaning | F ww | 1 | [-] | - | | Cleaning efficiency of the applicator’s clothes | **F**CE appl | 1 | [-] | ESDP PT18 | | Cleaning efficiency of the floor | **F**CE floor | 0.2 | [-] | Table 3.3-8 - ESD PT18  (RTU Aerosols – surface) | | Number of private houses connected to a STP | **N** HOUSE | 4 000 | [-] | Default value – Technical Agreements for Biocides (2016) | | Number of larger buildings (hotels) connected to a STP | **N** LARGER **BUILDING** | 300 | [-] | Default value – Technical Agreements for Biocides (2016) | | Simultaneity factor | F simultaneity | 0.815 | [%] | MITE-KILLER may be applied by spraying on surfaces three to eleven times per year. |   The table below presents output parameters needed to calculate the local emission for the barrier scenario   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **OUTPUTS FOR THE ACTIVE SUBSTANCE: SYNTHETIC AMORPHOUS SILICON DIOXIDE** | | | | | | | ***Emission during the application for one house and one larger building*** | | | | | | |  |  | | House | Large building |  | | **Emission to the applicator** | E applicator | | 5.34E-05 | 2.48E-04 | [kg.d-1] | |  | | | | | | | **Emission to the floor (in wet cleaned areas)** | E floor | | 4.97E-04 | 2.27E-03 | [kg.d-1] | |  | | | | | | | **Emission to treated surface (in wet cleaned areas)** | E treated | | 3.35E-03 | 1.53E-02 | [kg.d-1] | |  | | | | | | | ***Emission during the cleaning step for one house and one larger building*** | | | | | | | **Emission from treated area/floor to wastewater for one house and one larger building** | E treated/floor, ww | | 7.69E-04 | 3.52E-03 | [kg.d-1] | |  | | | | | | | **Emission from applicator to wastewater for one house and one larger building** | E applicator, ww | | 5.34E-05 | 2.48E-04 | [kg.d-1] | |  | | | | | | | **Total emission to the wastewater** | | E total,ww | 8.23E-04 | 3.77E-03 | [kg.d-1] | |  | | | | | | | ***Total Emission to the wastewater for one STP*** | | | | | | | **Total emission to the STP** | | E local water | 3.60E-02 | | [kg.d-1] | |  | | | | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **OUTPUTS FOR THE SUBSTANCE OF CONCERN:** | | | | | | ***Emission during the application for one house and one larger building*** | | | | | |  |  | House | Large building |  | | **Emission to the applicator** | E applicator | 1.87E-04 | 8.68E-04 | [kg.d-1] | |  | | | | | | **Emission to the floor** | E floor | 1.73E-03 | 7.94E-03 | [kg.d-1] | |  | | | | | | **Emission to treated surface** | E treated | 1.17E-02 | 5.35E-02 | [kg.d-1] | |  | | | | | | ***Emission during the cleaning step for one house and one larger building*** | | | | | | **Emission from treated area/floor to wastewater for one house and one larger building** | E treated/floor, ww | 2.69E-03 | 1.23E-02 | [kg.d-1] | |  | | | | | | **Emission from applicator to wastewater for one house and one larger building** | E applicator, ww | 1.87E-04 | 8.68E-04 | [kg.d-1] | |  | | | | | | **Total emission to the wastewater** | E total,ww | 2.87E-03 | 1.32E-02 | [kg.d-1] | |  | | | | | | ***Total Emission to the wastewater for one STP*** | | | | | | **Total emission to the STP** | E local water | 1.26E-01 | | [kg.d-1] | |  | | | | | |

***Calculated PEC values***

As explained above, silicon dioxide is an inorganic chemical. Based on the physico-chemical nature of this compound (inorganic structure, chemical stability, i.e. high stability of the Si-O bond), it is not scientifically founded to determine the rate and the route of biodegradation in the different compartments of the environment, as the process applies only to organic compounds. Also, it is not possible to calculate the distribution in the exposed environmental compartment. Therefore, PEC values can't be calculated for this substance. Exposure assessment models, like EUSES model are no adapted for inorganic substances.

Regarding the heptane isomers, available data are not sufficient to perform a quantitative risk assessment. Heptane isomers is a complex substance, made of different components with different chemical type, molecular weight and isomeric structure and whose content is variable. Consequently, some physical-chemical properties can’t be determined for the substance heptane isomers as a whole and it can’t either be considered as a substance as a whole for the environmental risk assessment. The identity of all components and the mean content of each component are not known. Without these data it is not possible to define “blocks” of components to be assessed.

Given the limited available data, it is therefore not possible to calculate the distribution in the exposed environmental compartment. PEC values can't be calculated for this complex substance.

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| Infobox 20 - FR CA position:  The results are summarised in the following table.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Active substance:  Synthetic amorphous silicon dioxide | Not relevant | Not relevant | Not relevant | 6.67E-01 | Not relevant | | Substance of concern: hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (heptane isomer) | 1.66E-03 | 1.63E-04 | 3.95E-02 | 6.44E-02 | 9.32E-02 |   For the synthetic amorphous silicon dioxide, no PEC values are calculated for surface water sediment, groundwater and STP compartments. Indeed, based on its physico-chemical properties (hydrophobicity, inert and inorganic character...), the distribution of silicon dioxide over the solid and liquid phase will be controlled by the precipitation of the agglomerated particles. When the product is removed in cleaning operation, the liquid waste is discharged to the STP. The silicon dioxide agglomerated particules are collected in the primary sedimentation tank of the STP. Therefore, the concentration of the compound in the liquid phase of the STP can be ignored, whereas 100% of the silicon dioxide emission can be considered in STP sludge.  Thus, only the PEC soil is calculated for the active substance of the product MITE-KILLER. |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning, i.e. the direct consumption of the product by birds or mammals is not considered as relevant for the product MITE-KILLER. Indeed, primary poisoning may mainly occur when a product is applied together with food attractant or is applied as granular formulation, which is not the case of the product MITE-KILLER.

