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

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

(submitted by the evaluating Competent Authority)



KAPO CHOC PUCES ET LARVES

Product type 18

s-methoprene and imiprothrin

Case Number in R4BP: BC-FV052464-19

Evaluating Competent Authority: France

Date: April 2022

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# CONCLUSION

KAPO CHOC PUCES ET LARVES is a PT18 biocidal product containing s-methoprene and imiprothrin. The product is intended for non-professional indoor use against flying insects, crawling insects, bedbug, fleas, flies, fruit flies and house dust mites.

The aerosol product is used by fumigation on one shot application.

**Conclusion on Physical, chemical and analytical method**

The physico-chemical properties of the biocidal product KAPO CHOC PUCES ET LARVES have been described and considered acceptable in the conditions of use detailed in the SPC.

A shelf-life (extrapolated) of 2 years can be granted for the product.

The product should be protected from frost and from direct sunlight.

The product should not be stored above 40°C.

The biocidal product falls under the criteria of the classification as Aerosol, category 1. Therefore, the product is classified H222: Extremely flammable aerosol and H229: Pressurised container: May burst if heated.

For self-reactive properties, a DSC test of the product should be provided in post-authorisation within 1 year to confirm the non-classification in this hazard class.

The analytical method provided is validated for the determination of imiprothrin and s-methoprene in the product.

The final results of the ambient storage study should be provided in post-authorisation within 1 year.

**Conclusion on efficacy**

The efficacy of the product KAPO CHOC PUCES ET LARVES at the application rate of 200 ml product / 17.5 to 100 m3 with an exposure time of 4 hours is demonstrated against:

* flying insects and crawling insects (adults – use#1),
* bedbugs (*Cimex lectularius*, eggs, larvae and adults – use #2),
* fleas (*Ctenocephalides felis*, eggs, larvae and adults – use #3),
* flies (*Musca domestica*) and fruit flies (*Drosophila melanogaster*, adults – use #4)
* house dust mites (*Dermatophagoides pteronyssinus*, eggs, larvae and adults – use #5).

**Conclusion on human risk assessment**

For the product KAPO CHOC PUCES ET LARVES, the risk is considered acceptable for non-professional users, considering a quantitative and qualitative risk assessment.

**Conclusion on dietary risk assessment**

Risk linked to indirect exposure to KAPO CHOC PUCES ET LARVES via food has been assessed and acute exposure to imiprothrin is above 10% of ARfD for adults and toddlers after refinements. According to ECHA guidance on estimating dietary risk from transfer of biocidal active substances into foods – non-professional uses, the nature of the residues needs to be defined in this case. Since no further data was submitted by the applicant, no conclusion of the risk linked to acute exposure to imiprothrin via food can be drawn. As a result, the following risk mitigation is proposed:

* Do not use in areas where food is stored and prepared such as kitchens.

**Conclusion on environmental risk assessment**

Considering the intended use of KAPO CHOC PUCES ET LARVES and particularly the maximal application rate (200 mL / 100 m3) and the use instruction ‘Allow to act for 4 hours, then ventilate (4 hours minimum) before reusing the room, creating a stream of air between doors and windows wide open’ that allows to refine the assessment, risks are acceptable for all the environmental compartments.

**Overall conclusion**

|  |  |  |
| --- | --- | --- |
| **Target organism** | **Application rate** | **Conditions of use** |
| Flying insects  Crawling insects  Development stage: adults | 200 mL (whole packaging content) in a room from 17.5 to 100 m³ (corresponding to a standard room from 7 to 40 m2). | Indoor domestic buildings  Fumigation - One-shot application  Exposure time: 4 hours  Ventilate (4 hours minimum) before reusing the room  Non professional  Maximum number of treatments per year = 2, not exceeding 4 devices per house |
| Bedbugs (*Cimex lectularius*)  Development stage: eggs, larvae and adults |
| Fleas (*Ctenocephalides felis*)  Development stage: eggs, larvae and adults |
| Flies (*Musca domestica*) and fruit flies (*Drosophila melanogaster*)  Development stage: adults |
| House dust mites (*Dermatophagoides pteronyssinus*)  Development stage: eggs, larvae and adults |

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| KAPO CHOC Puces et larves |  |
| KAPO EXPERT Puces et larves  KAPO Puces et larves  ORO Puces et larves  KAPO CHOC Punaises de lit  KAPO EXPERT Punaises de lit  KAPO Punaises de lit  ORO Punaises de lit  KAPO CHOC Volants rampants  KAPO EXPERT Volants rampants  KAPO Volants rampants  ORO Volants rampants  KAPO CHOC Acariens  KAPO EXPERT Acariens  KAPO Acariens  ORO Acariens  KAPO CHOC Tous insectes  KAPO EXPERT Tous insectes  KAPO Tous insectes  ORO Tous insectes  KAPO CHOC Mouches, moucherons  KAPO EXPERT Mouches, moucherons  KAPO Mouches, moucherons  ORO Mouches, moucherons  KAPO CHOC Puces, punaises de lit  KAPO EXPERT Puces, punaises de lit  KAPO Puces, punaises de lit  ORO Puces, punaises de lit  DIFCONT MAX  DIFAUTO MAX  DIFCONT X  DIFCONT A  DIFCONT K |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | SAS BRUNEL CHIMIE DERIVES |
| **Address** | 16 rue Harald Stammbach CS 80206  59445 WASQUEHAL Cedex  FRANCE |
| **Authorisation number** | FR-2022-0038 | |
| **Date of the authorisation** | **20/04/2022** | |
| **Expiry date of the authorisation** | **19/04/2032** | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | AMIVAL |
| **Address of manufacturer** | Rue Marc Jodot 59220 Rouvignies France |
| **Location of manufacturing sites** | Rue Marc Jodot 59220 Rouvignies France |

|  |  |
| --- | --- |
| **Name of manufacturer** | Volcke |
| **Address of manufacturer** | Industrielaan 15 8520 Kuurne Belgium |
| **Location of manufacturing sites** | Industrielaan 15 8520 Kuurne Belgium |

|  |  |
| --- | --- |
| **Name of manufacturer** | AEROLUB |
| **Address of manufacturer** | 22 Rue Paul Journée 60240 Chaumont-en-Vexin France |
| **Location of manufacturing sites** | 22 Rue Paul Journée 60240 Chaumont-en-Vexin France |

|  |  |
| --- | --- |
| **Name of manufacturer** | QUIMICAS ORO |
| **Address of manufacturer** | CV-35 Valencia-Ademuz Km 13.1, izq. 46.184 S.Antonio de Benagéber (Valencia) Spain |
| **Location of manufacturing sites** | CV-35 Valencia-Ademuz Km 13.1, izq. 46.184 S.Antonio de Benagéber (Valencia) Spain |

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

|  |  |
| --- | --- |
| **Active substance** | Imiprothrin |
| **Name of manufacturer** | Sumitomo Chemical (UK) Plc |
| **Address of manufacturer** | Hythe House, 200 Shepherds Bush Road,  Hammersmith, W6 7NL London,  United Kingdom |
| **Location of manufacturing sites** | Sumitomo Chemical Co.,Ltd.,  Aza-sabishirotai, Oaza-misawa, Misawa,  Aomori 033-0022, Japan. |

|  |  |
| --- | --- |
| **Active substance** | S-Methoprene |
| **Name of manufacturer** | Bábolna Bio Ltd. |
| **Address of manufacturer** | H-1170 Budapest, Szállás u. 6, Hungary. |
| **Location of manufacturing sites** | H-1170 Budapest, Szállás u. 6, Hungary. |

### 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** | Imiprothrin |
| **IUPAC or EC name** | Reaction mass of: 2,5-dioxo-3-prop-2-ynylimidazolidin-1-ylmethyl (1*R*)-*cis*-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate; 2,5-dioxo-3-prop-2-ynylimidazolidin-1-ylmethyl (1*R*)-*trans*-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate  (ca 20:80) |
| **EC number** | 428-790-6 |
| **CAS number** | 72963-72-5 |
| **Index number in Annex VI of CLP** | 613-259-00-5 |
| **Minimum purity / content** | 870 g/kg |
| **Structural formula** | Imiprothrin.svg |

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | S-Methoprene |
| **IUPAC or EC name** | Isopropyl-(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4–dodecadienoate |
| **EC number** | None |
| **CAS number** | 65733-16-6 |
| **Index number in Annex VI of CLP** | None |
| **Minimum purity / content** | 950 g/kg |
| **Structural formula** |  |

#### Candidates for substitution

The active substances contained in the biocidal products are not candidates for substitution.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)\*** |
| --- | --- | --- | --- | --- | --- |
| Imiprothrin | Reaction mass of: 2,5-dioxo-3-prop-2-ynylimidazolidin-1-ylmethyl (1*R*)-*cis*-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate; 2,5-dioxo-3-prop-2-ynylimidazolidin-1-ylmethyl (1*R*)-*trans*-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate  (ca 20:80) | Technical active substance | 72963-72-5 | 428-790-6 | 0.0575 |
| S-Methoprene | Isopropyl-(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4–dodecadienoate | Technical active substance | 65733-16-6 | - | 0.01053 |
| Acetone | Acetone | Non-active substance | 67-64-1 | 200-662-2 | 52.52 |
| \*composition including propellants | |  |  |  |  |

#### Information on technical equivalence

The source of Imiprothrin used for manufacture of the biocidal product matches the reference source which was defended for approval of the active substance.

The source of S-Methopren used for manufacture of the biocidal product matches the reference source which was defended for approval of the active substance.

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

The acetone classifies the product KAPO CHOC PUCES ET LARVES as Skin Irritant Cat (H319) and STOT SE 3 (H336) and is considered a Substance of Concern (SoC).

Please see the confidential annex for further details.

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

According to our assessment, none of the co-formulants contained in the product KAPO CHOC PUCES ET LARVES are regulatory identified as endocrine disruptors.

However, based on screening, 3 co-formulants show indications of endocrine activity and are currently being evaluated in the frame of REACH for its potential ED properties.

Hence, it is not possible to conclude whether these co-formulants should be considered to have ED properties or not before the end of the assessment. In case any co-formulants are finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

Please refer to Confidential Annex.

#### Type of formulation

|  |
| --- |
| AE: Aerosol dispenser |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Aerosol 1  Eye Irrit. 2  STOT SE 3  Aquatic chronic 3 |
| Hazard statement | H222: Extremely flammable aerosol.  H229: Pressurized container: may burst if heated.  H319: Causes serious eye irritation.  H336: May cause drowsiness or dizziness.  H412: Harmful to aquatic life with long lasting effects. |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H222: Extremely flammable aerosol.  H229: Pressurized container: may burst if heated.  H319: Causes serious eye irritation.  H336: May cause drowsiness or dizziness.  H412: Harmful to aquatic life with long lasting effects. |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand  P102: Keep out of reach of children and non-target animals/pets  P103: Read label before use  P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  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/fume/gas/mist/vapours/spray  P264: Wash … thoroughly after handling.  P271: Use only outdoors or in a well-ventilated area.  P273: Avoid release to the environment.  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P312: Call a POISON CENTER or doctor/physician if you feel unwell.  P337+P313: If eye irritation persists: Get medical advice/attention.  P403+P233: Store in a well-ventilated place. Keep container tightly closed.  P405: Store locked up.  P410 + P412: Protect from sunlight. Do no expose to temperatures exceeding 50°/122°F.  P501: Dispose of the contents/container in an approved hazardous waste collection centre, in accordance with local, regional, national and/or international regulations. |
|  | |
| Note | EUH066: Repeated exposure may cause skin dryness or cracking |

### Authorised uses

#### Use description

Table 1. Use # 1 – Insecticide against flying and crawling insects.

|  |  |
| --- | --- |
| **Product Type** | 18 |
| **Where relevant, an exact description of the authorised use** | Insecticide. |
| **Target organism (including development stage)** | Flying insects  Crawling insects  Development stage: adults |
| **Field of use** | Indoor domestic buildings |
| **Application method(s)** | Fumigation - One-shot application |
| **Application rate(s) and frequency** | 200 mL (whole packaging content) in a room from 17.5 to 100 m³ (corresponding to a standard room from 7 to 40 m2).  Exposure time: 4 hours  Ventilate (4 hours minimum) before reusing the room  Maximum number of treatments per year = 2, not exceeding 4 devices per house |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | 200 mL tin plate aerosol can |

#### Use-specific instructions for use

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| - |

#### Use-specific risk mitigation measures

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

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#### 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 – Insecticide one-shot against bedbugs.

|  |  |
| --- | --- |
| **Product Type** | 18 |
| **Where relevant, an exact description of the authorised use** | Insecticide. |
| **Target organism (including development stage)** | Bedbugs (*Cimex lectularius*)  Development stage: eggs, larvae and adults |
| **Field of use** | Indoor domestic buildings |
| **Application method(s)** | Fumigation - One-shot application |
| **Application rate(s) and frequency** | 200 mL (whole packaging content) in a room from 17.5 to 100 m³ (corresponding to a standard room from 7 to 40 m2).  Exposure time: 4 hours  Ventilate (4 hours minimum) before reusing the room  Maximum number of treatments per year = 2, not exceeding 4 devices per house |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | 200 mL tin plate aerosol can |

#### Use-specific instructions for use

|  |
| --- |
| * Close the doors and windows of the rooms to be treated. Do not apply the product on washable tissue (cloths, blankets, bedsheets and pilowcases): remove them before treatment and wash the sheets, blanket and pillowcases at 60°C (except contraindication of the manufacturer) to eliminate target organisms. * Vacuum carefully after treatment to eliminate dead insects and their faeces. |

#### Use-specific risk mitigation measures

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| - |

#### 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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| - |

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

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| - |

#### 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 3. Use # 3 – Insecticide one-shot against fleas.

|  |  |
| --- | --- |
| **Product Type** | 18 |
| **Where relevant, an exact description of the authorised use** | Insecticide. |
| **Target organism (including development stage)** | Fleas (*Ctenocephalides felis*)  Development stage: eggs, larvae and adults |
| **Field of use** | Indoor domestic buildings |
| **Application method(s)** | Fumigation - One-shot application |
| **Application rate(s) and frequency** | 200 mL (whole packaging content) in a room from 17.5 to 100 m³ (corresponding to a standard room from 7 to 40 m2).  Exposure time: 4 hours  Ventilate (4 hours minimum) before reusing the room  Maximum number of treatments per year = 2, not exceeding 4 devices per house |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | 200 mL tin plate aerosol can |

#### Use-specific instructions for use

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

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| --- |
| - |

#### 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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| - |

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

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| - |

#### 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 4. Use # 4 – Insecticide one-shot against flies.

|  |  |
| --- | --- |
| **Product Type** | 18 |
| **Where relevant, an exact description of the authorised use** | Insecticide. |
| **Target organism (including development stage)** | Flies (*Musca domestica*) and fruit flies (*Drosophila melanogaster*)  Development stage: adults |
| **Field of use** | Indoor domestic buildings |
| **Application method(s)** | Fumigation - One-shot application |
| **Application rate(s) and frequency** | 200 mL (whole packaging content) in a room from 17.5 to 100 m³ (corresponding to a standard room from 7 to 40 m2).  Exposure time: 4 hours  Ventilate (4 hours minimum) before reusing the room  Maximum number of treatments per year = 2, not exceeding 4 devices per house |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | 200 mL tin plate aerosol can |

#### Use-specific instructions for use

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#### Use-specific risk mitigation measures

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

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#### 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 5. Use # 5 – Insecticide one-shot against house dust mites.

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| **Product Type** | 18 |
| **Where relevant, an exact description of the authorised use** | Insecticide. |
| **Target organism (including development stage)** | House dust mites (*Dermatophagoides pteronyssinus*)  Development stage: eggs, larvae and adults |
| **Field of use** | Indoor domestic buildings |
| **Application method(s)** | Fumigation - One-shot application |
| **Application rate(s) and frequency** | 200 mL (whole packaging content) in a room from 17.5 to 100 m³ (corresponding to a standard room from 7 to 40 m2).  Exposure time: 4 hours  Ventilate (4 hours minimum) before reusing the room  Maximum number of treatments per year = 2, not exceeding 4 devices per house |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | 200 mL tin plate aerosol can |

#### Use-specific instructions for use

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| * Close the doors and windows of the rooms to be treated. Do not apply the product on washable tissue (cloths, blankets, bedsheets and pilowcases): remove them before treatment and wash the sheets, blanket and pillowcases at 60°C (except contraindication of the manufacturer). * Vacuum carefully after treatment to eliminate dead insects and their faeces. |

#### Use-specific risk mitigation measures

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

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#### 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 use

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| * Always read the label or leaflet before use and respect all the instructions provided. * Apply only on infested area. * Shake before use. In inhabited areas, use only in rooms that are easy to ventilate. Close the windows and doors delimiting the room to be treated. Take out the pets (dogs, cats ...) from the local and remove or cover terrariums, aquariums and animals cages before application. * Place the aerosol vertically, approx. 40 cm from the floor, in the center of the room. Protect the substrate and the floor with paper in a 50 cm radius around the aerosol. Do not position yourself above the aerosol when putting the product into action. Press the trigger of the diffuser all the way down to lock it. Leave the room. * Allow to act for 4 hours, then ventilate (4 hours minimum) before reusing the room, creating a stream of air between doors and windows wide open. * Clean and vacuum treated surfaces before reuse. * Inform the registration holder if the treatment is ineffective. |

#### Risk mitigation measures

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| * Apply only in domestic buildings. * Do not use in areas where food is stored and prepared such as kitchens. * Leave the room after spraying process is triggered. * Washing on hands after use. * Respect a maximum number of treatments per year of 2. * Do not use more than 4 devices per house. * The product has to be applied on a minimum volume area of 17.5 m3 corresponding to a minimal surface area of 7 m2. * Ventilate (4 hours minimum) before reusing the room. |

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

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| * If medical advice is needed, have product container or label at hand. * IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice. * IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor. * IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor. * IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor. |

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

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

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

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| * Keep out of reach of children and pets. * Protect from frost. * Do not store above 40°C. * Protect from direct sunlight. * Shelf-life: two years. |

### Other information

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### Packaging of the biocidal product

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| --- | --- | --- | --- | --- | --- |
| **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)** |
| Aerosol can | 200 mL | Tin plate | -PP hood  -PP diffusor (ST 400 One Shot)  -Metal and plastic valve (tin plate, stainless steel, PE, PA) | Non-professional | Yes |

### Documentation

#### Data submitted in relation to product application

**Efficacy data:**

* Simulated use tests according to CEB 135bis modified with the product KAPO CHOC PUCES ET LARVES on flies (*Musca* domestica, adults), mosquitoes (*Aedes spp*. and *Culex spp*., adults), wasps (*Vespula germanica*, adults), cockroaches (*Blattella germanica* and *Blatta orientalis*, adults), ants (*Lasius niger*, adults), gnats (*Drosophila melanogaster*, adults), fleas (*Ctenocephalides felis,* eggs, larvae and adults), house dust mites (*Dermatophagoides pteronyssinus*, eggs, larvae and adults) and on bedbugs (*Cimex lectularius*, eggs, larvae and adults).

#### Access to documentation

BRUNEL CHIMIE DERIVES S.A.S. provided a Letter of Access of Babolina Bio Ltd., owner of S-methoprene active substance dossier.

BRUNEL CHIMIE DERIVES S.A.S. provided a Letter of Access of Sumitomo Chemical (U.K.) Plc, owner of Imiprothrin active substance dossier.

## Assessment of the biocidal product

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

Table 6. Use # 1 – Insecticide one-shot general public use to fight against flying and crawling insects. Indoor. Domestic area.

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| --- | --- |
| **Product Type** | 18 |
| **Where relevant, an exact description of the authorised use** | Insecticide. |
| **Target organism (including development stage)** | Flying, crawling insects (adults) |
| **Field of use** | Indoor |
| **Application method(s)** | Spraying - One-shot application |
| **Application rate(s) and frequency** | 200 mL (whole packaging content) in rooms up to 100 m³.  1 application. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | 200 mL tin plate aerosol |

Table 7. Use # 2 – Insecticide one-shot general public use to fight against bedbugs. Indoor. Domestic area

|  |  |
| --- | --- |
| **Product Type** | 18 |
| **Where relevant, an exact description of the authorised use** | Insecticide. |
| **Target organism (including development stage)** | Bedbugs (*Cimex*) (eggs, larvae, adults) |
| **Field of use** | Indoor |
| **Application method(s)** | Spraying - One-shot application |
| **Application rate(s) and frequency** | 200 mL (whole packaging content) in rooms up to 100 m³.  1 application. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | 200 mL tin plate aerosol |

Table 8. Use # 3 – Insecticide one-shot general public use to fight against fleas. Indoor. Domestic area

|  |  |
| --- | --- |
| **Product Type** | 18 |
| **Where relevant, an exact description of the authorised use** | Insecticide. |
| **Target organism (including development stage)** | Fleas (*Ctenocephalides*) (eggs, larvae, adults) |
| **Field of use** | Indoor |
| **Application method(s)** | Spraying - One-shot application |
| **Application rate(s) and frequency** | 200 mL (whole packaging content) in rooms up to 100 m³.  1 application. A second treatment may be necessary in case of re-emergence/re-infestation of adults. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | 200 mL tin plate aerosol |

Table 9. Use # 4 – Insecticide one-shot general public use to fight against flies. Indoor. Domestic area

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| **Product Type** | 18 |
| **Where relevant, an exact description of the authorised use** | Insecticide. |
| **Target organism (including development stage)** | Flies and gnats (adults) |
| **Field of use** | Indoor |
| **Application method(s)** | Spraying - One-shot application |
| **Application rate(s) and frequency** | 200 mL (whole packaging content) in rooms up to 100 m³.  1 application. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | 200 mL tin plate aerosol |

Table 10. Use # 5 – Insecticide one-shot general public use to fight against Mites. Indoor. Domestic area

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| **Product Type** | 18 |
| **Where relevant, an exact description of the authorised use** | Insecticide. |
| **Target organism (including development stage)** | Mites (*Dermatophagoides*) (eggs, larvae, adults) |
| **Field of use** | Indoor |
| **Application method(s)** | Spraying - One-shot application |
| **Application rate(s) and frequency** | 200 mL (whole packaging content) in rooms up to 100 m³.  1 application. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | 200 mL tin plate aerosol |

### Physical, chemical and technical properties

The KAPO CHOC Puces et larves is a ready-to-use aerosol biocidal product, applied by complete discharge of the packaging.

The physicochemical and storage stability data supporting the authorisation of the biocidal product are summarised in the table below.

The appearance, relative density, surface tension, viscosity and content of active substances were all assessed on the liquid phase of the aerosol, after degassing.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCA assessment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Sensory observation | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | Homogeneous liquid | Dr L. Mack, 2020, Report Mo6525 (Interim report) | Acceptable |
| Colour at 20 °C and 101.3 kPa | Sensory observation | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | Colourless | Dr L. Mack, 2020, Report Mo6525 (Interim report) | Acceptable |
| Odour at 20 °C and 101.3 kPa | Sensory observation | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | Moderate solvent odour | Dr L. Mack, 2020, Report Mo6525 (Interim report) | Acceptable |
| pH / Acidity / alkalinity | Waiver | Not relevant because the formulation is not water-based and not intended to be used with water. | | | Acceptable |
| Relative density / bulk density | EU method A.3 (oscillating densitimeter) | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | Density at 20°C: 0.8194 g/cm³  Density at 40°C: 0.7956 g/cm³ | Dr L. Mack, 2020, Report Mo6525 (Interim report) | Acceptable |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  Analytical method MV224 | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | The storage period was of 8 weeks at 40°C.   * Active substances content:  |  |  |  | | --- | --- | --- | | Test time | (S)-Methoprene [% w/w] | Imiprothrin  [% w/w] | | Start | 0.0100 | 0.0533 | | 8 Weeks (40 °C) | 0.0100 | 0.0535 |  * Appearance:  |  |  |  |  | | --- | --- | --- | --- | | Test Time | Physical State | Color | Odor | | Start | homogenous liquid | colorless | moderate solvent | | 8 Weeks (40 °C) | homogenous liquid | colorless | moderate solvent |  * Packaging stability:  |  |  |  |  | | --- | --- | --- | --- | | Test Time | Integrity, sealing, and leakage | Internal wall, Can Dome & Base appearance | Corrosion | | Start | Test Item in sound condition, sealed and without leakages. No ballooning or change of the paneling was observed | No damage | No corrosion | | 8 Weeks (40 °C) | Test Item in sound condition, sealed and without leakages. No ballooning or change of the paneling was observed | No damage | No corrosion |  * Weight change:   The weight loss for the test items stored at 40 °C for 8 weeks was between 0.20 % and 0.46 %.   * Internal can pressure:  |  |  |  | | --- | --- | --- | | Test time | Pressure at 20 ± 1 °C (bar) | Pressure at 50 ± 1 °C (bar) | | | Start | 6.6 | 10.8 | | 8 Weeks (40 °C) | 5.7 | 9.9 |   A minor decease in the pressure of finished aerosol pack is observed.   * Discharge rate:  |  |  | | --- | --- | | Test time | Discharge rate (g/s) | | | | Start | 1.851 | | 8 Weeks (40 °C) | 1.957 |  * Residue after use (total discharge):  |  |  | | --- | --- | | Test time | Residue after use (g) | | Start | 1.23 | | 8 Weeks (40 °C) | 1.29 |   No clogging of aerosol dispenser valves was observed, at start and after 8 weeks.   * Spray pattern:  |  |  |  | | --- | --- | --- | | Test time | Spray diameter (cm) | Spray pattern | | Start | 12 | circular | | 15 (horizontal) 18 (vertical) | oval | | 8 Weeks (40°C) | 16.5 | circular | | 14 | circular |  * Particle size distribution:  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Test time | Dv (10 %) [µm] | Dv (50 %) [µm] | Dv (90 %) [µm] | % V < 50 µm | % V < 10 µm | | Start | 52 | 590 | 728 | 18.01 | 1.43 | | 8 weeks (40°C) | 27 | 563 | 723 | 21.13 | 2.33 |   The test item proved to be stable following a storage procedure at 40°C for 8 weeks in its commercial packaging. Its active substances content and physicochemical properties remained stable.  Therefore, pending the results of the ambient storage stability study, a provisional shelf-life of two years can be set for the product. | Dr L. Mack, 2020, Report Mo6525 (Interim report) | Acceptable  The product is considered stable after 8 weeks at 40°C.  Based on these results, a provisional shelf-life of two years can be granted for the product.  However, the product should not be stored above 40°C. |
| Storage stability test – **long term storage at ambient temperature** |  | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | The long term storage study is ongoing. |  | The long term storage study should be provided in post-authorisation within 1 year. |
| Storage stability test – **low temperature stability test for liquids** | Waiver | No testing is necessary as it is indicated on the product label that it should be protected from cold. | | | Acceptable  The product should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Waiver | No testing is necessary because the packing is opaque and therefore protects the product from light. The label states that the product should be protected from direct sunlight. | | | Acceptable  The product should be protected from direct sunlight. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | The results of the accelerated storage stability study show that no adverse effect occurs when the product is stored at temperatures up to 40°C.  The product is protected from humidity thanks to its impermeable packaging. | | | | Acceptable  The product should not be stored above 40°C. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Reactivity towards container material will be assessed during the long term storage at ambient temperature. | | | | The long term storage study should be provided in post-authorisation within 1 year. |
| Wettability | Waiver | Not relevant for an aerosol formulation. | | | Not relevant |
| Suspensibility, spontaneity and dispersion stability | Waiver | Not relevant for an aerosol formulation. | | | Not relevant |
| Wet sieve analysis and dry sieve test | Waiver | Not relevant for an aerosol formulation. | | | Not relevant |
| Emulsifiability, re-emulsifiability and emulsion stability | Waiver | Not relevant for an aerosol formulation. | | | Not relevant |
| Disintegration time | Waiver | Not relevant for an aerosol formulation. | | | Not relevant |
| Particle size distribution, content of dust/fines, attrition, friability | Particle size distribution, CIPAC MT 187 | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | Dv (10 %) [µm] | Dv (50 %) [µm] | Dv (90 %) [µm] | % V < 50 µm | % V < 10 µm | | Mean | 52 | 590 | 728 | 18.01 | 1.43 |   The results show that 10 % of all particles of the test item were smaller than 52 µm, 50 % were smaller than 590 µm and 90 % were smaller than 728 µm (overall mean value of three test items, 1 measurement per test item). In total 18.01 % (by volume) of the particles were smaller than 50 µm and 1.43 % (by volume) of the particles were smaller than 10 µm. | Dr L. Mack, 2020, Report Mo6525 (Interim report) | Acceptable |
| Content of dust/fines, attrition, friability | Not relevant for an aerosol formulation. | | | Not relevant |
| Persistent foaming | Waiver | Not relevant for an aerosol formulation. | | | Not relevant |
| Flowability/Pourability/Dustability | Waiver | Not relevant for an aerosol formulation. | | | Not relevant |
| Burning rate — smoke generators | Waiver | Not relevant for an aerosol formulation. | | | Not relevant |
| Burning completeness — smoke generators | Waiver | Not relevant for an aerosol formulation. | | | Not relevant |
| Composition of smoke — smoke generators | Waiver | Not relevant for an aerosol formulation. | | | Not relevant |
| Spraying pattern — aerosols | FEA 644 (Filled aerosols packs – Evaluation of aerosol spray patterns) | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | |  |  |  | | --- | --- | --- | | Test Item | Spray diameter [cm] | Spray pattern | | 1 | 12 | circular | | 2 | 15 (horizontal) 18 (vertical) | oval |   For each test item a clear transparent solution was deposited on the paper screen | Dr L. Mack, 2020, Report Mo6525 (Interim report) | Acceptable |
| Discharge rate | FEA 643: Filled aerosol packs – Measurement of discharge rate | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | 1.851 g/s | Dr L. Mack, 2020, Report Mo6525 (Interim report) | Acceptable |
| Internal can pressure | FEA 604: Filled aerosol packs – Measurement of the internal pressure | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | 6.6 bar at 20°C  10.8 bar at 50°C | Dr L. Mack, 2020, Report Mo6525 (Interim report) | Acceptable |
| Residue after use | The aerosol was weighed after total discharge (emptied mass) and again after rinsing with 2-propanol (rinsed mass). The residue is defined as the difference between the emptied and the rinsed masses. | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | The mean residue in the aerosol can after total discharge was 1.23 g | Dr L. Mack, 2020, Report Mo6525 (Interim report) | Acceptable |
| Clogging | Manual on development and use of FAO and WHO specifications for pesticides: Chapter 8.11.4.5: Clogging of aerosol dispenser valves | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | No clogging of aerosol dispenser valves was observed after total discharge of the test item | Dr L. Mack, 2020, Report Mo6525 (Interim report) | Acceptable |
| Physical compatibility | Waiver | Not relevant because the product is not intended to be used in combination with any other product. | | | Not relevant |
| Chemical compatibility | Not relevant |
| Degree of dissolution and dilution stability | Waiver | Not relevant for an aerosol formulation. | | | Not relevant |
| Surface tension | EU method A.5 (ring method) | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | 23.4 mN/m at 25°C | Dr L. Mack, 2020, Report Mo6525 (Interim report) | Acceptable |
| Viscosity | OECD test guideline 114 (rotational viscometer) | KAPO CHOC Puces et larves, batch No 19282 (0.05 % (w/w) Imiprothrin, 0.01 % (w/w) (S)-Methoprene) | Dynamic viscosity:  < 1 mPa.s at 20°C (at 20s-1, 40s-1, 60s-1, 80s-1 and 100s-1)  < 1 mPa.s at 40°C (at 20s-1, 40s-1, 60s-1, 80s-1 and 100s-1)  All values were < 1 mPa.s, thus below the lower measuring limit of the measuring system used. | Dr L. Mack, 2020, Report Mo6525 (Interim report) | Acceptable |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| All the relevant parameters for an aerosol formulation have been determined on the KAPO CHOC Puces et larves and were shown to be compliant with the intended uses of the product.  An accelerated storage study (8 weeks at 40°C) has been performed and allows to show that the product is stable after 8 weeks at 40°C. Therefore, a shelf-life (extrapolated) of two years at ambient temperature can be granted since no significant variation in the phys-chem parameters and active substances contents was observed.  An ambient storage study is ongoing and should be provided in post-authorisation within 1 year.  No cold storage study has been provided by the applicant.  Labelling implications:   * Protect from frost. * Do not store above 40°C. * Protect from direct sunlight. * Shelf-life: 2 years |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCA assessment** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Waiver | At the view of the product composition, it is not expected for it to possess explosive properties. Indeed, none of the ingredients contained in the product is classified as explosive. Observation of their structural formulas indicates that some constituents possess chemical functions potentially associated with explosive properties, but all of their oxygen balances are below -200.  Therefore, the screening criteria for the product to possess explosive properties are not met, and the classification procedure can be waived without further testing. | | | Acceptable  The product is not explosive. |
| Flammable gases | Waiver | The study does not need to be conducted because the product is an aerosol. | | | Not relevant |
| Flammable aerosols | Waiver | The product contains over 85% of flammable components. It is therefore considered that the classification criteria as Aerosol, category 1 are met. The product is thus classified as such without further testing. | | | Acceptable  The product is classified H222: Extremely  Flammable aerosol. |
| Oxidising gases | Waiver | The only gas present in the formulation is the propellant gas, which is known to be inert from an oxidising properties point of view. Therefore, the classification of the product as oxidising gas can be waived without further testing. | | | Acceptable  The product does not possess oxidizing properties. |
| Gases under pressure | Waiver | The product is classified as Aerosol, category 1. Therefore, the hazard statement *H229: Pressurised container: May burst if heated* applies*.* | | | Acceptable  The product is classified H229: Pressurised container: May burst if heated. |
| Flammable liquids | Waiver | The study does not need to be conducted because the product is an aerosol. | | | Not relevant |
| Flammable solids | Waiver | The study does not need to be conducted because the product is an aerosol. | | | Not relevant |
| Self-reactive substances and mixtures | Waiver | According to the Guidance on the application of the CLP criteria, “substances and mixtures must be considered for classification in hazard class self-reactive property unless there are no chemical groups present in the molecule associated with explosive or self-reactive properties. Examples of such groups are given in Tables A6.1 and A6.2 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria”. Based on the composition, we can expect that the product does not have self-reactive properties. However, this need to be confirmed.  Therefore, a DSC test of the product should be provided to confirm the non-classification in this hazard class. Moreover, if its heat of decomposition is higher than 300 J/g, the self-accelerating decomposition temperature (SADT) of the product should also be determined. | | | A DSC test of the product should be provided in post authorization to confirm the non-classification in this hazard class. |
| Pyrophoric liquids | Waiver | The study does not need to be conducted because the product is known to be stable in contact with air at room temperature for prolonged periods of time (days). | | | Acceptable |
| Pyrophoric solids | Waiver | The study does not need to be conducted because the product is an aerosol. | | | Not relevant |
| Self-heating substances and mixtures | Waiver | The study does not need to be conducted because the product is liquid at ambient temperature. | | | Not relevant |
| Substances and mixtures which in contact with water emit flammable gases | Waiver | The study does not need to be conducted because:   * The chemical structures of the components of the mixture do not contain metals or metalloids. * Experience in handling and use shows that the mixture does not react with water. | | | Acceptable |
| Oxidising liquids | Waiver | The study does not need to be conducted because the product does not contain oxygen or halogen atoms bound to other elements than carbon or hydrogen. | | | Acceptable |
| Oxidising solids | Waiver | The study does not need to be conducted because the product is an aerosol. | | | Not relevant |
| Organic peroxides | Waiver | According to its MSDS, one solvent in the composition of the product is considered to potentially react with air to form peroxides.  A clarification has been required from the applicant and has been reported in the confidential annex as the exact name of the co-formulant is cited.  It has been demonstrated that the formation of peroxide is not possible after the product has been packaged in the aerosol container as no oxygen is present in the aerosol.  Therefore, this is considered acceptable by eCA, no more data is required. | | | Acceptable |
| Corrosive to metals | Waiver | The product is solvent-based and contains no acidic or basic functional group. None of its constituents is able to form complexes with metals. Moreover, no component in the mixture contains halogen and experience in manufacture and use has shown no evidence of the product being corrosive to metals. Therefore, it is concluded that the product is not corrosive to metals and that this classification can be waived without further testing. | | | Acceptable  The product is not considered corrosive to metals |
| Auto-ignition temperatures of products (liquids and gases) | Waiver | The product is classified as Aerosol, category 1. Therefore, precautions measures are already advised to prevent the exposition of the product to heat sources. The determination of the auto-ignition temperature is thus considered irrelevant. | | | Acceptable |
| Relative self-ignition temperature for solids | Waiver | The study does not need to be conducted because the product is an aerosol. | | | Not relevant |
| Dust explosion hazard | Waiver | The study does not need to be conducted because the product is an aerosol. | | | Not relevant |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The biocidal product falls under the criteria of the classification as Aerosol, category 1. The product is classified H222: Extremely flammable aerosol and H229: Pressurised container: May burst if heated. The product is not explosive and does not possess oxidizing properties.  For self-reactive properties, a DSC test of the product should be provided in post authorization to confirm the non-classification in this hazard class. |