Secondary poisoning

Log Kow can't be determined for inorganic substance and the bio-concentration factor (BCF) has not been estimated or measured for silicon dioxide.

However, due to its physical-chemical nature, the particle size distribution of the silicon dioxide molecule, the practically non-solubility of the molecule in organic solvent, silicon dioxide has no bioaccumulation potential. Moreover, silicon dioxide has no mammalian toxicity and there is no indication of genotoxicity (see Assessment Report of silicon dioxide, PT18, 2014/03

Therefore, the risk of secondary poisoning via ingestion of potentially contaminated food (e.g. earthworm or fish) by birds or mammals is negligible and no risk assessment is deemed necessary.

Log Kow and BCF values are also not know for heptane isomers. However, the substance is readily biodegradable. According to the guidance on REACh information requirements, chapter R7.10.3.4, readily biodegradable chemicals will generally have a higher probability of being metabolised in exposed organisms to a significant extent than less biodegradable chemicals. Thus in general terms, concentrations of most readily biodegradable substances will be low in aquatic organisms.

Moreover, exposition of top predators is very limited. Indeed, heptane isomers is very volatile and the Petrorisk simulation calculates a distribution of only 1.8% in the surface water and 0.55% in the soil.

Considering the properties of the substances and the weak exposition of the environment to the product Mite Killer, the risk of secondary poisoning via ingestion of potentially contaminated food (e.g. earthworm or fish) by birds or mammals is negligible and no risk assessment is deemed necessary.

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| Infobox 21 - FR CA position:  For all the reasons detailed in the CAR of the synthetic amorphous silicon dioxide, it is not necessary to perform an assessment of secondary poisoning for this active substance.  Sufficient data are not available to set a PNEC value for the hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (heptane isomer), thus there is no secondary poisoning assessment. |

#### **Risk characterisation**

The risk characterisation is done only for the scenarios 1 and 2 (professional use of the product MITE-KILLER by spraying in bedrooms of private houses and hotels against bedbugs).

Regarding scenario 3, as explained above, no direct or indirect exposure of the environmental compartments is foreseen when using the product MITE-KILLER in aviaries, dovecotes and poultry houses, according to label recommendations. Therefore it can be considered that the risk for the environment is acceptable.

***Atmosphere***

Exposure of atmosphere can be expected considering the mode of application by spraying of the product MITE-KILLER, resulting in direct emission to air. However, based on the indoor application of the product it is likely that emissions to the atmosphere will be negligible.

Consequently, the risk to the atmospheric compartment is considered negligible when using the product MITE-KILLER according to label recommendations.

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| Infobox 22 - FR CA position:  Regarding the air compartment, the BPR vol IV part B+C (2017) (p.150) specifies: “It is evident that the quantitative characterisation of risk by comparison of the PECair to PNECair is not possible at the moment: only a qualitative assessment for air is feasible.” So, no PECair or PNECair are calculated for substances assessed.  According to the CAR of the active substance, Silicon dioxide is not volatile, and therefore exposure via the atmospheric compartment is not considered relevant.  For the the hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (heptane isomer), given that the intended use of the MITE-KILLER is limited to indoor application and on basis of the available substance information, the environmental risk for the atmosphere can be assumed as low. Indeed, according to the BPR vol IV part B+C (2017) (p.150):”Methods for the determination of effects of chemicals on species arising from atmospheric contamination have not yet been fully developed, except for inhalation studies with mammals.” In the case of hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics, the results of the acute and sub-chronic toxicity inhalation test showed that the test substance is not classified as toxic under the OECD guidelines. On the other hand, as pointed out in the BPR vol IV part B+C (2017) (p.151): “For the evaluation of an atmospheric risk, the following abiotic effects of a chemical on the atmosphere have to be considered: global warming, ozone depletion in the stratosphere, ozone formation in the troposphere, and acidification”. About the hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics, no data on its half-life in the air is available. However, no information highlight a role of hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics on global warming, on stratospheric or tropospheric ozone or on acidification. Moreover, the quantity of hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics released in the atmosphere related to the use of the product Mite Killer is very limited. So we can conclude, there is no risk to the atmospheric compartment.  Conclusion: Emissions in air are considered as negligible. It can be concluded that the use of the product MITE-KILLER will not pose a significant risk to the atmospheric compartment. |

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

As explained above, silicon dioxide is an inorganic substance. Therefore, PEC in the STP can't be calculated as methods to determinate the distribution and the rate and the route of biodegradation in the different compartments of the environment apply only to organic compounds. Exposure assessment models, like EUSES model are no adapted for inorganic substances.

However, concentration in untreated wastewater could be calculated in EUSES v2.1.2. The concentration in untreated wastewater following the use of the product Mite Killer on crack and crevices is equal to 5.93\*10-3 mg/L after a daily emission into the STP of 0.0119 kg silicon dioxide. The concentration in untreated wastewater following the use of the product Mite Killer as barrier treatment is equal to 0.104 mg/L after a daily emission into the STP of 0.208 kg silicon dioxide. It is therefore not expected that the concentration in the STP effluent will be above the PNECSTP of 100 mg/L. Moreover, due to its limited water solubility, silicon dioxide is expected to be distributed mainly into the sludge and weakly into water.

Regarding the heptane isomers, a quantitative risk assessment can’t be performed for this complex substance. However, as indicated by the vapour pressure of 6 kPa, heptane isomers is a very volatile substance. This is confirmed by the simulation with the Petrorisk model which indicates that 96% of the heptane isomers is distributed in the air at a regional scale. Therefore, it can be reasonably predicted that almost all the heptane isomers is volatilised very rapidly after the application step and thus long before the cleaning step (which could occur at a later date) allowing to conclude that emissions of heptane isomers into the environment are negligible.

Conclusion: The risk for STP microorganisms is considered as acceptable when using the product Mite¬Killer according to label recommendations.