### Methods for detection and identification

**Analytical method for the determination of the active substances in the product**

The analytical method and its validation according to the criteria laid out in SANCO/3030/99 rev.5 from 22/03/2019 are described in the study report “Validation of Method MV224: BRU: GC-Determination of Methoprene and Imiprothrin in Aerosols”, Mack L., 2019, BioGenius report No. Mo6620.

Imiprothrin and (S)-methoprene are analysed by gas chromatography with flame ionisation detection (GC-FID). Imiprothrin is used in the product as a mixture of isomers. The total content of imiprothrin and the contents of the individual isomers (cis- and trans-imiprothrin) are determined.

Sample preparation

The aerosol cans were weighed, degassed and opened. The remaining liquid solution was transferred into a beaker. The can was subsequently rinsed several times with acetone and the resulting solutions were collected in the beaker. The beaker’s content was transferred into a 500 mL volumetric flask. The beaker was subsequently rinsed several times and the resulting solutions were collected in the volumetric flask. Subsequently 5.0 mL of the internal standard solution (10 g/L dibutyl phthalate) were added. The remaining gases were removed by the placing the volumetric flask into an ultrasonic bath for 15 min. After acclimatization the volumetric flask was filled up to the calibration mark with acetone and mixed well. All parts of the empty and dried aerosol can were weighed. The test solutions are filtered through a syringe filter prior to injection.

Chromatographic conditions

|  |  |
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| Instrument | Hewlett Packard HP6890 Gas chromatograph with autosampler, FID and chromatography software Agilent GC ChemStation Rev. A.10.02 [1757] |
| Detector | Flame Ionisation Detector |
| Insert liner | CarboFrit Inlet Liner (Restek Corp., cat. No. 20772-209.1) |
| Column | RTX-1 (100 %) Dimethylpolysiloxane  SN: 695730; (Restek Corp., cat. No. 10124)  Length 30 m  Internal diameter 0.32 mm  Film thickness 0.25 µm |
| Temperatures | Injector 200°C  Detector 300°C |
| Oven | Initial temp. 175°C  Initial time 0 min   |  |  |  |  | | --- | --- | --- | --- | | Ramp | Rate [°C/min] | Final temp. [°C] | Final time [min] | | 1 | 5 | 245 | 5 | | 2 | 10 | 300 | 0 | |
| Column pressure | Constant. 12 psi |
| Carrier gas | Helium, approx. 1.5 mL/min |
| Split ratio | 10:1 |
| Hydrogen | ca 40 mL/min |
| Synth. air | ca 400 mL/min |
| Make-up gas (Helium) | ca 45mL/min |
| Injection volume | 1 µL |
| Retention time of internal standard | 4.7 min |
| Retention time of (S)-Methoprene | 6.1 min |
| Retention time of Imiprothrin | 8.2 min (cis-imiprothrin)  8.4 min (trans-imiprothrin) |
| Run time | 24.5 min |

Method validation

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Imiprothrin (active substance)* | GC-FID (see above) | Level 1 (70%): 0.0389% w/w  Level 2 (100%): 0.0556% w/w  Level 3 (130%): 0.0723% w/w  3 solutions prepared at each level. | 6 solutions prepared between 0.1092 and 0.2912 mg/mL (60% to 160%)  y = 0.83988524\*x + 0.00601521  r=0.9999 | Examination of the placebo chromatogram demonstrates that no interferences occurred at the retention times of the active substances or the internal standard.  Chromatograms of the standard solution with imiprothrin, of the placebo sample and of the test item have been provided. | Level 1: 94.6 – 98.4  Level 2: 97.4 - 98.6  Level 3: 97.4 – 98.9 | 96.8  98.1  97.9 | 2  0.7  0.8 | Not relevant  Precision at 0.0518% (n=6), sum of isomers  RSD= 1.15%  Horrat value =0.27 | L. Mack, 2019 report no. Mo6620 |
| *S-Methoprene (active substance)* | Level 1 (70%): 0.00779% w/w  Level 2 (100%): 0.0111% w/w  Level 3 (130%): 0.0145% w/w  3 solutions prepared at each level. Duplicate injection of all solutions. | 6 solutions prepared between 0.02185 and 0.05826 mg/mL (60% to 160%)  y = 1.16786064\*x + 0.00128249  r = 0.9998. | Examination of the placebo chromatogram demonstrates that no interferences occurred at the retention times of the active substances or the internal standard.  Chromatograms of the standard solution with S-methoprene, of the placebo sample and of the test item have been provided. | Level 1: 94.5 – 97.6  Level 2: 97.0 – 97.8  Level 3: 97.6 – 97.8 | 96.5  97.3  97.7 | 1.8  0.4  0.1 | Not relevant  Precision at 0.0096% (n=6)  RSD= 0.51%  Horrat value =0.09 |

**Analytical methods for monitoring of residues on treated surfaces**

Validation of the method AQ115 used in the BioGenius, L. Mack, BRU: GC-MS-Determination of Residues of Methoprene and Imiprothrin on Surfaces” report no: BioG Q115-02E and 2 documents “Table of Results”, reports no: CoA – AQ144-19 – Mo6526 – method validation residue (3 surfaces) and CoA – AQ149-19 – Mo6526 – RT – method validation residue (glazed tile)

Report: Mack L. 2019, BRU: GC-MS-Determination of Residues of Methoprene and Imiprothrin on Surfces

Report no BioG Q115-02E

Test facilities: BioGenius

TechnologiePark, Campus 1

Friedrich-Ebert-Straße 75

51429 Bergisch Gladbach,

Germany

Principle of the method:

The active substance content is determined by gas chromatography (GC) according to the internal standard method with mass spectrometric detection (MS).

The surfaces are sprayed in a fume hood in which the air extractor can be regulated so that the sprayed jet is unaffected.

Kapo Choc intermediate liquid is sprayed with a pump spray flask onto the surfaces (porous unglazed tile, carpet, vinyl linoleum and glazed tile)

Prior to use the discharge rate of the pump spray flask is determined with one test sample ccording to SOP-PR-008, section 4.4.1 for pump sprays (analogous to the method FE 643).

The applied quantity onto surfaces is 0.2 ml/surface that is equivalent to 9.1 ml/m².

The treated surfaces are transferred to the test room and subjected to post-treatments. The surfaces are wiped off with acetone soaked cellulose towels, which are extracted in acetone and the content of active substances is dertermined by gas chromatography with mass spectrometric detection.

For method validation, specificity samples were prepared in the same way without spraying test item onto the surfaces.

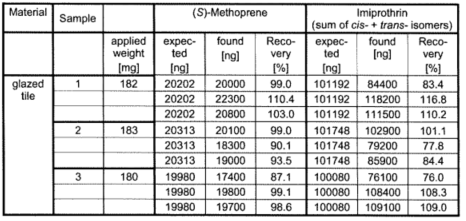
Validation data:

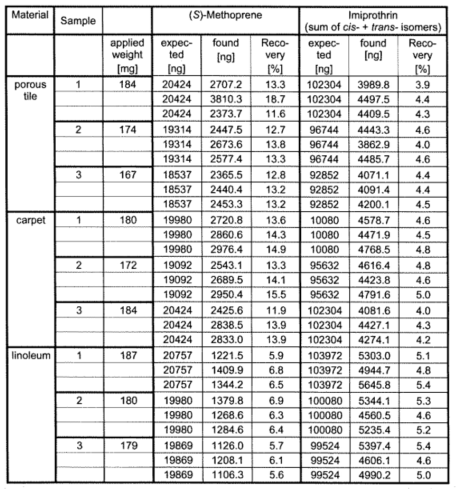
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| Test item weight applied | Porous unglazed tile: 175 mg | |
| Carpet: 179 mg | |
| Vinyl linoleum: 182 mg | |
| Glazed tile: 185 mg | |
| Test item volume applied | Porous unglazed tile: 0.213 mL | |
| Carpet: 0.218 mL | |
| Vinyl linoleum: 0.222 mL | |
| Glazed tile: 0.225 mL | |
| Residue concentration [%] | **(S)-Methoprene** | **Imiprothrin** |
| Porous unglazed tile:  13.6 | Porous unglazed tile:  4.3 |
| Carpet:  13.9 | Carpet:  4.5 |
| Vinyl linoleum:  6.2 | Vinyl linoleum:  5.1 |
| Glazed tile:  97.7 | Glazed tile:  96.4 |
| RSD [%] | **(S)-Methoprene** | **Imiprothrin** |
| Porous unglazed tile:  5.7 | Porous unglazed tile:  3.0 |
| Carpet:  4.4 | Carpet:  7.4 |
| Vinyl linoleum:  6.6 | Vinyl linoleum:  0.8 |
| Glazed tile:  5.7 | Glazed tile:  8.2 |
| Recovery [%] | **(S)-Methoprene** | **Imiprothrin** |
| Porous unglazed tile:  Mean: 13.62 | Porous unglazed tile:  Mean: 4.34 |
| Carpet:  Mean: 4.53 | Carpet:  Mean: 13.93 |
| Vinyl linoleum:  Mean: 5.04 | Vinyl linoleum:  Mean: 6.24 |
| Glazed tile:  Mean: 97.76 | Glazed tile:  Mean:96.33 |

The analytical method is validated for the determination of the active substances S-methoprene and Imiprothrin thanks to the recovery rate found on the glazed tile which is the only non-permeable surface. Indeed, the other porous surfaces absorbed the active substances which are not available anymore.

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Imiprothrin (active substance)* | GC-MS-Determination of Residues of Methoprene and Imiprothrin on Surfaces | 3 per surface type | N.a. | Fulfilled. No interference from other substances i.e. no peak area detected at the retention times of the active substances.  Chromatograms of the standard solution, of the test solution for residual analysis on all surfaces and of a test solution from product intermediate liquid have been provided. | see tables below | Porous tile: 4.34%  Carpet: 13.93%  Linoleum: 6.24%  Glazed tile: 96.33% | Porous tile: 3.0%  Carpet: 7.4%  Linoleum: 0.8%  Glazed tile: 8.2% |  | * BioG Q115-02E (2019) * AQ144-19 – Mo6526 – method validation residue (3 surfaces) and CoA (2019) * AQ149-19 – Mo6526 – RT – method validation residue (glazed tile) |
| *S-Methoprene (active substance)* | see tables below | Porous tile: 13.62%  Carpet: 4.53%  Linoleum: 5.04%  Glazed tile: 97.76% | Porous tile: 5.7%  Carpet: 4.4%  Linoleum: 6.6%  Glazed tile: 5.7% |  |

Calculation of active substances recoveries at method validation





Considering the recovery rate of the non-permeable surface, the method is considered fir for purpose. However, the linearity and the repeatability of the method are missing.

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| **Analytical methods for soil** | | | | | | | | | |
| **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 |
| *Imiprothrin (active substance)* | Not required, as described in the CAR. | | | | | | | | |
| *S-Methoprene (active substance)* | Not relevant because s-methoprene degrades rapidly in the soil. | | | | | | | | |

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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 |
| *Imiprothrin (active substance)* | Covered by the letter of access to the active substance dossier. | | | | | | | | |
| *S-Methoprene (active substance)* | Not required, because S-methoprene has a low vapour pressure and is therefore not expected to be significantly present in air after product application. Also, s-methoprene undergoes rapid photodegradation in air. Therefore, it is not foreseen for s-methoprene to be able to travel long distances, or to accumulate, in air. | | | | | | | | |

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| **Analytical methods for water** | | | | | | | | | |
| **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 |
| *Imiprothrin (active substance)* | Covered by the letter of access to the active substance dossier. | | | | | | | | |
| *S-Methoprene (active substance)* | Covered by the letter of access to the active substance dossier. | | | | | | | | |

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| **Analytical methods for animal and human body fluids and tisues** | | | | | | | | | |
| **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 |
| *Imiprothrin (active substance)* | Not required because imiprothrin is not classified as toxic or very toxic. | | | | | | | | |
| *S-Methoprene (active substance)* | Not required because s-methoprene is not classified as toxic or very toxic. | | | | | | | | |

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| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** | | | | | | | | | |
| **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 |
| *Imiprothrin (active substance)* | Not required because no contact with food producing animals, food of plant or animal origin or feeding stuffs is foreseen following the intended uses of the product. | | | | | | | | |
| *S-Methoprene (active substance)* | Not required because no contact with food producing animals, food of plant or animal origin or feeding stuffs is foreseen following the intended uses of the product. | | | | | | | | |

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| **Conclusion on the methods for detection and identification of the product** |
| The analytical method for the determination of both active substances (Imiprothrin and S-Methoprene) has been provided and is considered validated, according to SANCO/3030/99 rev.5.  The method AQ115 is considered fit for purpose. However, linearity and repeatability have not been assessed.  Analytical methods for monitoring in soil, air, water, body fluids/tissues and food/feed of plant/animal origin are active substance data. The applicant has letters of access to the active substance dossiers. |

### 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

The product KAPO CHOC PUCES ET LARVES is a ready-to-use one-shot insecticide and acaricide aerosol against flying insects (including gnats) and crawling insects (adults), mites (eggs, larvae, adults), bedbugs (eggs, larvae, adults) and fleas (eggs, larvae, adults).

The product is used indoor by non-professional users.

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

According to the uses claimed by the applicant, the product KAPO CHOC PUCES ET LARVES is a ready-to-use aerosol

The specifics target organisms to be controlled are:

* flying insects: flies (*Musca domestica*), mosquitoes (*Culex sp* and *Aedes sp*) and wasps (*Vespula germanica*) – adult stage
* fruit flies (*Drosophila melanogaster*) – adult stage
* crawling insects: cockroaches (*Blattella germanica* and *Blatta orientalis*), ants (*Lasius niger*) – adult stage
* house dust mites (*Dermatophagoides pteronyssinus*) - eggs, larvae and adult stage
* bedbugs (*Cimex lectularius*) - eggs, larvae and adult stage
* fleas (*Ctenocephalides felis*) - eggs, larvae and adult stage

No residual efficacy is claimed and vacuum cleaning is recommended at least 4 hours after application, to remove dead insects and residual product.

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

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

According to the Assessment Report of s-methoprene, it displays no immediate killing effect on the target organisms but inhibits the egg-laying capacity. S-methoprene acts as a juvenile hormone.

According to the Assessment Report of imiprothrin, target insects are knocked down and killed upon contact with the pyrethroid active substance.

#### Mode of action, including time delay

According to the Assessment Reports of the actives substances:

1. **(S)-methoprene** is an insect growth regulator (IGR) from the class of juvenile hormone analogues; it inhibits the development of the immature stages of insects. Mimicking the action of juvenile hormone, the compound causes impaired development and death of immature stages. Moreover, (S)-methoprene can include ovicidal activity, due to either its direct penetration into the shell flea eggs which have been laid or its absorption through the cuticle of the adult fleas. This one is not claimed in this dossier.
2. **Imiprothrin** is a synthetic pyrethroid insecticide. Pyrethroid insecticides act on the sodium channel in the nerve membranes of the invertebrate nervous system and are termed sodium channel modulators. They cause pronounced repetitive activity and a prolongation of the transient increase in sodium permeability of the nerve membranes. This results in continual nerve impulse transmission leading to tremors and death. This action is demonstrated by the rapid knockdown action caused by pyrethroid compounds, such as imiprothrin, against target insects.

#### Efficacy data

#### The applicant submitted following studies:

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| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| PT18 | **Insecticide One-shot,**  **Spraying treatment**  **Indoor application** | KAPO CHOC VOLANTS & RAMPANTS (0.05% w/w imiprothrin and 0.01% w/w S-methoprene) | **Flying insects:**  *Mandatory orgainisms:*  Flies (100±5 adults per replicate):  *Musca domestica –* adults  Mosquitoes (80 ±2 adults per replicate):  *Culex pipiens –* adults  Wasps (20 adults per replicate):  *Vespula germanica –* adults  ***Additional organisms***  Fruit flies (100±5 adults per replicate):  *Drosophila melanogaster –* adults  Mosquitoes (80 ±2 adults per replicate):  *Aedes aegypti –* adults | Simulated-use test - Method C.E.B. 135bis  A biological preliminary test was done 2 days before the trial to check there was no pollution inside that can kill the insects. Between each replicate, the chamber was open, vigorously ventilated (1200 m3/h) during 24 hours. | The one-shot aerosol is set at a 40 cm height in the centre of the test chamber.  5 replicates of treatment are conducted (x 4 replicates of batches of target organisms exposed in each replicate).  For each replicate, 4 batches are exposed in the test chamber, 2 at 1.80 m height and 2 on the floor, on the test chamber's diagonal but not closer than 50 cm from the walls.  Temperature: 22°C ± 1 °C  Relative humidity: 65% ± 5%  Application rate: 200 ml in 100 m³  Volume: 102 m³  Contact time: 4 hours | On all the treated spaces, all flying insects were killed after 24 hours exposure, with a knockdown time (KT100) of 4 hours.  Mortality in untreated controls (after 24 hours):   * 0% for flies, gnats and wasps and mosquitoes (*Aedes*) * 1% for mosquitoes (*Culex*) | Report n° 2483/0719  R.I: 1 |
| PT18 | **Insecticide One-shot,**  **Spraying treatment**  **Indoor application** | KAPO CHOC VOLANTS & RAMPANTS (0.05% w/w imiprothrin and 0.01% w/w S-methoprene) | **CRAWLING INSECTS:**  *Mandatory organisms:*  Cockroaches (100 ± 5 adults per replicate):  *Blattella germanica –* adults  *Blatta orientalis –* adults  *Additional organisms:*  Ants (100±5 adults per replicate):  *Lasius niger–* adults  Fleas (100±5 adults, 100±5 nymphs, 80±5 eggs per replicate):  *Ctenocephalides felis -* adults+ larvae + eggs  Bedbugs (100±5 adults, 100±5 nymphs, 80±5 eggs per replicate):  *Cimex lectularius -* adults + larvae + eggs | Simulated-use test - Method C.E.B. 135bis  A biological preliminary test was done 2 days before the trial to check there was no pollution inside that can kill the insects. Between each replicate, the chamber was open, vigorously ventilated (1200 m3/h) during 24 hours. | The one-shot aerosol is set at a 40 cm height in the centre of the test chamber.  5 replicates of treatment are conducted (x 4 replicates of batches of target organisms exposed in each replicate).  For each replicate, 4 batches are exposed in the test chamber of dimensions: 6.60 m long x 5.50 m wide x 2.8 m high  Temperature: 22°C ± 1 °C  Relative humidity: 65% ± 5%  Application rate: 200 ml in 100 m³  Volume: 102 m³ (36.3 m2)  Contact time: 4 hours | On all the treated spaces, all crawling insects were killed after 24 hours exposure, with a knockdown time (KT100) of 4 hours.  Mortality in untreated controls (after 24 hours):   * O% for cockroaches, ants, fleas and bedbugs (adults and larvae) * 1% for bedbugs (eggs) | Report n° 2483/0719  R.I: 1 |
| PT18 | ***Insecticide One-shot,***  ***Spraying treatment***  ***Indoor application*** | KAPO CHOC VOLANTS & RAMPANTS (0.05% w/w imiprothrin and 0.01% w/w S-methoprene) | **MITES (100±5 adults, 100±5 nymphs, 80±5 eggs per replicate):**  *Dermatophagoides pteronyssinus -* mixed populations ofadults + larvae + eggs | Simulated-use test - Method C.E.B. 135bis  A biological preliminary test was done 2 days before the trial to check there was no pollution inside that can kill the insects. Between each replicate, the chamber was open, vigorously ventilated (1200 m3/h) during 24 hours. | The one-shot aerosol is set at a 40 cm height in the centre of the test chamber.  5 replicates of treatment are conducted (x 4 replicates of batches of target organisms exposed in each replicate).  For each replicate, 4 batches are exposed in the test chamber of dimensions: 6.60 m long x 5.50 m wide x 2.8 m high  Temperature: 22°C ± 1 °C  Relative humidity: 65% ± 5%  Application rate: 200 ml in 100 m³  Volume: 102 m³ (36.3 m2)  Contact time: 4 hours | On all the treated spaces, all mites insects were killed after 24 hours exposure, with a knockdown time (KT100) of 4 hours.  Mortality in untreated controls (after 24 hours): between 0 and 1%. | Report n° 2483/0719  R.I: 1 |

The tests have been performed with the product KAPO CHOC VOLANTS & RAMPANTS (0.05% w/w imiprothrin and 0.01% w/w S-methoprene) which corresponds to the product KAPO CHOC PUCES ET LARVES of the authorisation.

Regarding the claimed uses, submitted efficacy data are compliant with the requirements of the ECHA guidance parts B+C and the results of these tests are respecting the requirements and criteria of the ECHA guidance parts B+C.

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the product KAPO CHOC PUCES ET LARVES according to the uses (exposure time: 4 hours) and the application rate claimed:

* Regarding the efficacy claims against flying insects and crawling insects (adult stage) – **use #1**:
* The product is efficient at the application rate of 200 ml product /100 m3 with a KT 100 of 4 hours and a mortality of 100 % 24 hours after the treatment in simulated use tests.
* Regarding the efficacy claims against bedbugs (*Cimex lectularius*, eggs larvae and adults) – **use #2**:
* The product is efficient at the application rate of 200 ml product /100 m3 with a KT 100 of 4 hours and a mortality of 100 % 24 hours after the treatment in simulated use tests.
* Regarding the efficacy claims against fleas (*Ctenocephalides felis*, eggs larvae and adults) – **use #3**:
* The product is efficient at the application rate of 200 ml product /100 m3 with a KT 100 of 4 hours and a mortality of 100 % 24 hours after the treatment in simulated use tests.
* Regarding the efficacy claims against flies (*Musca domestica*) and fruit flies (*Drosophila melanogaster*, adults) – **use #4**:
* The product is efficient at the application rate of 200 ml product /100 m3 with a KT 100 of 4 hours and a mortality of 100 % 24 hours after the treatment in simulated use tests.
* Regarding the efficacy claims against house dust mites (*Dermatophagoides pteronyssinus*, eggs larvae and adults) – **use #5**:
* The product is efficient at the application rate of 200 ml product /100 m3 with a KT 100 of 4 hours and a mortality of 100 % 24 hours after the treatment in simulated use tests.

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| **Conclusion on the efficacy of the product** |
| French competent authorities consider that the elements submitted in the dossier demonstrated the efficacy of the product KAPO CHOC PUCES ET LARVES at the application rate of 200 ml product / 17.5 to 100 m3 with an exposure time of 4 hours against:   * flying insects and crawling insects (adults – use#1), – * bedbugs (*Cimex lectularius*, eggs, larvae and adults – use #2), * fleas (*Ctenocephalides felis*, eggs, larvae and adults – use #3), * flies and fruit flies (*Musca domestica* and *Drosophila melanogaster*, adults – use #4) * house dust mites (*Dermatophagoides pteronyssinus*, eggs, larvae and adults – use #5). |

#### Occurrence of resistance and resistance management

Imiprothrin:

Imiprothrin belongs to the group of pyrethroids. These substances act as sodium channel modulators, causing hyperexcitation and, in some cases, nerve block. Some records of resistance in target organisms were documented in the recent scientific literature (2010-2020) against imiprothrin:

1. the study of Rahayu *et al.* (2016)[[2]](#footnote-3) showed that the use of insecticides containing imiprothrin (amongst other substances as cypermethrin, permethrin and esbiothrin) can lead to a resistance level varying from low to very high in cockroach *Blattella germanica* populations;
2. another publication studying the mosquitoes *Aedes aegypti* suggested that pyrethroids-containing aerosolized products can be an additional selection source for pyrthroid resistance in this species (Gray *et al*., 2018)[[3]](#footnote-4).

S-methoprene:

S-methoprene acts as a juvenile hormone analogue, disrupting and preventing metamorphosis when applied in the pre-metamorphic instar.

Some records of resistance have been documented for years under the Resistant Pest Management Arthropod Database (IRAC) for the active substance methoprene (mixture ratio 1:1 S-methoprene, R-methoprene): on mosquito *Aedes aegypti[[4]](#footnote-5)* and *Culex pipiens[[5]](#footnote-6)*, on fruit fly[[6]](#footnote-7) (*Drosophila melanogaster)* and on house fly[[7]](#footnote-8) (*Musca domestica).*

We consider that even if the product is intended to be used by non-professional users and is a one shot treatment, the occurrence of resistance cannot be excluded.

Therefore to ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented:

* In the case of reduced efficacy or suspected development of resistance, the use of the product has to be discontinued. The user is advised to contact a professional pest control operator.
* Implement a monitoring of scientific literature related to the resistance of the claimed target organisms to the active substances S-methoprene and Imiprothrin and provide an assessment of this monitoring at the renewal of the authorisation.
* The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

#### Known limitations

None.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product KAPO CHOC PUCES ET LARVES has shown a sufficient efficacy at the application rate of 200 ml product /100 m3 with an exposure time of 4 hours against:

* flying insects and crawling insects (adults – use#1),
* bedbugs (*Cimex lectularius*, eggs, larvae and adults – use #2), agaisnt fleas (*Ctenocephalides felis*, eggs, larvae and adults – use #3),
* flies (*Musca domestica*)and fruit flies (*Drosophila melanogaster*, adults – use #4)
* house dust mites (*Dermatophagoides pteronyssinus*, eggs, larvae and adults – use #5).

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

Not relevant

### Risk assessment for human health

#### Assessment of effects on Human Health

No toxicological studies have been submitted for the product KAPO CHOC PUCES ET LARVES. The classification of the product has been set according to the calculation rules laid down in the CLP regulation 1272/2008/EC.

According to the CLP regulation, “an aerosol form of a mixture shall be classified in the same hazard category as the non-aerosolised form of the mixture”. Therefore, the classification of the product has been made following the product’s composition without propellant and with the content of the other co-formulants recalculated accordingly.

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not corrosive to skin |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification is required |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Causes eye irritation |
| Justification for the value/conclusion | The concentration of one of the co-formulant is above the threshold value of 10% for classification as Category 2 Eye Irritant. |
| Classification of the product according to CLP | The product KAPO CHO PUCES ET LARVES is classified as Eye Irrit. 2; H319, according to the CLP criteria. |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | Not irritating for the respiratory tract. |
| Justification for the conclusion | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification is required. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising to skin |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitising for the respiratory tract |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not acutely toxic via oral route |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not acutely toxic via inhalation route. |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not acutely toxic via dermal route. |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Information on dermal absorption***

|  |  |  |
| --- | --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | | |
| Substance | Imithroprin | S-methoprene |
| Value(s) | 70% | 35% |
| Justification for the selected value(s) | Default dermal absorption value for ready-to-use formulation, based on the EFSA guidance on dermal absorption (2017) | According to the EFSA Guidance on dermal absorption (2017), “in exceptional cases, if oral absorption is less than 70% for organic solvent-based or other formulations or less than 50% for water-based/dispersed or solid formulations, this can be used as a surrogate dermal absorption value for (in-use) dilutions”.  In the CAR of S-methoprene (2016), the oral absorption value of 35% has been derived from a toxicokinetics study where [14C]-S-Methoprene was administered to different groups of rats, including a bile duct cannulated group. The concentration of S-methoprene administrated in the study is equal to 25 mg/kg, which is below the concentration of 0.0117% w/w of S-methoprene, equivalent to 117 mg/kg, in the product KAPO CHOC PUCES ET LARVES. As that the lowest dose is considered the worst-case for the determination of absorption values, the ADME study can be used for the establishment of dermal absorption of the biocidal product.  Also, in this study, the active substance was contained in sunflower seed oil, which is a vehicle facilitating the oral absorption. Therefore an extrapolation on the organic solvent-based product KAPO CHOC PUCES ET LARVES is considered acceptable.  Considering this, the oral absorption value of 35% derived for the active substance can be used as a dermal absorption value. |

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

According to the definition of Substance of Concern (SoC) laid down in the *Guidance on the BPR for Human Health Assessment & Evaluation, volume III Part B+C (2017)*, the product KAPO CHOC PUCES ET LARVES contains one SoC.

Indeed, acetone is considered a SoC, as it is present in the product in sufficient concentration to trigger the classification as Eye Irritant Cat. 2 (H319) and STOT SE 3 (H336) by itself. Taking into account this classification of the product, a Band A is assigned to the substance, leading to the application of P-statements normally associated with the concerned H-statements.

Acetone is also a substance for which a Community and international workplace exposure limits is associated, but since the product is only used by non-professional users, acetone is not considered as SoC regarding this criteria and no risk assessment is needed.

Please refer to the Confidential Annex for further information.

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

Not relevant

***Other***

Not relevant

#### Exposure assessment and Risk characterisation

The biocidal product KAPO CHOC PUCES ET LARVES is a PT 18 product “Insecticides, acaricides and products to control other arthropods”.

The product is a RTU insecticide used by non-professionals against different targets: flying and crawling insects, bedbugs, fleas, flies and mites.

As it is to be used only in case of infestation, the product is only applied once a year (twice in case of re-emergence of adult fleas) by one-shot spraying application of the whole packaging content (200ml) in a room until 100 m3.

After the activation of the valve of the aerosol, the user leaves the room and kept it closed during 4 hours. After this delay, the user can enter the room and open the windows in order to ventilate the room for another 4 hours.

Secondary exposure to Imiprothrin and S-methoprene could happen when the user re-enters the room to ventilate and accidently be in contact with wet treated surface. It could also arise from the infant crawling into the room after the ventilation time and the general public sleeping into the bed present in the room during the treatment.

In order to determine the smallest treatable surface area, a residue study[[8]](#footnote-9) submitted by the applicant is used in Tier 2, in which residue quantities of Imiprothrin and S-methoprene were quantified on different types of surfaces after the application of the product, followed by different post-application treatments. In Treatment A (Tier 2A), the residue quantities of the active substances are measured directly after the product application and in Treatment B (Tier 2B), the residues are quantified in the conditions claimed by the applicant, meaning after a contact time of 4h, then 4h of natural ventilation (open window).

In this study, the highest recoveries for Imiprothrin and S-methoprene (respectively 76.2% and 82.6% in treatment A and 36.5% and 59.5% in treatment B, normalized at 47.5% and 72%, see Confidential Annex) are quantified on glazed tile, therefore the results on this type of surface are taking into account as a worst-case. It allows us to determine that the surface area minimum to be treated is 11 m² (or 27.5 m3) and 7 m² (or 17.5m3), depending on the post-application parameters (treatment A or B).

The product contains two active substances: Imiprothrin present at 0.0638% w/w and S-methoprene present at 0.0117% w/w.

According to the Assessment Report of Imiprothrin and S-methoprene (respectively UK, 2017, and Ireland, 2016), these two active substances are characterised by systemic effects observed in toxicity studies. Consequently, a quantitative risk assessment for systemic effects is performed for the biocidal product for dermal, inhalation and oral routes.

An AEC for inhalation was also derived for the active substance Imiprothrin. Therefore, a quantitative risk assessment for local effects is provided.

A combined risk assessment is also provided for Imiprothrin and S-methoprene contained in the product.

As the product is classified as Eye irritant Cat 2 (H319), a qualitative assessment for local effects is also performed.