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| Infobox 23 - FR CA position:   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC/PNEC values** | | **Conclusion** | |  | **PEC/PNECSTP** | | Active substance:  Synthetic amorphous silicon dioxide | Not relevant | Acceptable | | Substance of concern:  Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (heptane isomer) | 6.19E-04 | No data |   For the active substance:  According to the explanation given in the infobox 20, no risks to the aquatic environment as well as STP microorganisms after cleaning operations are expected. Moreover, as demonstrated in the CAR of the synthetic amorphous silicon dioxide, the active substance is not toxic at all for the STP microorganisms.  For the substance of concern:  No ecotoxicological data are available to set a PNEC value for the hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (heptane isomer) for the STP compartment. Nevertheless considering the vapor pressure of the substance, the risk is assumed to be low.  Conclusion: The risk for the STP is acceptable when using the products MITE-KILLER. |

***Aquatic compartment***

Silicon dioxide is an inorganic substance. Therefore, PEC in the surface water and in sediments can't be calculated as methods to determinate the distribution and the rate and the route of biodegradation in the different compartments of the environment apply only to organic compounds. Exposure assessment models, like EUSES model are no adapted for inorganic substances.

However, as explained above, the aquatic compartment may be contaminated only indirectly, via the STP effluent. In the STP, silicon dioxide, which is insoluble in water, will be distributed mainly into the sludge and weakly into water. Therefore, quantity of silicon dioxide reaching the surface water via the STP effluent is expected to be very weak and below the worst case concentration in untreated wastewater of 0.104 mg/L calculated in EUSES. In surface water, silicon dioxide will also be mainly adsorbed onto sediments. The predicted concentration of silicon dioxide into surface water is therefore not expected to be above the PNECfreshwater of 0.086 mg/L.

Moreover, it has to be pointed out that the PNECfreshwater of 0.086 mg/L is a very conservative value, calculated using an assessment factor of 1000, as only short-term toxicity studies are available. This PNECfreshwater is lower than the background levels of dissolved silica found in the natural aquatic compartments, reported to be from 0.4 to 26 mg/L.

Regarding sediments, as explained above, quantity of silicon dioxide reaching the surface water via the STP effluent is expected to be very weak. Indeed, concentration in STP effluent reaching the surface water compartment will be below the concentration in untreated wastewater of 0.104 mg/L. The predicted concentration of silicon dioxide into freshwater sediment is therefore not expected to be above the silica natural background in sediment, which varies in a range from 2.19 to 16.48 mg Si/kgwwt and will not be above the PNECsediment set as 2.19 mg/kgwwt.

Regarding the heptane isomers, a quantitative risk assessment can’t be performed for this complex substance. However, as indicated by the vapour pressure of 6 kPa, heptane isomers is a very volatile substance. This is confirmed by the simulation with the Petrorisk model which indicates that 96% of the heptane isomers is distributed in the air at a regional scale. Therefore, it can be reasonably predicted that almost all the heptane isomers is volatilised very rapidly after the application step and thus long before the cleaning step (which could occur at a later date) allowing to conclude that emissions of heptane isomers into the environment are negligible.

Conclusion: The risk for the aquatic compartment is considered as acceptable when using the product MITE-KILLER according to label recommendations.

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| Infobox 24 - FR CA position:   |  |  |  |  | | --- | --- | --- | --- | | **Summary table on calculated PEC/PNEC values** | | | **Conclusion** | |  | **PEC/PNECwater** | **PEC/PNECsed** | | Active substance:  Synthetic amorphous silicon dioxide | Not relevant | Not relevant | Acceptable | | Substance of concern:  Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (heptane isomer) | 9.61E-02 | 9.62E-02 | Acceptable |   For the active substance:  According to the explanation given in the infobox 20, the exposure to the aquatic compartment (surface water and sediment) can be discarded; no emission to the aquatic environment after the use of the product is expected. Moreover, as demonstrated in the CAR of the synthetic amorphous silicon dioxide, the active substance is not toxic for the aquatic organisms.  For the substance of concern:  The risk characterisation ratios are below 1 for the surface water and/or the sediment compartments for the substance of concern.  Conclusion:The risk for the aquatic compartment is acceptable when using the product MITE-KILLER. |

***Terrestrial compartment***

Silicon dioxide is an inorganic substance. Therefore, PEC in the soil can't be calculated as methods to determinate the distribution and the biodegradation in the different compartments of the environment apply only to organic compounds. Exposure assessment models, like EUSES model are no adapted for inorganic substances.

However, silicon, in the form of silicon dioxide and silicates, occurs ubiquitously in the environment. Silicon dioxide and silicates correspond to about 25% of the earth’s crust. The PNECsoil is equal to the silica background in soil estimated to be about 706 g/kgdwt. Soil may be contaminated by the product

MITE-KILLER only indirectly, via sewage sludge applications. Considering a daily emission in the STP of silicon dioxide of 208 g/d, it can be stated that the predicted concentration in soil of silicon dioxide following the use of the product MITE-KILLER will not be above the natural background of silica in soil estimated to be about 706 g/kgdwt.

Regarding the heptane isomers, a quantitative risk assessment can’t be performed for this complex substance. However, as indicated by the vapour pressure of 6 kPa, heptane isomers is a very volatile substance. This is confirmed by the simulation with the Petrorisk model which indicates that 96% of the heptane isomers is distributed in the air at a regional scale. Therefore, it can be reasonably predicted that almost all the heptane isomers is volatilised very rapidly after the application step and thus long before the cleaning step (which could occur at a later date) allowing to conclude that emissions of heptane isomers into the environment are negligible.

Conclusion: The risk for the terrestrial compartment is considered as acceptable when using the product MITE-KILLER according to label recommendation.

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| Infobox 25 - FR CA position:   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC/PNEC values** | | **Conclusion** | |  | **PEC/PNECSoil** | | Active substance:  Synthetic amorphous silicon dioxide | 1.07E-06 | Acceptable | | Substance of concern:  Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (heptane isomer) | 1.88E-01 | Acceptable |   Conclusion:The risk characterisation ratios are below 1 for the active substance and the substance of concern for the soil compartment. Therefore, the risks for the soil compartment are acceptable when using the product MITE-KILLER. |

***Groundwater***

As explained above, the predicted concentration in soil of silicon dioxide following the use of the product MITE-KILLER, will not be above the natural background of silica in soil estimated to be about 706 g/kgdwt. Moreover due to its limited water solubility in natural conditions, silicon dioxide is not expected to leach into groundwater.

Regarding the heptane isomers, a quantitative risk assessment can’t be performed for this complex substance. However, as indicated by the vapour pressure of 6 kPa, heptane isomers is a very volatile substance. This is confirmed by the simulation with the Petrorisk model which indicates that 96% of the heptane isomers is distributed in the air at a regional scale. Therefore, it can be reasonably predicted that almost all the heptane isomers is volatilised very rapidly after the application step and thus long before the cleaning step (which could occur at a later date) allowing to conclude that emissions of heptane isomers into the environment are negligible.s

Based on this assessment, it can be concluded that silicon dioxide is not expected to reach groundwater in unacceptable amounts following the use of the product MITE-KILLER.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 26 - FR CA position:   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC groundwater (µg/L)**  **Comparison with the limit value of 0.1 µg/L.** | | | |  | **PEC groundwater** | **Conclusion** | | Active substance:  Synthetic amorphous silicon dioxide | Not relevant | Acceptable | | Substance of concern:  Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (heptane isomer) | 9.32E-02 (<0.1) | Acceptable |   For the active substance:  As explained in the infobox 20, the amorphous silica is hydrophobic and non-soluble in water, a risk of leaching and contamination of groundwater can be discarded.  For the substance of concern:  The concentration in groundwater compartment is below the threshold value of 0.1µg/L.  Conclusion:The risk for the groundwater compartment is acceptable when using the product MITE-KILLER. |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning, i.e. the direct consumption of the product by birds or mammals is not considered as relevant for the product MITE-KILLER. Indeed, primary poisoning may mainly occur when a product is applied together with food attractant or is applied as granular formulation, which is not the case of the product MITE-KILLER.

Secondary poisoning

Log Kow can't be determined for inorganic substance and the bio-concentration factor (BCF) has not been estimated or measured for silicon dioxide.

However, due to its physical-chemical nature, the particle size distribution of the silicon dioxide molecule, the practically non-solubility of the molecule in water and in organic solvent, silicon dioxide has no bioaccumulation potential. Moreover, silicon dioxide has no mammalian toxicity and there is no indication of genotoxicity (see Assessment Report of silicon dioxide, PT18, 2014/03).

Log Kow and BCF values are also not know for heptane isomers. However, the substance is readily biodegradable. According to the guidance on REACh information requirements, chapter R7.10.3.4, readily biodegradable chemicals will generally have a higher probability of being metabolised in exposed organisms to a significant extent than less biodegradable chemicals. Thus in general terms, concentrations of most readily biodegradable substances will be low in aquatic organisms.

Considering the properties of the substances and the weak exposition of the environment to the product Mite Killer, the risk of secondary poisoning via ingestion of potentially contaminated food (e.g. earthworm or fish) by birds or mammals is negligible.

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| Infobox 27 - FR CA position:  Not relevant. |

***Mixture toxicity***

The mixture toxicity assessment is performed according to the "Transitional guidance on mixture toxicity assessment for the environment of May 2014".

|  |
| --- |
| Infobox 28 - FR CA position:  See infobox 1 at the beginning of the part 2.2.8 Risk assessment for the environment for screening step (identification of substances of concern). |

*Screening step*

Screening Step 1: Identification of the concerned environmental compartments

According to the intended use of the product MITE-KILLER, a contamination of the environment is likely to occur. Sewage treatment plants through wet cleaning of surfaces are the primary receiving compartments. Indirect releases into freshwater bodies (including sediment) and onto the soil (including groundwater) are also possible via sewage treatment plant effluents and sewage sludge applications, respectively.

Screening Step 2: Identification of relevant substances

The composition of the product is given in the following table. The detailed composition is given in Section 2 of the IUCLID file and in the confidential annex Section 13 of the IUCLID file (see document "A3.6\_Confidential\_Composition\_ MITE-KILLER \_151029").

**Table 2.2.8.3.7-1: Composition of the product MITE-KILLER and identification of relevant substances**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ingredient | Content in the formulation [w/w %] | Substance of concern(1) | Active  substance from other PT | Relevant substance for mixture assessment |
| Active substance:  silicon dioxide | 1.50 |  |  | Yes |
| Hydrocarbons, C7-C9, n-alkanes, isoalkanes,  cyclics (heptane isomers) | 58.33 | Yes | No | Yes |
| Component 3 | 40.00 | No | No | No |

1. The exact definition of substance of concern is still on discussion. Such a substance would, unless there are other grounds for concern, normally be:

\* a substance classified as dangerous or that meets the criteria to be classified as dangerous according to Directive 67/548/EEC, and that is present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, or

\* a substance classified as hazardous or that meets the criteria for classification as hazardous according to Regulation (EC) No.1272/2008, and that is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation,

\* a substance which meets the criteria for being a persistent organic pollutant (POP) under Regulation (EC) No. 850/2004, or which meets the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No.1907/2006.

Beside the active substance, the product MITE-KILLER contains one substance classified for the environment and present at a concentration leading the product to be classified. Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics is classified as Aquatic chronic 2, H411 and is present at 58.33% w/w, leading the product MITE-KILLER to be classified Aquatic chronic 2, H411. This substance should therefore be considered as relevant substance for mixture toxicity assessment.