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

| **Summary table: relevant paths of human exposure** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | **Secondary (indirect) exposure** | | |
| **Professional use** | **Non-professional use** | **Professional use** | **Non-professional bystanders/ General public** | **Via food** |
| Inhalation | n.a. | Yes | n.a. | Yes |  |
| Dermal | n.a. | No | n.a. | Yes |  |
| Oral | n.a. | No | n.a. | Yes | Yes |

***List of scenarios***

| **Summary table: scenarios** | | |
| --- | --- | --- |
| **Scenario** | **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| **Primary exposure** | | |
| [Scenario 1] | Air space application | Non-professional |
| **Secondary exposure – Exposure of the general public** | | |
| [Scenario 2] | Inhalation of volatilised residues after application | General public |
| [Scenario 3] | Contact with wet treated surface | General public |
| [Scenario 4] | Infant crawling on treated surface and hand-to-mouth transfer | General public |
| [Scenario 5] | Contact with dry product while sleeping in bed | General public |

Reference values of Imiprothrin to be used in Risk Characterisation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Reference** | **Study** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | Rabbit developmental study | 100 | n.a. | 0.3 mg/kg bw/day |
| AELmedium-term | 90-day dog study | 100 | n.a. | 0.1 mg/kg bw/day |
| AELlong-term | 90-day and 1-year dog study | 100 | n.a. | 0.1 mg/kg bw/day |
| AEC inhalation short-term | 28-day rat study | 25 | n.a. | 0.9 mg/m3 |
| ARfD | Rabbit developmental study | 100 | n.a. | 0.3 mg/kg bw/day |
| ADI | 1-year dog study | 100 | n.a | 0.1 mg/ kg bw |

Reference values of S-methoprene to be used in Risk Characterisation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Reference** | **Study** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | Rabbit developmental study | 100 | 35% | 0.35 mg/kg bw/day |
| AELmedium-term | 90-day dog study | 100 | 35% | 0.35 mg/kg bw/day |
| AELlong-term | 2-year rat study | 100 | 35% | 0.076 mg/kg bw/day |
| ARfD | n.a. | | | |
| ADI | n.a. | | | |

ADI and ARfD were not derived in the assessment report of S-methoprene. Nevertheless, those reference values were derived in this dossier in order to conduct the dietary risk assessment. An ADI of 0.217 mg/kg bw/ day is derived by applying an assessment factor of 100 to the NOAEL of 21.7 mg/kg bw/d from the 2-year rat study. An ARfD of 1 mg/kg bw is derived by applying an assessment factor of 100 to the NOAEL of 100 mg/kg bw/day from the rabbit developmental study.

***Industrial exposure***

Not relevant.

***Professional exposure***

Not relevant.

***Non-professional exposure***

**Primary exposure**

*Scenario [1] – Automatic air space application*

| **Description of Scenario [1] – Automatic air space application** | | | |
| --- | --- | --- | --- |
| The product is applied indoor by automatic and continuous spraying to kill flying and crawling insects, bedbugs, fleas, flies and mites.  The aerosol is placed in the centre of the room and activated by pressing the trigger of the diffuser. The entirety of the packaging is released into the room, i.e. 200ml equivalent to 164 g of product with a density of 0.8194 without propellant, and containing 0.0638% w/w of imiprothrin and 0.0117% w/w of S-methoprene.  The user is expected to leave the room immediately after the activation of the aerosol but it is supposed as a worst-case that the user is still exposed to the product via inhalation route.  To assess exposure during the application, the air space application model from the ConsExpo Pest Control Products Fact Sheet (RIVM report 320005002) is used.  The spray duration is the net spraying time between start and finish of spraying.  With a mass generation rate of 2.1 g/s and an amount of product of 164g, it takes 78 sec (164/2.1), or 1.18 min to empty the aerosol.  The exposure duration corresponds to the total time the exposed person is in the room where the product is released.  Even if the user is supposed to exit the room directly after the activation of the spray, an exposure duration of 4h is taken into account in the calculations, assuming that the user stays in the room during the entire contact time.  In Tier 1, the max room volume of 100 m3 has been taken into account as claimed by the applicant.  As this room volume does not represent a worst-case approach, room volumes of 27.5m3 and 17.5m3 have been used in Tier 2A and 2B, respectively.  These values are based on the results of the residues study (presented below in the dietary RA section and the Confidential Annex) taking into account a room surface of 11 m² and 7 m² (for details please see scenario 4), and a room height of 2.5m (default value from ConsExpo General fact sheet). | | | |
|  | **Parameters** | **Value** | **Justification** |
|  | Concentration of Imiprothrin | 0.0638% w/w | Applicant’s data |
| Concentration of S-methoprene | 0.0117% w/w | Applicant’s data |
| **Inhalation exposure** | | | |
| Tier 1 | Frequency | 2/year | Applicant’s data |
| Spray duration | 1.18 min | See calculation above |
| Exposure duration | 240 min | See explanation above |
| Room volume | 100 m3 | Applicant’s data |
| Room height | 2.5 m | Default value in ConsExpo |
| Ventilation rate | 0.6/h | Default value in General ConsExpo Fact Sheet for unspecified room |
| Inhalation rate | 1.25 m3/h | HEAd Hoc Recommendation 14 |
| Mass generation rate | 2.1 g/s | Applicant’s data |
| Airborne fraction | 1 | Default value for air space sprays (Pest Control Products Fact Sheet) |
| Inhalation absorption | 100% | Default value |
| Body weight | 60 kg | HEAd Hoc Recommendation 14 |
| Tier 2A | Room volume | 27.5 m3 | See explanation above |
| Tier 2B | Room volume | 17.5 m3 | See explanation above |

**Calculations for Scenario [1]**

* **Imiprothrin**

Systemic effects

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg/d bw)** | **Estimated dermal uptake (mg/kg/d bw)** | **Estimated oral uptake (mg/kg/d bw)** | **Estimated total uptake (mg/kg/d bw)** |
| Scenario [1] | 1/ No PPE | 1.03x10-3 | nr | nr | 1.03x10-3 |
| 2A/ No PPE | 3.76x10-3 | nr | nr | 3.76x10-3 |
| 2B/ No PPE | 5.9x10-3 | nr | nr | 5.9x10-3 |

Local effects

| **Summary table: systemic exposure from non-professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure (mg/m3)** |
| Scenario [1] | 1/ No PPE | 1.24x10-2 |
| 2A/ No PPE | 4.51x10-2 |
| 2B/ No PPE | 7.09x10-2 |

* **S-methoprene**

Systemic effects

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg/d bw)** | **Estimated dermal uptake (mg/kg/d bw)** | **Estimated oral uptake (mg/kg/d bw)** | **Estimated total uptake (mg/kg/d bw)** |
| Scenario [1] | 1/ No PPE | 1.89x10-4 | nr | nr | 1.89x10-4 |
| 2A/ No PPE | 6.89x10-4 | nr | nr | 6.89x10-4 |
| 2B/ No PPE | 1.08x10-3 | nr | nr | 1.08x10-3 |

Outcome of systemic exposure and risk characterisation

**Summary table: estimated systemic exposure and risk characterisation for non-professional users**

* **Imiprothrin**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for non-professional users** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELshort-term = 0.3  mg/kg bw/d |
| Scenario [1] | 1/no PPE | 1.03x10-3 | nr | nr | 1.03x10-3 | 0.34% |
| 2A/ No PPE | 3.76x10-3 | nr | nr | 3.76x10-3 | 1.25% |
| 2B/ No PPE | 5.9x10-3 | nr | nr | 5.9x10-3 | 1.97% |

* **S-methoprene**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for non-professional users** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELshort-term= 0.35  mg/kg bw/d |
| Scenario [1] | 1/no PPE | 1.89x10-4 | nr | nr | 1.89x10-4 | 0.054% |
| 2A/ No PPE | 6.89x10-4 | nr | nr | 6.89x10-4 | 0.20% |
| 2B/ No PPE | 1.08x10-3 | nr | nr | 1.08x10-3 | 0.31% |

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

The product KAPO CHOC PUCES ET LARVES contains two active substances: Imiprothrin and S-methoprene.

For both substances, systemic effects have been observed, therefore a combined exposure to both substances is performed according the *Guidance for Human Health Risk Assessment and Evaluation, Volume III, Part B & C (2017)*, as follow:

* Tier 1: risk assessment of substance by substance;
* Tier 2: assessment of combined exposure by concentration addition;
* Tier 3: confirmation of concentration addition.

If a risk is considered acceptable in Tier 2, Tier 3 is not necessary.

**Tier 1 and Tier 2**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Primary exposure** | **Imiprothrin** | | **S-methoprene** | **Conclusions** |
| **Scenario 1 (Tier 1)** | | | | |
| **Without PPE** | | |  |  |
| Tier 1 | 0.3% AEL | | 0.05% AEL | Acceptable |
| Tier 2 | 0.003 | | 0.0005 | Acceptable |
| HI = 0.0035 < 1 | | |
| **Scenario 1 (Tier 2A)** | | | | |
| **Without PPE** | | | | |
| Tier 1 | 1.25% AEL | 0.20% AEL | | Acceptable |
| Tier 2 | 0.0125 | 0.002 | | Acceptable |
| HI = 0.0145 < 1 | | |
| **Scenario 1 (Tier 2B)** | | | | |
| **Without PPE** | | | | |
| Tier 1 | 1.97% AEL | 0.31% AEL | | Acceptable |
| Tier 2 | 0.0197 | 0.0031 | | Acceptable |
| HI = 0.0228 < 1 | | |

Outcome of quantitative local exposure and risk characterisation

**Summary table: estimated local exposure and risk characterisation for non-professional users**

* **Imiprothrin**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated local exposure and risk characterisation for professional users** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure**  **[mg/m3]** | **Estimated total exposure [mg/m3]** | **Estimated exposure / AEC**  **(%)**    AECinhalation = 0.9 mg/m3 |
| Scenario [1] | 1/no PPE | 1.24x10-2 | 1.24x10-2 | 1% |
| 2A/ No PPE | 4.51x10-2 | 4.51x10-2 | 5% |
| 2B/ No PPE | 7.09x10-2 | 7.09x10-2 | 8% |

**Outcome of qualitative local risk assessment for non-professional users:** Products are eye irritant.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** |  | **Exposure information** | | |  |  |  | **Risk** |  |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant PPE and RMMs** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| LOW | Eye Irrit. Cat 2 (H319) | 18 | Air space application | Eyes | Frequency: maximum 2/year  Duration:  1.18 min | Eye exposure through potential spraying or hand-to-eye transfer | No PPE  Labelling:   * Labelling according to CLP * Instructions for use and storage * “Washing on hands after use” * “Leave room after spraying process is triggered” | **Acceptable** | (**↓**) instruction of use and RMM on the label (washing on hands after use, leave room after spraying process is triggered)  (**↓**) Low exposure duration (less than one hour per day)  (**↓**) Practically no exposure  (**↓**) Low frequency |
| EUH066 | Repeated exposure may cause skin dryness or cracking | Dermal | Dermal contact |

**Conclusion on direct exposure during the use of the product**

For the product KAPO CHOC PUCES ET LARVES, the risk is acceptable for both active substances Imiprothrin and S-methoprene for non-professional users during the application of the product by automatic spraying.

**Secondary exposure *– Exposure of the general public***

*Scenario [2] – Inhalation of volatilised residues after application*

| **Description of Scenario [2] – Inhalation of volatilised residues after application** |
| --- |
| Adults or children re-entering the room after the product application can be exposed to volatilised residues.  In the HEEG Opinion 13 on the Assessment of Inhalation Exposure of Volatilised Biocide Active Substance, a calculation is developed and determines if the risk from inhalation exposure is negligible or should be included in the risk assessment.  This formula is based on the toddler representing the worst-case and covering every age group:  With *mw* being the molecular weight and *vp* the vapour pressure.  If the result is below 1, then the risk from inhalation exposure is considered negligible.  The following parameters are used for the approach:  For Imiprothrin:   * Mw = 318.37 g/mol * Vp = 1.86x10-6 Pa at 25°C * AEL long-term = 0.1 mg/kg bw/day   For S-methoprene:   * Mw = 210.48 g/mol * Vp = 623.10-6 Pa at 20°C * AEL long-term = 0.076 mg/kg bw/day   For both active substances, the result is < 1, and therefore the inhalation exposure is negligible after the application of the product and is not taking into account in the risk assessment. |

*Scenario [3] – Contact with wet treated surface*

| **Description of Scenario [3] – Contact with wet treated surface** | | | |
| --- | --- | --- | --- |
| After the application of the product, the non-professional re-enters the room to ventilate and can accidentally be in contact with wet treated surfaces.  The systemic exposure by dermal route is determined using different parameters.  The volume of product which could be in contact with the skin is determined thanks to the volume of product applied (200ml\*40m²) and the surface area in contact with the surface, corresponding to two hands.  In Tier 1, a surface area of 40m² is determined using the maximum claimed room volume of 100m3 and a default height value of 2.5m.  This surface area does not represent a worst-case assumption for the use of the product.  Therefore, as it has been performed for scenario [1] above, surface areas of 11 m² and 7 m² have been used in Tier 2A and 2B, respectively. For details please refer to the scenario [4].  The product contains 0.0638% w/w of imiprothrin and 0.0117% w/w of S-methoprene.  As inhalation is considered negligible during secondary exposure, no assessment of local effects of Imiprothrin by inhalation route is required. | | | |
|  | Parameters | Value | Justification |
|  | Concentration of Imiprothrin | 0.0638% w/w | Applicant’s data |
| Concentration of S-methoprene | 0.0117% w/w | Applicant’s data |
| Tier 1 | Volume of product on the surface | 200 ml | Applicant’s data |
| Surface treated | 40 m² | Applicant’s data |
| Surface area (one palm) | 410 cm² | HEAd Hoc Recommendation 14 |
| Layer of thickness | 0.01 cm | Default value |
| Body weight | 60 kg | HEAd Hoc Recommendation 14 |
| Dermal absorption of Imiprothrin | 70% | EFSA Guidance 2017 |
| Dermal absorption of S-methoprene | 35% | Derived from oral absorption value of the AR of S-methoprene (2016) |
| Tier 2A | Surface treated area | 11 m² | See explanation above and scenario [4] |
| Tier 2B | Surface treated area | 7 m² | See explanation above and scenario [4] |

**Calculations for Scenario [3]**

* **Imiprothrin**

Systemic effects

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg/d bw)** | **Estimated dermal uptake (mg/kg/d bw)** | **Estimated oral uptake (mg/kg/d bw)** | **Estimated total uptake (mg/kg/d bw)** |
| Scenario [3] | 1/ No PPE | nr | 1.25x10-8 | nr | 1.25x10-8 |
| 2A/ No PPE | nr | 4.55x10-8 | nr | 4.55x10-8 |
| 2B/ No PPE | nr | 7.14x10-8 | nr | 7.14x10-8 |

* **S-methoprene**

Systemic effects

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg/d bw)** | **Estimated dermal uptake (mg/kg/d bw)** | **Estimated oral uptake (mg/kg/d bw)** | **Estimated total uptake (mg/kg/d bw)** |
| Scenario [3] | 1/ No PPE | nr | 1.15x10-9 | nr | 1.15x10-9 |
| 2A/ No PPE | nr | 4.17x10-9 | nr | 4.17x10-9 |
| 2B/ No PPE | nr | 6.55x10-9 | nr | 6.55x10-9 |

*Scenario [4] – Infant crawling on treated surface and hand-to-mouth transfer*

| **Description of Scenario [4] – Infant crawling on treated surface and hand-to mouth transfer** | | | | |
| --- | --- | --- | --- | --- |
| After the application of the product, the user ventilates the room for another 4 hours and leaves the product to dry.  After that time, infants (considered as the worst-case population) can crawl into the room and be dermally exposed to the treated surface. They also can be orally exposed to the active substances after hand-to-mouth transfer.  The systemic exposure by dermal and oral route is determined using the parameters established in the HEEG Opinion 7 on Choice of secondary exposure parameters for PTs 2, 3 and 4, which can also be used for PT18.  It is indicated that the external dose is calculated as follow:  External dose = Sarea x Fdislod x Wf  Sarea is the total area rubbed during exposure, calculated as the product of the transfer coefficient and exposure duration.  Fdislog is the amount of product applied on a surface area that may potentially be wiped off per unit of surface area. This factor is dependent on the application rate (164g of product (200 ml\*0.8194) applied on 40 m²) and the dislodgeable fraction of residues from the surface.  According to the ConsExpo Pest Control Products Fact Sheet, 10% of the dermal exposure is taken in orally due to hand-to-mouth transfer.  The product contains 0.0638% w/w of imiprothrin and 0.0117% w/w of S-methoprene.  As inhalation is considered negligeable during secondary exposure, no assessment of local effects of Imiprothrin by inhalation route is needed.  According to the intended uses claimed by the applicant, the product can be used in room with a volume of up to 100 m3 (corresponding to a treated surface area of max 40 m2).  For the scenario of the infant crawling on treated surface, the more the treated surface is small the more the infant is exposed to large amount of product.  In this context, the smallest surface area to be treated has been calculated for this scenario using the residue study.  The objective of the study was to generate data on the residual amount of S-methoprene and Imiprothrin after application of the product (liquid used for the production of the aerosol can KAPO CHOC) on four different kinds of surfaces (porous unglazed tiling, carpet, linoleum and glazed tiling). Four types of situations (called treatment in the study) have been tested:   * A: directly after application; * B: after 4h of treatment and 4 additional hours of ventilation with open doors and windows (natural ventilation); * C: after 4h of treatment and 4h of natural ventilation followed by a vacuum cleaning (one wipe per surface); * D: after 4h of treatment and 4h of natural ventilation followed by dry cleaning (one wipe per surface).   For more details on residue study, please refer to the dietary RA section and the Confidential Annex.  According to the results, the maximum recoveries are observed after treatment A for glazed tiling with 76.2% and 82.6% for Imiprothrin and S-methoprene respectively.  Taking into account that one of the applicant’s recommendation is to ventilate the room after the treatment, recoveries after treatment B (4h natural ventilation) on glaze tiling have also been taken into account corresponding to 36.5% and 59.5% for Imiprothrin and S-methoprene, respectively. As explained in the Confidential Annex, as a worst-case, the treatment A has been considered as 100% of cleaning efficiency and the fraction measured after treatment B have be normalized by treatment A, as following :  (% of residues for treatment B / % of residues for treatment A) x 100  Therefore, the fraction of residues taking into account for Tier 2B is 47.5% and 72% for Imiprothrin and S-methoprene, respectively.  Considering the maximum recoveries of each a.s and the exposure parameters listed below, the maximum treated area on which an infant can crawl have calculated as follows:   * After 4h treatment: 11 m2; * After 4h treatment and 4h natural ventilation: 7 m2. | | | | |
|  | Parameters | | Value | Justification |
| **Systemic effects** | | | | |
|  | Concentration of Imiprothrin | | 0.0638% w/w | Applicant’s data |
| Concentration of S-methoprene | | 0.0117% w/w | Applicant’s data |
|  | | Body weight | 8 kg | HEAd Hoc Recommendation 14 |
| **Dermal exposure** | | | | |
| Tier 1 | Transfert coefficient | | 2000 cm²/h | HEAd Hoc Recommendation 12 |
| Exposure duration | | 1h | Default value. It is supposed that an infant crawls on the treated floor one hour per day. |
| Amount of product applied on the surface | | 164 g | Applicant’s data |
| Surface treated | | 40 m² | Applicant’s data |
| Dislodgeable fraction | | 18% | BHHEM (p.171). For various type of surfaces. |
| Dermal absorption of Imiprothrin | | 70% | EFSA Guidance 2017 |
| Dermal absorption of S-methoprene | | 35% | Derived from oral absorption value of the AR of S-methoprene (2016) |
| Tier 2A | Mean recovery of Imiprothrin | | 76.2% | Residue study submitted by the applicant |
| Mean recovery of S-methoprene | | 82.6% | Residue study submitted by the applicant |
| Tier 2B | Mean recovery of Imiprothrin | | 47.5% | Residue study submitted by the applicant |
| Mean recovery of S-methoprene | | 72% | Residue study submitted by the applicant |
| **Oral exposure** | | | | |
| Tier 1 | | Fraction of dermal exposure taken orally | 10% | ConsExpo Pest Control Products Fact Sheet |
|  | Oral absorption of Imiprothrin | | 100% | Default value |
| Oral absorption of S-methoprene | | 35% | AR of S-methoprene (2016) |