Screening Step 3: Screen on synergistic interactions

There are no indications for synergistic effects for the product or its constituents in the literature.

|  |  |
| --- | --- |
| **Screening step** | |
|  | Significant exposure of environmental compartments? Yes |
|  | Number of relevant ssubstances >1? No |
|  | Indication for synergistic effects for the product or its constituents in the literature? No |
|  |  |

Conclusion: the environmental risk assessment of the product MITE-KILLER is based on the active substance and on the heptane isomers. However, as explained above, a quantitative assessment is not possible neither for the active substance silicon dioxide nor for the substance of concern heptane isomers

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 29 - FR CA position:  The result of mixture toxicity assessment of the product containing the active substance amorphous silicon dioxine and the substance of concern ‘Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (heptane isomer)’ is summarised in the following table.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Summary table on calculated ΣPEC/PNEC values** | | | | | | **ΣPEC/PNECSTP** | **ΣPEC/PNECwater** | **ΣPEC/PNECsed** | **ΣPEC/PNECsoil** | **ΣPECGW (µg/L)** | | 6.19E-04 | 9.61E-02 | 9.62E-02 | 0.188 | 9.32E-02 |   Conclusion:The sum of RCRs is below 1 for all compartments considered (STP, water, sediment, soil and the groundwater). Therefore, the risk assessment for the environment is acceptable when using the product MITE-KILLER. |

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

According to the decision scheme developed by UBA (see Figure 1) an overlap in time and space may be possible following the uses of different products containing silicon dioxide. However, there is no guidance currently available for performing an aggregated exposure. It is therefore not possible to perform this assessment.

Moreover, silicon, in the form of silicon dioxide and silicates, occurs ubiquitously in the environment: silicon dioxide and silicates correspond to about 25% of the earth’s crust. Silicon dioxide and silicates are present in practically all plants, animals and in natural waters. Furthermore, as stated in the Assessment Report, although silicon dioxide is obtained from chemical synthesis, the produced substance is chemically equivalent to the natural silicon dioxide.

Therefore, no aggregated exposure estimation for silicon dioxide seems necessary.

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| --- |
| Infobox 30 - FR CA position:  Aggregated exposure is not relevant for the product MITE-KILLER. |



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

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The product MITE-KILLER is an aerosol insecticide and acaricide for direct surface treatment containing 1.5% w/w silicon dioxide as active substance.  The product is applied by spray application at the dose of 40 g aerosol/m2.  It is used indoors:  - by professionals in bedrooms of private houses and hotels against bedbugs in inaccessible locations such as cracks and crevices and on localised surfaces to create barriers,  - by non-professionals in aviaries, dovecotes and poultry houses against red mites on surfaces.  The environmental risk assessment has been performed for the active substance silicon dioxide and for the substance of concern heptane isomers.  According to the intended use of the product MITE-KILLER, sewage treatment plants are the primary receiving compartments through wet cleaning of surfaces following application by professionals in bedrooms. Indirect releases into freshwater bodies (including sediment) and onto the soil (including groundwater) are also possible via sewage treatment plant effluents and sewage sludge applications, respectively.  No exposure of the environment is foreseen when non-professionals use the product to treat aviaries, dovecotes and poultry houses against red mites.  Emissions were calculated in EUSES v2.1.2 according to the ESD for PT18. PEC values can't be calculated for silicon dioxide as it is an inorganic substance. Indeed methods to determinate the distribution and the biodegradation in the different compartments of the environment, apply only to organic compounds and exposure assessment models, like EUSES model are no adapted for inorganic substances. However, emissions into the STP are very low. Moreover, as silicon dioxide occurs ubiquitously in the environment and no toxicity has been shown in available studies, it has been thus concluded that the risk for the aquatic and terrestrial environment is acceptable following the use of the product MITE-KILLER.  Regarding the heptane isomers, a quantitative risk assessment can’t be performed for this complex substance. However, as indicated by the vapour pressure of 6 kPa, heptane isomers is a very volatile substance. This is confirmed by the simulation with the Petrorisk model which indicates that 96% of the heptane isomers is distributed in the air at a regional scale. Therefore, it can be reasonably predicted that almost all the heptane isomers very rapidly after the application step and thus long before the cleaning step (which could occur at a later date) allowing to conclude that emissions of heptane isomers into the environment are negligible.  The aggregated assessment is not deemed necessary as silicon dioxide occurs naturally in the environment. Moreover, no guidance is available to perform the aggregated assessment.  Overall, the risk for the environment of the product MITE-KILLER is acceptable when using the product according to the label recommendations and considering no more thant 11 applications per year. |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 31 - FR CA position:   |  |  |  | | --- | --- | --- | |  | **MITE-KILLER is used by professionals in bedrooms of private houses and hotels against bedbugs on localised surfaces to create barriers. The product is also applied by no professionals in aviaries, dovecotes and poultry houses against red mites infestations** | **Conclusion** | | STP | Acceptable | **Acceptable** | | Surface water | Acceptable | | Sediment | Acceptable | | Soil | Acceptable | | Groundwater | Acceptable | | Secondary poisoning | Not relevant | |

* **Major change application for MITE KILLER – 2021 :**

The major change relates to the addition of non professional users for bedbugs (use 1) and the addition of an application system. These changes have no impact on the environmental risk assessment.

Therefore the conclusions set during the initial assessment are considered extrapolable and risks are deemed acceptable for all the uses of MITE KILLER.