**Calculations for Scenario [4]**

* **Imiprothrin**

Systemic effects

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg/d bw)** | **Estimated dermal uptake (mg/kg/d bw)** | **Estimated oral uptake (mg/kg/d bw)** | **Estimated total uptake (mg/kg/d bw)** |
| Scenario [4] | 1/ No PPE | nr | 8.23x10-2 | 1.18x10-2 | 9.41x10-2 |
| 2A/ No PPE | nr | 2.28x10-1 | 3.26x10-2 | 2.61x10-1 |
| 2B/ No PPE | nr | 2.23x10-1 | 3.19x10-2 | 2.55x10-1 |

* **S-methoprene**

Systemic effects

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg/d bw)** | **Estimated dermal uptake (mg/kg/d bw)** | **Estimated oral uptake (mg/kg/d bw)** | **Estimated total uptake (mg/kg/d bw)** |
| Scenario [4] | 1/ No PPE | nr | 7.55x10-3 | 7.55x10-4 | 8.30x10-3 |
| 2A/ No PPE | nr | 2.27x10-2 | 2.27x10-3 | 2.49x10-2 |
| 2B/ No PPE | nr | 3.11x10-2 | 3.11x10-3 | 3.42x10-2 |

*Scenario [5] – Contact with dry product while sleeping in bed*

| **Description of Scenario [5] – Contact with dry product while sleeping in bed** | | | | |
| --- | --- | --- | --- | --- |
| After the application of the product in the bedroom and the contact time, adults and children can be in contact with dry product that could have been deposed on the mattress.  The systemic exposure by dermal route is determined using different parameters for both the adult and the infant (determined as the worst-case population).  The amount of product which could be in contact with the skin is determined thanks to the volume of product applied (200ml\*0.8194\*40m²), the surface area in contact with the mattress, corresponding at a worst-case to the whole body, and a dislodgeable fraction of residues from cotton.  The product contains 0.0638% w/w of imiprothrin and 0.0117% w/w of S-methoprene.  As inhalation is considered negligeable during secondary exposure, no assessment of local effects of Imiprothrin by inhalation route is required.  As in the previous scenarios, in Tier 1 a maximum treated surface of 40 m2 has been considered (directly related to the intended uses from the applicant).  In Tier 2, the mean recoveries of of both a.s determined in the residue study and the treated surface area of 11 m² and 7 m² (depending on the treatment A or B) calculated in scenario 4, have been used. | | | | |
|  | Parameters | | Value | Justification |
| **Systemic effects** | | | | |
|  | Concentration of Imiprothrin | | 0.0638% w/w | Applicant’s data |
| Concentration of S-methoprene | | 0.0117% w/w | Applicant’s data |
| **Dermal exposure** | | | | |
| Tier 1 | | Volume of product on the surface | 200 ml | Applicant’s data |
| Surface treated | 40 m² | Applicant’s data |
|  | Surface area (body) | | 16600 cm² (adult) | HEAd Hoc Recommendation 14 |
| 4100 cm² (infant) |
| Dislodgeable fraction | | 30% | BHHEM (p.171), for cotton (wet skin) |
| Body weight | | 60 kg (adult) | HEAd Hoc Recommendation 14 |
| 8 kg (infant) |
| Dermal absorption of Imiprothrin | | 70% | EFSA Guidance 2017 |
| Dermal absorption of S-methoprene | | 35% | Derived from oral absorption value of the AR of S-methoprene (2016) |
| Tier 2A | Mean recovery of Imiprothrin | | 76.2% | Residue study submitted by the applicant |
| Mean recovery of S-methoprene | | 82.6% | Residue study submitted by the applicant |
| Minimum surface area | | 11 m² | See scenario [4] |
| Tier 2B | Mean recovery of Imiprothrin | | 47.5% | Residue study submitted by the applicant, after normalization |
| Mean recovery of S-methoprene | | 72% | Residue study submitted by the applicant, after normalization |
| Minimum surface area | | 7 m² | See scenario [4] |

**Calculations for Scenario [5]**

* **Imiprothrin**

Systemic effects

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg/d bw)** | **Estimated dermal uptake (mg/kg/d bw)** | **Estimated oral uptake (mg/kg/d bw)** | **Estimated total uptake (mg/kg/d bw)** |
| Scenario [5] - adult | 1/ No PPE | nr | 1.52x10-8 | nr | 1.52x10-8 |
| 2A/ No PPE | nr | 4.21x10-8 | nr | 4.21x10-8 |
| 2B/ No PPE | nr | 4.12x10-8 | nr | 4.12x10-8 |
| Scenario [5] - infant | 1/ No PPE | nr | 2.81x10-8 | nr | 2.81x10-8 |
| 2A/ No PPE | nr | 7.80x10-8 | nr | 7.80x10-8 |
| 2B/ No PPE | nr | 7.64x10-8 | nr | 7.64x10-8 |

* **S-methoprene**

Systemic effects

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg/d bw)** | **Estimated dermal uptake (mg/kg/d bw)** | **Estimated oral uptake (mg/kg/d bw)** | **Estimated total uptake (mg/kg/d bw)** |
| Scenario [5] - adult | 1/ No PPE | nr | 7.59x10-9 | nr | 7.59x10-9 |
| 2A/ No PPE | nr | 2.28x10-8 | nr | 2.28x10-8 |
| 2B/ No PPE | nr | 3.12x10-8 | nr | 3.12x10-8 |
| Scenario [5] - infant | 1/ No PPE | nr | 1.41x10-8 | nr | 1.41x10-8 |
| 2A/ No PPE | nr | 4.22x10-8 | nr | 4.22x10-8 |
| 2B/ No PPE | nr | 5.79x10-8 | nr | 5.79x10-8 |

Outcome of systemic exposure and risk characterisation

**Summary table: estimated systemic exposure and risk characterisation for non-professional bystanders/general public**

* **Imiprothrin**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AEL = 0.3  mg/kg bw/d |
| Scenario [3] - adult | 1/no PPE | nr | 1.25x10-8 | nr | 1.25x10-8 | 0.000004% |
| 2A/ No PPE | nr | 4.55x10-8 | nr | 4.55x10-8 | 0.000015% |
| 2B/ No PPE | nr | 7.14x10-8 | nr | 7.14x10-8 | 0.000024% |
| Scenario [4] - infant | 1/No PPE | 1.18x10-2 | 8.23x10-2 | nr | 9.41x10-2 | 31% |
| 2A/ No PPE | 3.26x10-2 | 2.28x10-1 | nr | 2.61x10-1 | 87% |
| 2B/ No PPE | 3.19x10-2 | 2.23x10-1 | nr | 2.55x10-1 | 85% |
| Scenario [5] - adult | 1/ No PPE | nr | 1.52x10-8 | nr | 1.52x10-8 | 0.000005% |
| 2A/ No PPE | nr | 4.21x10-8 | nr | 4.21x10-8 | 0.000014% |
| 2B/ No PPE | nr | 4.12x10-8 | nr | 4.12x10-8 | 0.000014% |
| Scenario [5] - infant | 1/ No PPE | nr | 2.81x10-8 | nr | 2.81x10-8 | 0.000009% |
| 2A/ No PPE | nr | 7.80x10-8 | nr | 7.80x10-8 | 0.000026% |
| 2B/ No PPE | nr | 7.64x10-8 | nr | 7.64x10-8 | 0.000025% |

* **S-methoprene**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AEL = 0.35  mg/kg bw/d |
| Scenario [3] - adult | 1/no PPE | nr | 1.15x10-9 | nr | 1.15x10-9 | 0.0000003% |
| 2A/ No PPE | nr | 4.17x10-9 | nr | 4.17x10-9 | 0.0000012% |
| 2B/ No PPE | nr | 6.55x10-9 | nr | 6.55x10-9 | 0.0000019% |
| Scenario [4] - infant | 1/ No PPE | 7.55x10-4 | 7.55x10-3 | nr | 8.30x10-3 | 2% |
| 2A/ No PPE | 2.27x10-3 | 2.27x10-2 | nr | 2.49x10-2 | 7% |
| 2B/ No PPE | 3.11x10-3 | 3.11x10-2 | nr | 3.42x10-2 | 10% |
| Scenario [5] - adult | 1/ No PPE | nr | 7.59x10-9 | nr | 7.59x10-9 | 0.000002% |
| 2A/ No PPE | nr | 2.28x10-8 | nr | 2.28x10-8 | 0.000007% |
| 2B/ No PPE | nr | 3.12x10-8 | nr | 3.12x10-8 | 0.000009% |
| Scenario [5] - infant | 1/ No PPE | nr | 1.41x10-8 | nr | 1.41x10-8 | 0.000004% |
| 2A/ No PPE | nr | 4.22x10-8 | nr | 4.22x10-8 | 0.000012% |
| 2B/ No PPE | nr | 5.79x10-8 | nr | 5.79x10-8 | 0.000017% |

**Combined scenarios – Primary and secondary exposure**

Outcome of combined systemic exposure and risk characterisation for primary and secondary exposure

**Summary table: combined systemic exposure and risk characterisation for non-professionals and general public**

* **Imiprothrin**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure and risk characterisation for non-professionals and general public** | | | | | | |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake**  **[mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**  AEL = 0.3  mg/kg bw/d |
| Scenarios [1+3+5] - adult | 1/ No PPE | nr | 2.77x10-8 | 1.03x10-3 | 1.03x10-3 | 0.3% |
| 2A/ No PPE | nr | 8.75x10-8 | 3.76x10-3 | 3.76x10-3 | 1% |
| 2B/ No PPE | nr | 1.13x10-7 | 5.9x10-3 | 5.9x10-3 | 2% |
| Scenarios [4+5] - infant | 1/ No PPE | 1.18x10-2 | 8.23x10-2 | nr | 9.41x10-2 | 31% |
| 2A/ No PPE | 3.26x10-2 | 2.28x10-1 | nr | 2.61x10-1 | 87% |
| 2B/ No PPE | 3.19x10-2 | 2.23x10-1 | nr | 2.55x10-1 | 85% |

* **S-methoprene**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure and risk characterisation for non-professionals and general public** | | | | | | |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake**  **[mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**  AEL = 0.35  mg/kg bw/d |
| Scenarios [1+3+5] - adult | 1/no PPE | nr | 8.74x10-9 | 1.89x10-4 | 1.89x10-4 | 0.05% |
| 2A/ No PPE | nr | 2.70x10-8 | 6.89x10-4 | 6.89x10-4 | 0.2% |
| 2B/ No PPE | nr | 3.78x10-8 | 1.08x10-3 | 1.26x10-3 | 0.31% |
| Scenarios [4+5] - infant | 1/ No PPE | 7.55x10-4 | 7.55x10-3 | nr | 8.30x10-3 | 2% |
| 2A/ No PPE | 2.27x10-3 | 2.27x10-2 | nr | 2.49x10-2 | 7% |
| 2B/ No PPE | 3.11x10-3 | 3.11x10-2 | nr | 3.42x10-2 | 10% |

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

**Tier 1 and Tier 2**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Secondary exposure** | **Imiprothrin** | | | | **S-methoprene** | **Conclusions** |
| **Scenario 2** | | | | | | |
| Not relevant | | | | | | |
| **Scenario 3 (Tier 1)** | | | | |  |  |
| Tier 1 | 0.000004% AEL | | | | 0.0000003% AEL | Acceptable |
| Tier 2 | 0.00000004 | | | | 0.000000003 | Acceptable |
| HI = 0.000000043 < 1 | | | | |
| **Scenario 3 (Tier 2A)** | | | | | | |
| Tier 1 | 0.000015% AEL | | 0.0000012% AEL | | | Acceptable |
| Tier 2 | 0.00000015 | | 0.000000012 | | | Acceptable |
| HI = 0.000000162 < 1 | | | | |
| **Scenario 3 (Tier 2B)** | | | | | | |
| Tier 1 | 0.000024% AEL | | 0.0000019% AEL | | | Acceptable |
| Tier 2 | 0.00000024 | | 0.000000019 | | | Acceptable |
| HI = 0.000000259 < 1 | | | | |
| **Scenario 4 (Tier 1)** | | | | | | |
| Tier 1 | | 31% AEL | | | 2% AEL | Acceptable |
| Tier 2 | | 0.31 | | | 0.02 | Acceptable |
| HI = 0.33 < 1 | | | |
| **Scenario 4 (Tier 2A)** | | | | | | |
| Tier 1 | | 87% AEL | | | 7% AEL | Acceptable |
| Tier 2 | | 0.87 | | | 0.07 | Acceptable |
| HI = 0.94 < 1 | | | |
| **Scenario 4 (Tier 2B)** | | | | | | |
| Tier 1 | | 85% AEL | | | 10% AEL | Acceptable |
| Tier 2 | | 0.85 | | | 0.1 | Acceptable |
| HI = 0.95 < 1 | | | |
| **Scenario 5 – adult (Tier 1)** | | | | | | |
| Tier 1 | | 0.000005% AEL | | | 0.000002% AEL | Acceptable |
| Tier 2 | | 0.00000005 | | | 0.00000002 | Acceptable |
| HI = 0.00000007 < 1 | | | |
| **Scenario 5 – adult (Tier 2A)** | | | | | | |
| Tier 1 | | 0.000014% AEL | | 0.000007% | | Acceptable |
| Tier 2 | | 0.00000014 | | 0.00000007 | | Acceptable |
| HI = 0.00000021 < 1 | | | |
| **Scenario 5 – adult (Tier 2B)** | | | | | | |
| Tier 1 | | 0.000014% AEL | | 0.000009% | | Acceptable |
| Tier 2 | | 0.00000014 | | 0.00000009 | | Acceptable |
| HI = 0.00000023 < 1 | | | |
| **Scenario 5 – infant (Tier 1)** | | | | | | |
| Tier 1 | 0.000009% AEL | | | | 0.000004% AEL | Acceptable |
| Tier 2 | 0.00000009 | | | | 0.00000004 | Acceptable |
| HI = 0.00000013 < 1 | | | | |
| **Scenario 5 – infant (Tier 2A)** | | | | | | |
| Tier 1 | 0.000026% AEL | | 0.000012% AEL | | | Acceptable |
| Tier 2 | 0.00000026 | | 0.00000012 | | | Acceptable |
| HI = 0.00000038 < 1 | | | | |
| **Scenario 5 – infant (Tier 2B)** | | | | | | |
| Tier 1 | 0.000025% AEL | | 0.000017% AEL | | | Acceptable |
| Tier 2 | 0.00000022 | | 0.00000017 | | | Acceptable |
| HI = 0.00000042 < 1 | | | | |
| **Combined exposure** | | | | | | |
| **Scenarios 1+3+5 – adult (Tier 1)** | | | | | | |
| Tier 1 | 0.3% AEL | | 0.05% AEL | | | Acceptable |
| Tier 2 | 0.003 | | 0.0005 | | | Acceptable |
| HI = 0.0035 < 1 | | | | |
| **Scenarios 1+3+5 – adult (Tier 2A)** | | | | | | |
| Tier 1 | 1% AEL | | 0.2% AEL | | | Acceptable |
| Tier 2 | 0.01 | | 0.002 | | | Acceptable |
| HI = 0.012 < 1 | | | | |
| **Scenarios 1+3+5 – adult (Tier 2B)** | | | | | | |
| Tier 1 | 2% AEL | | 0.31% AEL | | | Acceptable |
| Tier 2 | 0.02 | | 0.0031 | | | Acceptable |
| HI = 0.0231 < 1 | | | | |
| **Scenarios 4+5 – infant (Tier 1)** | | | | | | |
| Tier 1 | 31% AEL | | 2% AEL | | | Acceptable |
| Tier 2 | 0.31 | | 0.02 | | | Acceptable |
| HI = 0.33 < 1 | | | | |
| **Scenarios 4+5 – infant (Tier 2A)** | | | | | | |
| Tier 1 | 87% AEL | | 7% AEL | | | Acceptable |
| Tier 2 | 0.87 | | 0.07 | | | Acceptable |
| HI = 0.94 < 1 | | | | |
| **Scenarios 4+5 – infant (Tier 2B)** | | | | | | |
| Tier 1 | 85% AEL | | 10% AEL | | | Acceptable |
| Tier 2 | 0.85 | | 0.10 | | | Acceptable |
| HI = 0.95 < 1 | | | | |

**Overall conclusion on the risk assessment for human health from systemic and local exposure to both active substances**

For the product KAPO CHOC PUCES ET LARVES, used by non-professionals by one-shot spraying application, the risk is acceptable considering the quantitative risk assessment for systemic effects for both active substances Imiprothrin and S-methoprene and considering the quantitative risk assessment for local affects for Imiprothrin, using the following risk mitigations measures (RMM):

* Washing on hands after use;
* Leave the room after spraying process is triggered;
* The product has to be applied on a minimum volume area of 17.5 m3 corresponding to a minimal surface area of 7 m2;
* Ventilate (4 hours minimum) before reusing the room

***Monitoring data***

*[Please add any information on surveys or studies with the actual product or with a surrogate.]*

***Dietary exposure***

Use of KAPO CHOC PUCE ET LARVES can possibly lead to contamination of food since the product is intended to be used as a one-shot aerosol for air space treatment in domestic area such as kitchens.

*List of scenarios*

| **Summary table of main representative dietary exposure scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Type of use1** | **Description of scenario** | **Subject of exposure2** |
| 1. | Residential use | Dietary exposure to biocide residues deposited on kitchen counter, dishes with food contact and food after kitchen airspace treatment | Food |

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. | Plant Protection Products | « not approved » | MRL from 0.02\* mg/kg to 5 mg/kg listed in Reg. (EU) No 899/2012 |

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

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

| **Description of Scenario [1]** | | | | |
| --- | --- | --- | --- | --- |
| **Calculation of biocide residues deposited from air to horizontal surfaces**  Rsurface = m24h x hroom / Vroom  Rsurface : biocide residues deposited from air to horizontal surfaces within 24 h (mg a.s./m²)  m24h : mass of active substance released over 24h (mg)  Vroom : room volume treated (m³)  hroom : room height (m)  **Estimation of consumer exposure**  Expcons = Rsurface x Afood contact x TF x D / bw  Expcons : dietary exposure (mg a.s./kg bw/d)  Rsurface : biocide residues on surface (mg a.s./m²), (see calculation above)  Afood contact : area in contact with food (m²)  TF : mass transfer efficiency factor (fraction of biocide residue transferred from surface to food)  bw : body weight (kg)  D dietary intake fraction: acute = 1.0/d and chronic = 0.5/d per default | | | | |
|  | Parameters1 | Value | | Justification |
| Imiprothrin | S-methoprene |
| Tier 1 | Concentration of active substance in biocidal product: cas in bp (mg/kg) | 555 | 111 | product specific information |
| Mass of biocidal product released over 24h: mbp\_24h (g) | 164 | | 0.2 L of product per application x 820 g/L (product's density without propellant) |  |
| mass of active substance released over 24h: mas\_24h (mg) | 91.02 | 18.20 | calculated as  mas\_24h =  (mbp\_24h ÷ 1000) x  cas in bp |
| ADI (mg/kg bw/d) | 0,1 | 0,217 |  |
| ARfD (mg/kg bw/d) (if applicable) | 0,3 | 1 |  |
| room height for domestic homes: hroom (m) | 2,5 | | default value |
| volume of domestic kitchen: Vroom (m3) | 15 | | default value |
| surface residues: Rsurface (mg a.s./m²) | 15.17 | 3.034 | calculated as Rsurface= mas\_24h x hroom ÷ Vroom |
| area in contact with food: Afood contact (m²) | 0.53 | | default for  airspace treatment taking into account 0.2 m² for the area of food contact on kitchen counter, 0.27 m² for the area of exposed dishes with food contact and 0.06 m² for the area of exposed food. |
| dietary intake fraction (chronic exposure): D (1/d) | 0.5 | | default for chronic assessment |
| dietary intake fraction (acute exposure): D (1/d) | 1 | | default for acute assessment |
| mass transfer efficiency: TF | 1 | | default 100% |
| optional: RF (additional refinement factor) | 1 | | No RF in tier 1. |
|  | Refinement Factor for post-application treatment | 0.48 | 0.72 | Residue recovery after 4 hours of treatment and 4 additional hours of ventilation with open doors and windows natural ventilation.  (Study No. Mo6527, Dr Lienhard Mack, 2019, Residue analysis of methoprene and imiprothrin on surfaces for aerosol ‘Kapo choc’) |
| Tier 2 |
| Tier 3 | Refinement factor of area in contact with food on kitchen counter and exposed dishes **for toddlers** | 0.5 | | According to EFSA PRIMo rev 3.1 and EFSA guidance on default values (2012)[[9]](#footnote-10), food consumption of toddlers is about half food consumption of adults. As a result, a refinement factor of 0.5 is proposed for toddlers. |  | |
| Tier 4 | Refinement factor regarding frequency of use (only for **chronic** consumer exposure) | 0.0055 | | The product is intended to be used only in case of infestation, at a frequency of once to twice a year. As a result, for chronic exposure, a factor of 0.0055 corresponding to 2 uses divided by 365 days is applied. |

**Calculations for Scenario [1]**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Dietary exposure – imiprothrin** | | | | | |
| Tier | | Estimation of chronic consumer exposure via food  (mg/kg bw/d) | Estimation of chronic consumer exposure via food  (% ADI) | Estimation of acute consumer exposure via food  (mg/kg bw/d) | Estimation of acute consumer exposure via food  (% ARfD) |
| Tier 1 | Adult  (60 kg bw) | 0.067 | 67 | 0.134 | 44.7 |
| Toddler  (10 kg bw) | 0.402 | 402 | 0.804 | 268 |
| Tier 2 | Adult  (60 kg bw) | 0.032 | 32.2 | **0.064** | **21.4** |
| Toddler  (10 kg bw) | 0.193 | 193 | 0.386 | 128.6 |
| Tier 3 | Adult  (60 kg bw) | - | - | - | - |
| Toddler  (10 kg bw) | 0.107 | 107.4 | **0.215** | **64.3** |
| Tier 4 | Adult  (60 kg bw) | **0.0002** | **0.2** | - | - |
| Toddler  (10 kg bw) | **0.001** | **0.6** | - | - |

In tier 1, chronic and acute exposure to imiprothrin via food are respectively above ADI and ARfD for toddlers and above 10% of ARfD and 10% of ADI for adults. As a result, a refinement of chronic and acute exposure exposure calculation is necessary for both toddlers and adults.

Applicant submitted a residue study[[10]](#footnote-11) in which imiprothrin (cis and trans isomers) and S-methoprene were quantified on several surfaces (porous unglazed tiling, carpet, linoleum, glazed tiling) after product application followed by different post-application treatments. It should be noted that surfaces tested in the study correspond to soil surfaces but has been considered to cover surfaces in contact with food in domestic kitchens. A summary of the study was provided by the applicant and can be found in annex 3.4.

It is indicated as instruction for use that the product should be allowed to act for 4 hours and then the treated room should be ventilated during a minimum of four hours before reuse. As a result, residue quantified on surfaces after 4 hours of treatment and additional 4 hours of room ventilation were selected to derive a refinement factor.

In tier 3, a refinement factor (RF) was applied to refine area in contact with food for toddlers as default value of 0.53 m² were derived for adults. Consumption data for EFSA PRIMo rev 3.1 and EFSA guidance on default values (2012) have been used to estimate food consumption of toddlers compared to adults. A RF of 0.5 is used as food consumption of toddlers was found to represent about half food consumption of adults.

In tier 4, a RF of 0.0055 to take into account frequency of use of the product (maximum twice a year) was applied to the calculation.

After refinements, chronic exposure to imiprothrin via food is below 10% ADI for both toddlers and adults. However acute exposure remains above 10% ARfD for adults (tier 2) and toddlers (tier 3). According to ECHA guidance 2017[[11]](#footnote-12), if the exposure is above 10% of ADI or 10% ARfD after refinements of exposure estimation, a potential concern is identified and the nature of the residue needs to be defined. Since no nature-of-residues studies were submitted in the framework of this dossier, **no conclusion on the risk linked to acute exposure to imiprothrin via food can be drawn.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Dietary exposure – S-methoprene** | | | | | |
| Tier | | Estimation of chronic consumer exposure via food  (mg/kg bw/d) | Estimation of chronic consumer exposure via food  (% ADI) | Estimation of acute consumer exposure via food  (mg/kg bw/d) | Estimation of acute consumer exposure via food  (% ARfD) |
| Tier 1 | adult  (60 kg bw) | 0.013 | 6.2 | 0.027 | 2.7 |
| toddler  (10 kg bw) | 0.08 | 37.1 | 0.161 | 16.1 |
| Tier 2 | adult  (60 kg bw) | 0.01 | 4.4 | **0.019** | **1.9** |
| toddler  (10 kg bw) | 0.058 | 26.7 | 0.116 | 11.6 |
| Tier 3 | adult  (60 kg bw) | - | - | - | - |
| toddler  (10 kg bw) | 0.322 | 14.8 | **0.064** | **6.4** |
| Tier 4 | adult  (60 kg bw) | **0.0001** | **0.02** | - | - |
| toddler  (10 kg bw) | **0.0003** | **0.1** | - | - |

In tier 1, chronic and acute exposure to S-methoprene via food are respectively above 10% ADI and 10 % ARfD for toddlers and below 10% ADI and 10% ARfD for adults. As a result, refinement of chronic and acute exposure exposure calculation is necessary only for toddlers. Same refinement options as for imiprothrin has been applied for S-methoprene (see description of scenario 1). In tier 4, chronic and acute consumer exposures are respectively below 10% ADI and 10 % ARfD of S-methoprene.

It should be noted that acetone has been identified as a substance of concern (SoC) of the product (human health section). However, as criteria which have led to consider this substance as a SoC are not linked to oral exposure, no risk assessment linked to dietary exposure to acetone has been conducted.

#### Risk characterisation for human health

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

Indirect exposure via food to S-methoprene and imiprothrin arising from intended uses of KAPO CHOC PUCES ET LARVES has been estimated and compared to ADI and ARfD in section “dietary exposure” (2.2.6.2).

Risk linked to chronic and acute consumer exposures to S-methoprene is acceptable.

Regarding imiprothrin, risk linked to chronic exposure is acceptable. However, as acute exposure remains above 10% ARfD for adults and toddlers after refinements and no futher data were submitted by the applicant, no conclusion on the risk linked to acute exposure to imiprothrin via food can be drawn.

As a result, the following risk mitigation measure is proposed:

- Do not use in areas where food is stored and prepared such as kitchens.

### Risk assessment for animal health

In the risk assessment for human health, the risk is considered acceptable for infant crawling into the treated floor and being orally exposed to the product by hand-to-mouth transfer. Therefore, the risk for animal health is covered by the risk for human health and is considered acceptable.

### Risk assessment for the environment

The following environmental exposure and risk assessment was conducted for the biocidal product (BP) KAPO CHOC PUCES ET LARVES that is a one-shot insecticide aerosol to be applied indoor, in case of infestation of flying and crawling insects (including flies and gnats), bedbugs, fleas and mites. The emission assessment has been based on the product containing 0.5% (w/w) pure Imiprothrin and 0.01% (w/w) of pure S-Methoprene as the active substances with an insecticidal action (product type (PT) 18).

Five relevant metabolites have been identified for Imiprothrin: PGH, d-c/t-CRA, t-COOH-CA, CPG and PG. No relevant metabolite has been identified for S-Methoprene.

The assessment has been conducted for the two active substances and their relevant metabolites only. No substance of concern was defined for the environment. More details about the identification of co-formulants as potential SoC can be found in the confidential PAR.

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

#### Effects assessment on the environment

An overview for the PNECs for the active substance S-Methoprene, imiprothrin and its relevant metabolite MNG are given in the tables below:

|  |  |  |
| --- | --- | --- |
| **Compartment** | **PNEC (S-Methoprene)** | **Remarks** |
| STP microorganisms | 6.85 mg/L (CAR) | - |
| Surface water | 0.19 µg/L (CAR) | - |
| Sediment (EPM) | 0.38 µg/kg wwt (CAR) | An additional factor of 10 was directly included in the PNEC considering the use of the EPM method for PNEC derivation and the high Koc value (cf CAR) |
| Soil | 0.148 mg/kg wwt (agreed at BPC-28) | Initial |
| Mammals | 43.60 mg/kg food | - |

The CAR addendum of S-Methoprene (June 2016) shows the presence of significant metabolites in water and sediment phases. However, the DT50 of S-Methoprene metabolites are lower than the S-Methoprene DT50. Therefore, S-Methoprene metabolites are not considered in the environmental risk assessment.

|  |  |  |  |
| --- | --- | --- | --- |
| **Compartment** | **PNEC (Imiprothrin)** | **PNEC (d-c/t-CRA, PGH, CPG, and PG)** | **PNEC (t-COOH-CA)** |
| STP microorganisms | 9.35 mg/L (CAR) | n.r. | n.r. |
| Surface water | 0.038 µg/L (CAR) | 0.038 µg/L (CAR) | 75 µg/L (CAR) |
| Sediment | 0.25µg/kgwwt (CAR) | n.r. | n.r. |
| Soil | 0.184 µg/kgwwt (EPM) | n.r. | n.r. |

With regard to the formation of metabolites in aquatic systems, five major metabolites –d-c/t-CRA, PGH, CPG, PG and t-COOH-CA – were detected in the CAR at significant concentrations (i.e. >10 %) in the water-sediment degradation study.

***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***

|  |  |
| --- | --- |
| **Classification of the Active Substance Imiprothrin** | |
| Value/conclusion | Very toxic to aquatic life - H400 with M-factor= 10  Very toxic to aquatic life with long-lasting effects - H410 with M-factor = 10 |

|  |  |
| --- | --- |
| **Classification of the Active Substance S-methoprene** | |
| Value/conclusion | Very toxic to aquatic life- H400 with M-factor= 1  Very toxic to aquatic life with long-lasting effects - H410 with M-factor = 1 |

|  |  |
| --- | --- |
| **Classification and labelling of the Product KAPO CHOC PUCES ET LARVES** | |
| Value/conclusion | **Aquatic Chronic Cat 3; H412** |

***Further Ecotoxicological studies***

No new data is available.

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

No new data is available.

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

No new data is available.

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

No new data is available.

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

No new data is available.

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

The product is intended to be used indoor. Therefore, the active substance can reach the STP after wet cleaning of the treated surfaces. The active substance is then distributed at a local scale to surface water, sediment, agricultural soil and groundwater.

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

No new data is available.

***Leaching behaviour (ADS)***

No new data is available.

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

No new data is available.

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

No new data is available.

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

No new data is available.

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

The biocidal product is applied indoor and is not intended to be sprayed near to surface waters. Therefore a risk assessment for spray application is not relevant.

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

The biocidal product is used indoor. Therefore a risk assessment for spray application is not relevant.

#### Exposure assessment

General information

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | Scenario 1: Indoor application – one-shot aerosol |
| ESD(s) used | *Emission Scenario Document for Product Type 18:* Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses, July 2008. |
| Approach | Scenario 1: Average consumption |
| Distribution in the environment | *Calculated based on ESD model, EUSES 2.1 and Simple Treat 4.0* |
| Groundwater simulation | No |
| Confidential Annexes | Residue analysis of Methoprene and Imiprothrin on Surfaces for Aerosol “KAPO CHOC” |
| Life cycle steps assessed | Scenario 1:  Production: No  Formulation No  Use: Yes  Service life: Yes |
| Remarks | No |

***Emission estimation***

**Scenario [1] - Indoor application – one-shot aerosol**

KAPO CHOC PUCES ET LARVES is a one-shot aerosol insecticide for households. The product is intended to be used by non-professional consumers for indoor applications. To treat the infested area, the device is placed in a raised position in the centre of the treated area. The trigger of the diffuser is pushed to activate the diffusion. The only pack size of 200 mL is used to treat rooms up to 100 m3. The product can be used once to twice a year (simultaneity factor of 0.204 %).

The quantity of active substance in this product is 0.05% and 0.01% of pure Imiprothrin and S-Methoprene, corresponding respectively to technical values of 0.0575% and 0.01053%. These fraction are calculated considering the propellant present at 10% in the final product. However, the density of the product was calculated without the propellant (0.820 kg.L-1). Therefore, all the emission calculation were done using the fraction of the two active substances without propellant. This results to fraction of active substance of 0.0555% and 0.111% of pure Imiprothrin and S-Methoprene, corresponding respectively to technical values of 0.0639% and 0.0117%.