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

*See the SPC in chapter 2.1.*

### Assessment of a combination of biocidal products

*Not relevant*

### Comparative assessment

*Not relevant*

# Annexes

## List of studies for the biocidal product

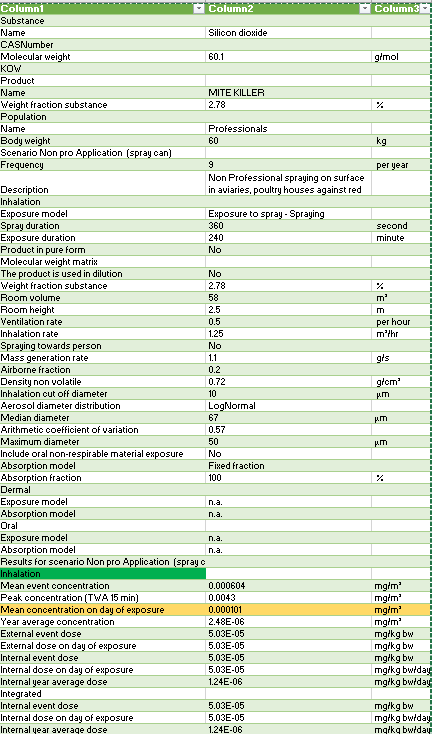
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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |  |
| **Section** | **Author** | **Year** | **Title** | **Testing laboratory** | **Report no.** | **Legal entity owner** | **Letter of access** | **Data protection** | **Essential for the assessment**  **Yes/No** |
| S3.4.1.3. S3.5. | Demangel B. | 2017 | Physico-chemical tests before and after a low temperature storage stability test at 0 ± 2°C for 7 days on the aerosol MITE-KILLER in compliance with CIPAC Handbook J - MT 39.3 method (2000) | Défitraces (Brindas, France) | 15-904017-001 | Denka Registrations BV | No | Yes | Yes |
| S3.1. S3.4.1.1.  S3.15. | Demangel B. | 2017 | Physico-chemical tests and chemical analyses before and after an accelerated storage procedure for 8 weeks at 40 ± 2°C on the aerosol MITE-KILLER in compliance with CIPAC Handbook J - MT 46.3 method (2000) | Défitraces (Brindas, France) | 15-904017-002 | Denka Registrations BV | No | Yes | Yes |
| S3.4.1.1. | Meersman B. | 2015 | MITE-KILLER - Stability - Interim report of the accelerated storage (8 weeks at 40°C) | Edialux-Formulex N.V. (Bornem, Belgium) - Lovap N.V. (Geel, Belgium) | 2015\_01 EDI MITE-KILLER | Edialux-Formulex N.V. | No | Yes | Yes |
| S3.4.1.2. | Trebert R. | 2017 | CERTIFICATE OF ANALYSIS | SGS Multilab (Saint Etienne du Rouvray, France) | BPL17-0008 A | Denka Registrations BV | No | Yes | Yes |
| S3.4.1.2. | Trebert R. | 2017 | CERTIFICATE OF ANALYSIS | SGS Multilab (Saint Etienne du Rouvray, France) | BPL17-0008 D | Denka Registrations BV | No | Yes | Yes |
| S3.4.1.2. | Trebert R. | 2017 | CERTIFICATE OF ANALYSIS | SGS Multilab (Saint Etienne du Rouvray, France) | BPL17-0008 E | Denka Registrations BV | No | Yes | Yes |
| S3.8. S3.9. | Demangel B. | 2015 | Physico-chemical tests on MITE-KILLER | Défitraces (Brindas, France) | 15-904017-005 | Denka Registrations BV | No | Yes | Yes |
| S3.3. S3.8. S3.9. | Demangel B. | 2016 | Relative density of liquids test on MITE-KILLER | Défitraces (Brindas, France) | 15-904017-005 | Denka Registrations BV | No | Yes | Yes |
| S3.5. | Brux A. | 2016 | Determination of the Particle Size Distribution of MITE-KILLER | BioGenius GmbH (Bergisch Gladbach, Germany) | Mo5605 | Denka Registrations BV | No | Yes | Yes |
| S3.5. | Demangel B. | 2019 | . Physico-chemical tests on the aerosol MITEKILLER  stored since 25 July 2016 at 20 ± 2°C | Défitraces  (Brindas, France) | 19-904017-001 | DENKA  REGISTRATIONS BV | No | Yes | Yes |
| S3.5. | Rodriguez N. | 2019 | Determination of the Particle Size Distribution for MITE-KILLER | BioGenius GmbH  (Bergisch  Gladbach,  Germany) | Mo6392 | DENKA  REGISTRATIONS BV | No | Yes | Yes |
| S3.5 | Van der Werff B. | 2020 | Spray pattern and spray output Mite Killer | Denka  International B.V.  (Barneveld, The  Netherlands) |  | DENKA  REGISTRATIONS BV | No | Yes | Yes |
| S3.4.1.2. | Demangel B. | 2015 | Physico-chemical tests and chemical analyses before, during and after a storage procedure for 24 months at 20 ± 2°C on the aerosol MITE-KILLER in compliance with Technical Monograph No.17, 2nd edition CropLife International | Défitraces (Brindas, France) | 15-904017-003 | Denka Registrations BV | No | Yes | Yes |
| S5 | Trebert R. | 2017 | Validation of Analytical Method for determination of silicon dioxide in the liquid part of the biocide formulation  “MITE-KILLER” | SGS Multilab (Saint Etienne du Rouvray, France) | BPL17-0007 | Denka Registrations BV | No | Yes | Yes |
| S5 | Colaux H. et  all | 2019 | Trace level detection and quantification of  crystalline silica in an amorphous silica matrix  with 29Si NMR | Leuven KU (M2S)  (Leuven, Belgium) |  | Denka  Registrations  BV | No | Yes | Yes |
| S6.7\_01  S6.7\_04 | Radecki C. | 2015 | Acaricidal and insecticidal efficacy of 3 products against red poultry mites, Dermanyssus gallinae, and bed bugs, Cimex lectularius. | Biogenius | BIO003b-15 | Edialux Formulex NV | No | Yes | Yes |
| S6.7\_02 | Kinsey R. | 2016 | Laboratory bioassay to determine the residual efficacy of Mite Killer against bed bugs on mattress fabric surface. | i2L Research Ltd | 16/217 | Denka Registrations BV | No | Yes | Yes |
| S6.7\_03 | Foltan P. | 2016 | Field trial to determine the efficacy of Mite Killer against bedbugs, *Cimex lectularius*. | i2L Research Central Europe | 16/218 | Denka Registrations BV | No | Yes | Yes |
| S6.7\_05 | Guicherd A. | 2017 | Study on the efficacy and the treatment persistence with an amorphous silicon dioxide treatment on red mite. | Izipest, Innovaway SA | 16EDI001 | Denka Registrations BV | No | Yes | Yes |

## Output tables from exposure assessment tools



* **Major change application for MITE KILLER – 2021 :**

Inhalation non-professional exposure – spray application with blow-pipe



## Summaries of the efficacy studies

| **Experimental data on the efficacy of the biocidal product Mite-Killer against target organisms** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide | Indoors | Mite-Killer  (silicon dioxide, 1.5% w/w) | *Cimex lectularius* (bedbugs)  20 insects per replicate, adults of mixed sex. | Laboratory insecticidal and residual efficacy test on non porous surfaces (glazed tile) and porous surfaces (wallpaper, mattress fabric). | Application rate: 40.13 g/m², applied only on the whole surfaces.  Surfaces: 225 cm² (15\*15 cm), of glazed tile (non-porous), wallpaper and mattress fabric (porous).  Temperature = 24-25°C  Relative humidity = 65-70 %  Application: spraying.  Exposure: 6 hours of exposure, then transfer in a clean plastic beaker.  Tests: Day 1, the day after application, and 8 and 12 weeks after application.  Mortality evaluated after 1, 2, 3, 5, 7, 10 and 14 days after beginning of exposure.  For each surface and each treatment (test product/untreated control), 3 replicates. | The residual efficacy against bed bugs on partially tiles after 1 day, 8 and 12 weeks of treatment were:  **Glazed tile**  1 day = 100 % within 24 h  8 weeks = 100 % within 48 h  12 weeks = 100 % within 24 h  **Wallpaper**  1 day = 100 % within 24 h  8 weeks = 100 % within 24 h  Aged 12 weeks = 100 % within 24 h  **Mattress fabric**  Aged 1 day = 100 % within 24 h  Aged 8 weeks = 80 % within 14 days  Thus, according to the TNsG requirements for the residual effect ("≥ 95% mortality within 24 hours"), the aerosol Mite-Killer is sufficiently effective against bedbugs, and has a 12 weeks residual efficacy on glazed tiles and wallpaper. | Radecki C., 2015  RI = 2 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Insecticide | Indoors | Mite-Killer  (silicon dioxide, 1.5% w/w) | *Cimex lectularius* (bedbugs)  10 insects per replicate, adults of mixed sex. | Laboratory residual efficacy test on mattress fabric (porous surface) | Application rate: 44.9 g/m²  Surfaces: 144 cm² (12\*12 cm) of mattress fabric (porous surface).  Application: spraying.  Exposure: 6 hours of exposure, then transfer in a clean plastic beaker.  Tests: Day 0, the day of application, and 2, 4 and 6 weeks after application.  Mortality evaluated 5, 15, 30, 45, 60  minutes, and 2, 4, 6, 24, 48 and 72 hours after beginning of the 6 hours exposure.  For each ageing and each treatment (test product/untreated control), 5 replicates. | The assessment 24 hours after beginning of exposure of affected bed bugs on treated surface aged between 0 to 6 weeks (mean values of 5 replicates):  T0 🡪 76 %  2 weeks aged 🡪 80 %  4 weeks aged 🡪 84 %  6 weeks aged 🡪 94 %  Control:  T0 🡪 0.2 %  2 weeks aged 🡪 0 %  4 weeks aged 🡪 0 %  6 weeks aged 🡪 0 %  The product Mite-Killer didn’t show a residual efficacy against bedbugs on porous mattress fabric as mortality on treated fabric surfaces 2, 4, 6 and 8 weeks aged, wasn’t ≥ 95 % within 24 hours according to the criteria of TNsG PT 18  Furthermore, the application rate was higher than the one claimed. | Kinsey R., 2016  RI = 3 |
| Insecticide | Indoors | Mite-Killer  (silicon dioxide, 1.5% w/w) | *Cimex lectularius* (bedbugs) wild  Live bedbugs found before 1st treatment:  Site 1 (total surface = 36.1 m²): 261  Site 2 (total surface = 41.48 m²): 12  Site 3 (total surface = 104.49 m²): 29  Fresh eggs, fresh blood spots and cast skins were also found.  Inhabitants showed signs of bites | Field test | Application rates in the 3 sites treated: Site 1: 36.1 m² => dose applied = 62.24 g/m²  Site 2: 41.48 m² => dose applied = 30.95 g/m²  Site 3 : 104.49 m² => dose applied = 21.5 g/m²  In the first and third site, 7 sprays were used for each treatment, i.e.  2247 g of product (complete product, liquid + propellant) applied each time. In the second site, 4 sprays were used, i.e. 1 284 g of product applied at each treatment.  Application: spraying.  Frequency:  first treatment after the first visual inspection determining the infestation level. Second and third treatment after the inspections: 2 weeks and 6 weeks after initial treatment, respectively.  Assessment: visual observation before each treatment and 8 weeks after initial treatment.  Percentage efficacy calculated as percentage reduction of live bed bugs compared to pre-treatment levels. | |  |  |  |  | | --- | --- | --- | --- | | site | Assessment week | Dose applied (g/m²) | Efficacy (%) | | 1 | 2  6  8 | 62.24  62.24  62.24 | 59  99.2  100 | | 2 | 2  6  8 | 30.95  30.95  30.95 | 100  75  100 | | 3 | 2  6  8 | 21.5  21.5  21.5 | 86.2  93.1  100 |   The amount of product applied in the site 1 is higher than the dose claimed therefore this site is not taken into account.  The requirements mentioned in the TNsG on Efficacy of PT18 products (2012) for field tests against bedbugs are "after a period of 6-10 weeks, the population reduction exceeds 90% relative to either untreated sites or pre- treatment levels. Treatment repeats usually are necessary in bedbug control. At the end of a treatment, 100 % efficacy should be achieved". This criterion is fulfilled, and the product Mite-Killer is effective against bedbugs.  No residual effect was proven in this field test as results on sites 2 and 3 are not consistent 2 weeks after the application | Foltan P., 2016  RI = 2 |
| Acaricide | Indoors | Mite-Killer  (silicon dioxide, 1.5% w/w) | *Dermanyssus gallinae* (poultry red mites)  20 mites per replicate, adults of mixed sex. | Laboratory residual efficacy test. | Application rate: 40.13 g/m², applied only on one half of the surfaces.  Surfaces: 225 cm² (15\*15 cm), of glazed tile (non-porous), wallpaper and mattress fabric (porous).  Temperature = 24-25°C  Relative humidity = 65-70 %  The untreated part of each surface was covered with a folded paper to serve as harbourage.  Application: spraying.  Exposure: 14 days of exposure, inside a glass ring on the surface. The mites have the choice between the treated and untreated parts of the surface.  Tests: Day 1, the day after application, and 8 and 12 weeks after application.  Mortality evaluated after 1, 2, 3, 5, 7,  10 and 14 days after beginning of exposure.  For each surface and each treatment (test product/untreated control), 3 replicates. | The residual efficacy against red poultry mites on partially tiles after 1 day, 8 and 12 weeks of treatment were:  **Glazed tile**  1 day = 100 % within 24 h  8 weeks = 100 % within 24 h  12 weeks = 100 % within 24 h  **Wallpaper**  1 day = 100 % within 24 h  8 weeks = 100 % within 24 h  12 weeks = 100 % within 48 h  **Mattress fabric**  1 day = 100 % within 24 h  8 weeks = 100 % within 48 h  Thus, according to the TNsG requirements for this kind of tests ("≥ 90% mortality in 24 hours"), the aerosol Mite-Killer is sufficiently effective against poultry red mites, and has a 12 weeks residual efficacy. | Radecki C., 2015  RI = 2 |
| Acaricide | Indoors | Mite-Killer  (silicon dioxide, 1.5% w/w) | *Dermanyssus gallinae* (poultry red mites) | Field test | Pre-Test Period:  The field test was conducted in cages from the Club poules (VetAgroSup) in Marcy at Lyon (France) infested by red mites.  The henhouse was outside, but not exposed to bad weather because covered, (cages (treated or not) being under a covered structure).  Four to three days before the treatment, 10 scotch tapes were placed in each individual cage (3 cages for the control and 3 treated cages) to look for populations of red mite.  For this, scotch tapes were positioned in the morning and removed the morning after. The trapped red mites were counted to have the estimated population.  Test Period:  At D0, poultry were taken away and individual cages from the test site were treated with the Test Item (treated area) at 0,6 g silicon dioxide /m², as to say 40 g /m² of the whole product.  For the treated area, the Test Item was sprayed on the roosts, nesting boxes, under the trays and in all the corners, cracks and crevices where the mites can hide.  As the treated zone was corresponding to 8.73m², 2 aerosols (the first was emptied and the second was partially emptied) were needed to apply the treatment.  Chickens were reintroduced in cage after liquid has dried up and fresh air has reached the cages. | Pre-Test Period:  Treated area: 371 red mites  Control area: 417 red mites  Treated area:  D8 🡪 4  D15 🡪 0  D22 🡪 0  D36 🡪 0  D50 🡪 2  Control area:  D8 🡪 248  D15 🡪 311  D22 🡪 424  D36 🡪 273  D50 🡪 301  One week after treatment, there were only 4 mites trapped on the scotch tapes in the treated area. And from two weeks after treatment, no mite was trapped, up to 5 weeks after treatment. At the last assessment, 7 weeks after treatment, only 2 mites were trapped. A new infestation is considered only from 5 mites trapped. Thus, from the first treatment, no new infestation occurred within 7 weeks, and no other treatment was applied after the first one. | Guicherd A., 2017  RI = 2 |

## Confidential annex

Please see the separated document.

## Other

1. Value reported in the NMR study. [↑](#footnote-ref-2)
2. At the end of the treatment, the solvent is totally evaporated therefore only pure SiO2 remains on the treated surface. [↑](#footnote-ref-3)
3. Joint FAO/ WHO Expert Committee on Food Additives which met in Geneva, 25 June - 4 July 1973 (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53)

   http://www.inchem.org/documents/jecfa/jecmono/v05je04.htm [↑](#footnote-ref-4)
4. Annex II – Commission regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to regulation (EC) No 1333/2008 of the european Parliament and of the council by establishing a Union list of food additives (OJ L 295, 12.11.2011) [↑](#footnote-ref-5)
5. Community Register of Feed Additives pursuant to Regulation (EC) No 1831/2003, Appendixes 3&4, Annex: List of additives, Released 21 October 2008 [Rev. 35]). [↑](#footnote-ref-6)
6. European parliament and council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners (OJ No L 61, 18.3.1995, p.1) [↑](#footnote-ref-7)
7. Expert Group on Vitamins and Minerals of the UK Food Standards Agency: Safe Upper Levels for Vitamins and Minerals, May 2003 https://cot.food.gov.uk/sites/default/files/vitmin2003.pdf [↑](#footnote-ref-8)
8. Review Report for the active substance kieselgur (diatomaceous earth). Finalised in the Santing Committee on the food Chain and Animal Health at its meeting on 28 October 2008 in view of the inclusion of kieselgur (diatomaceous earth) in Annex I of Directive 91/414/EEC. (SANCO/2617/08 – rev. 5; 3 October 2013) [↑](#footnote-ref-9)
9. Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products. [↑](#footnote-ref-10)
10. Annex II – Commission regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to regulation (EC) No 1333/2008 of the european Parliament and of the council by establishing a Union list of food additives (OJ L 295, 12.11.2011) [↑](#footnote-ref-11)
11. Community Register of Feed Additives pursuant to Regulation (EC) No 1831/2003, Appendixes 3&4, Annex: List of additives, Released 21 October 2008 [Rev. 35]). [↑](#footnote-ref-12)
12. DRAWG (2014): Dietary Risk Assessment Working Group (now ARTFood) « Guidance on estimating livestock exposure to biocidal active substances” – draft not yet published. A draft was publicly available in 2010. [↑](#footnote-ref-13)