It is important to note that, in the risk assessment of the Imiprothrin CAR, the fraction concentration used was a pure concentration, i.e. the active substance without its impurities. Indeed, the ecotoxicological endpoints (e.g. LC50 value on fish) represent the average concentrations of Imiprothrin measured in the experiments, which are pure Imiprothrin without its impurities. The environmental PNECs are therefore given as the pure Imiprothrin concentration which should not be exceeded in the environmental compartments. Furthermore, the risk assessment of the representative product of the CAR was performed using pure value of Imiprothrin. Thus, it was decided that the PECs in this PAR will be calculated using pure Imiprothrin value as well as in the CAR. Concerning S-Methoprene, as it is not clear in the CAR whether the ecotoxicological concentrations determined during the studies represent the amount of technical S-Methoprene added to the experimental medium or they represent measured concentrations, therefore, the technical concentration of S-Methoprene in the product is taken into account in the risk assessment as a worst-case.

The product is a ready-to-use insecticide, therefore no emission is calculated for the preparation step.

Emissions to air is also not considered due to the form of the product and the mode of application.

In order to refine the risk for the environment, the applicant has conducted a study to define the residue quantities of both active substances on the ground after treatment of different surfaces. The results of this study allows to lower the cleaning efficiency to 47.5% and 72.0% for Imiprothrin and S-Methoprene respectively considering the use instruction “Allow to act for 4 hours, then ventilate (4 hours minimum) before reusing the room, creating a stream of air between doors and windows wide open”. The analysis of the study validity is proposed in the Confidential PAR.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **Scenario 1 - Indoor application – one-shot aerosol (private house only) – Air space treatment** | | | |
| Fraction of active substance (Imiprothrin) | 5.55E-04 | - | (pure without propellant) |
| Fraction of active substance (S-methoprene) | 1.17E-04 |  | (technical without propellant) |
| Density of the product | 0.820 | kg.L-1 | (without propellant at 20°C) |
| Application rate of the biocidal product | 0.002 | L.m-3 | 200 mL for a room up to 100 m3 |
| Treatment rate of the biocidal product | 1.64E-03 | kg.m-3 | (without propellant) |
| Volume treated per house | 325 | m3 | =130m2\*2.5m |
| Volume cleaned per house | 96.25 | m3 | =38.5m2\*2.5m |
| Number of application per day | 1 | d-1 | Intended use |
| Fraction emitted to applicator during application step (Fapplication, applicator) | 0.012 | - | Table 3.3-1 –ESD PT18 |
| Fraction emitted to floor during application step | 0.988 | - | 1- Fapplication, applicator |
| Fraction emitted to wastewater during cleaning (Fww) | 1 | - | Default value.. |
| Cleaning efficiency of the applicator’s clothes (Fce appl) | 100 | % | ESD PT18 |
| Cleaning efficiency of the floor (Fce floor)- Tier 1 | 100 | % | Table 3.3-8 –ESD PT18 (RTU Aerosols – Space Spray/diffuser) |
| Cleaning efficiency of the floor (Fce floor)- Tier 2  S-methoprene  Imiprothrin | 72.0  47.5 | % | Measured percentage **4 hours after the treatment on non-absorbent surface and 4 additional hours of ventilation** (cf Instruction of use). This refinement was proposed by the applicant. See confidential annex for FR CA comments and agreement. |
| Number of private houses connected to the STP | 4000 | - | Default value – TAB (2016) |
| Simultaneity factor | 0.204 | % | Once to twice a year |

Calculations for Scenario [*1*]

| **Resulting local emission to relevant environmental compartments - STP** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| **Tier 1 (Fce=1):**  STP - Imiprothrin  STP - S-Methoprene | 7.35E-04  1.55E-04 | (based on pure value without propellant)  (based on technical value without propellant) |
| **Tier 2 (Fce refinement):**  STP - Imiprothrin  STP - S-Methoprene | 3.65E-04  1.13E-04 | (based on pure value without propellant)  (based on technical value without propellant) |

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

**Active substances**

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | STP | Air | Soil | Ground-water |
| Scenario 1 | Yes | Yes | Yes | n.r. | Yes | Yes |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| **Input** | Value | Unit | Remarks |
| **Imiprothrin** | | | |
| Molecular weight | 318.37 | g.mol-1 |  |
| Vapour pressure (at 25°C) | 1.86E-06 | Pa |  |
| Water solubility (at 25°C) | 93.5 | mg.L-1 | At pH6.5 |
| Log Octanol/water partition coefficient (LogKow) | 2.9 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 268 | L.kg-1 |  |
| Henry’s Law Constant (at 25° C) | 6.33E-06 | Pa.m-3.mol-1 | calculated |
| Biodegradability | Not readily biodegradable |  |  |
| DT50 for degradation in soil (at 12°C) | 1000 | d | WGI2017 |
| BCF fish | 144 | L.kg-1 | Normalised total residue – secondary poisoning not relevant |
| **S-Methoprene** |  |  |  |
| Molecular weight | 310.48 | g.mol-1 |  |
| Vapour pressure (at 20°C) | 6.23E-04 | Pa |  |
| Water solubility (at 20°C) | 6.85 | mg.L-1 |  |
| Log Octanol/water partition coefficient (LogKow) | 6.34 | Log 10 | pH7 |
| Organic carbon/water partition coefficient (Koc) | 876 | L.kg-1 |  |
| Henry’s Law Constant (at 20° C) | 0.0306 | Pa.m-3.mol-1 |  |
| Biodegradability | Not readily biodegradable |  |  |
| DT50 for degradation in soil (at 12°C) | 1.55 | d |  |
| BCF fish | 516 | L.kg-1 |  |
| BMF fish | 1 | - |  |
| BCF earthworm | 26254 | L.kg-1 | calculated |

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculated fate and distribution in the STP** | | | |
| Compartment | Percentage [%] | | Remarks |
| Imiprothrin | S-Methoprene |  |
| Air | 0.0 | 0.1 | Simple treat 4.0 |
| Water | 96.65 | 89.8 | Simple treat 4.0 |
| Sludge | 3.35 | 10.1 | Simple treat 4.0 |
| Degraded in STP | 0.0 | 0.0 | Simple treat 4.0 |

**Metabolites**

No relevant metabolite of S-Methoprene has been identified.

For Imiprothrin, 5 relevant metabolites have been identified during environmental fate studies: PGH, d-c/t-CRA, t-COOH-CA, CPG and PG. According to the CAR of Imiprothrin, the only compartment for which a specific assessment of the metabolites needs to be performed is surface water. For all other compartments, the assessment of the metabolites is covered by the parent compound Imiprothrin.

The risk assessment of metabolites in surface water is carried out by taking into account the maximum amount formed in water from the water/sediment study, adjusted for molecular weight. Those input values are summarised in the table below.

|  |  |  |
| --- | --- | --- |
| **Input parameters for calculating the surface water exposure to the relevant metabolites of Imiprothrin** | | |
| Metabolite | Maximum amount formed (%) | Molecular weight (g/mol) |
| PGH | 38.8 | 138.13 |
| d-c/t-CRA | 100 | 168.24 |
| t-COOH-CA | 100 | 158.15 |
| CPG | 49.2 | 156.14 |
| PG | 16.7\* | 113.12 |

\*Levels not observed in water so maximum level found in sediment used

***Calculated PEC values***

**Active substances**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** |
| [mg/L] | [mg/L] | [mg/kgwwt] | [mg/kg] | [μg/L] |
| **Tier 1 (Fce=1)**  Imiprothrin  S-Methoprene | 3.55E-04  6.96E-05 | 3.55E-05  6.95E-06 | 2.35E-04  1.38E-04 | 1.46E-04  2.94E-05\* | 2.79E-02  2.35E-05 |
| **Tier 2 (Fce refinement)**  Imiprothrin  S-Methoprene | 1.76E-04  5.09E-05 | 1.76E-05  5.08E-06 | 1.16E-04  1.01E-04 | 7.22E-05  2.15E-05\* | 1.38E-02  1.71E-05 |

NR: Not relevant (covered by surface water as EPM)

\* Initial concentration in agricultural soil after 10 years

**Metabolites**

As explained above, the risk assessment of metabolites in surface water is carried out by taking into account the maximum amount formed in water from the water/sediment study, adjusted for molecular weight (MW). Therefore, the PEC values of the metabolites are calculated using the following formula:

PECwater,metabolite = PECwater,imiprothrin \* MWmetabolite / MWimiprothrin\*Maximum amount formed

The obtained values are summarised in the table below.

|  |  |
| --- | --- |
| **Summary table on calculated PEC values – Imiprothrin metabolites** | |
|  | **PECwater** |
| [mg/L] |
| PGH | 5.98E-06 |
| d-c/t-CRA | 1.88E-05 |
| t-COOH-CA | 1.76E-05 |
| CPG | 8.57E-06 |
| PG | 2.11E-06 |

***Primary and secondary poisoning***

Primary poisoning

The product is aimed to be only used indoor. Therefore the potential for primary poisoning is negligible for the use evaluated.

Secondary poisoning

The active substance S-Methoprene has a log Kow > 3 (log Kow = 6.34) and a BCF > 100 (BCF in fish = 516 L.kg-1, BMF = 1 and BCF in earthworm = 26253.9 L.kg-1). According to the scenario, secondary poisoning may occur via the aquatic food chain and/or via the terrestrial food chain. The concentration of S-Methoprene in food (i.e. in fish and in earthworm) of fish-eating and worm-eating predators (mammals) has been calculated.

Results are summarised in the following table.

|  |  |  |
| --- | --- | --- |
| **Summary table on secondary poisoning** | | |
|  | **PECoral predator, fish** | **PECoral predator, earthworm** |
| [mg/kgwwt] | [mg/kgwwt] |
| **Tier 1 (Fce=1)**  S-Methoprene | 1.79E-03 | 3.08E-04 |
| **Tier 2 (Fce refinement):**  S-Methoprene | 1.31E-03 | 2.25E-04 |

Considering the very low BCF value for the Imiprothrin and its metabolites, no secondary poisoning is foreseen.

#### Risk characterisation

***Atmosphere***

Significant exposure of the environment via air is not expected.

Volatilization of Imiprothrin and S-Methoprene are considered to be negligible based on their respective vapour pressure (1.86E-06 Pa and 1.08E-03 Pa at 25°C) and Henry constant (6.33E-06 Pa.m3.mole-1 at 25°C and 1.78E-02 Pa.m3.mole-1 at 20°C). Imiprothrin and S-Methoprene would not be transported over large distances in the atmosphere in gaseous phase.

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

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

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECSTP** |
| **Tier 1 (Fce=1)**  Imiprothrin  S-Methoprene | 3.80E-05  1.02E-05 |
| **Tier 2 (Fce refinement):**  Imiprothrin  S-Methoprene | 1.88E-05  7.43E-06 |

Conclusion: PEC/PNEC for the STP compartment are <1. The risk is therefore acceptable.

***Aquatic compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
|  | **PEC/PNECwater** | **PEC/PNECsediment** |
| **Tier 1 (Fce=1)**  Imiprothrin  PGH  d-c/t-CRA  t-COOH-CA  CPG  PG  S-Methoprene | 9.35E-01  1.57E-01  4.94E-01  2.35E-04  2.26E-01  5.55E-02  3.66E-02 | 9.35E-01  NR  NR  NR  NR  NR  3.63E-01 |
| **Tier 2 (Fce refinement):**  Imiprothrin  PGH  d-c/t-CRA  t-COOH-CA  CPG  PG  S-Methoprene | 4.64E-01  7.80E-02  2.45E-01  1.17E-04  1.12E-01  2.75E-02  2.67E-02 | 4.64E-01  NR  NR  NR  NR NR  2.65E-01 |

NR: Not relevant (covered by surface water as EPM)

Conclusion: PEC/PNEC for the aquatic compartment are <1. The risks are therefore acceptable.

***Terrestrial compartment***

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values** | |
|  | **PEC/PNECsoil** |
| **Tier 1 (Fce=1)**  Imiprothrin  S-Methoprene | 7.91E-01  1.99E-04 |
| **Tier 2 (Fce refinement):**  Imiprothrin  S-Methoprene | 3.92E-01  1.45E-04 |

Conclusion: PEC/PNEC for the terrestrial compartment are <1. The risk is therefore acceptable.

***Groundwater***

Imiprothrin and S-Methoprene concentrations in groundwater do not exceed the trigger value of 0.1 µg/L. The risk is therefore acceptable.

***Primary and secondary poisoning***

Primary poisoning

Not relevant considering the application method of the biocidal product.

Secondary poisoning

The assessment of secondary poisoning is only relevant for S-Methoprene.

No ecotoxicological studies on bird are available in the CAR of S-Methoprene. Only data on small mammals are used to set a PNEC oral small mammals = 43.6 mg.kg food and only the PEC/PNECmammals ratios are presented below.

|  |  |  |
| --- | --- | --- |
| **Summary table on secondary poisoning – S-Methoprene** | | |
|  | **PEC/PNECmammals (aquatic)** | **PEC/PNECmammals (terrestrial)** |
| **Tier 1 (Fce=1)**  S-Methoprene | 4.11E-05 | 7.06E-06 |
| **Tier 2 (Fce refinement)**  S-Methoprene | 3.01E-05 | 5.16E-06 |

Conclusion: PEC/PNEC for secondary poisoning are <1. The risks are therefore acceptable.

***Mixture toxicity***

A mixture toxicity assessment was performed taking into account the simultaneous presence of both active substances (Imiprothrin and S-Methoprene). No substance of concern has been identified for the environment.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Summary table on calculated ∑PEC/PNEC value | | | | |
| STP Emission | PEC/PNECSTP | PEC/PNECwater | PEC/PNECsed | PEC/PNECsoil |
| **Indoor** | | | | |
| **Tier 1 (Fce=1)** | 4.82E-05 | 9.72E-01 | **1.30** | 7.91E-01 |
| **Tier 2 (Fce refinement)** | 2.63E-05 | 4.90E-01 | 7.29E-01 | 3.92E-01 |

Conclusion: For Tier 1, considering a default cleaning efficiency factor of 100%, PEC/PNEC summation are <1 for all environmental compartments, except for the sediment compartment where RCR is higher than 1.

Refinement of the fraction emitted to wastewater due to cleaning based on a study proposed by the applicant was discussed in confidential annex and agreed by FR CA. There it was concluded that data support the proposed reduction of cleaning efficiency factor (Fce) to 72.0% for S-Methoprene and 47.5% for Imiprothrin, decreasing PEC/PNEC values to <1 also for sediment. The risks are therefore acceptable after refinement.

Please note that this assessment was conducted considering an application rate of 200 mL per 100m3. However, as the intended uses are of 200 mL to treat rooms **up to** 100m3, than the product could be used in rooms smaller than 100 m3. For example, a bedroom is considered to be between 7 and 11 m2, corresponding to a volume of 17.5 to 27.5 m3 (cf ConsExpo General Factsheet[[12]](#footnote-13)). Therefore, in order to define a maximum of devices that can be applied in a domestic house without any risk for the environment, a reverse calculation was performed. Results are presented in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Summary table on calculated ∑PEC/PNEC value | | | | | |
| STP Emission | Max. number of device | PEC/PNECSTP | PEC/PNECwater | PEC/PNECsed | PEC/PNECsoil |
| **Tier 1 (Fce=1)** | 2 | 2.96E-05 | 5.98E-01 | 7.98E-01 | 4.87E-01 |
| **Tier 2 (Fce refinement)** | 4 | 3.23E-05 | 6.03E-01 | 8.96E-01 | 4.83E-01 |

The risk for the environment is considered to be acceptable if the number of device used in the domestic house does not exceed 4. Therefore, it was decided to add this following risk mitigation measure:

“Do not use more than 4 devices per house”

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

Aggregated exposure is not relevant since the environmental emissions are covered using a single scenario.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| FR CA concludes the product KAPO CHOC PUCES ET LARVES poses no risk to the aquatic and terrestrial environmental compartments for an indoor use, taking into account the intended application rate (200 mL until 100 m3) and the cleaning efficiency refinement supported by the following use recommendations:   * “Allow to act for 4 hours, then ventilate (4 hours minimum) before reusing the room, creating a stream of air between doors and windows wide open”.   Overall conclusion on the risk assessment for the environment of the product is summarized in the table below:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Summary table for the risk assessment of the product KAPO CHOC PUCES ET LARVES | | | | | | | Emission | PEC/PNECSTP | PEC/PNECwater | PEC/PNECsediment | PEC/PNECsoil | PECGW | | **Indoor** | | | | | | | STP | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | |

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

*See the SPC.*

### Assessment of a combination of biocidal products

Not relevant

# Annexes

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| B. Serrano | 2019 | SIMULATED-USE TRIAL OF THE EFFICACY OF AN INSECTICIDAL PRODUCT APPLIED AS A SPACE TREATMENT (ONE-SHOT AEROSOL)  Laboratoire T.E.C  No GLP; unpublished  Report n° 2483/0719 | Yes | BRUNEL CHIMIE  DERIVES S.A.S. |
| Dr L. Mack | 2020 | Determination of physico-chemical Properties and Accelerated Storage Stability Tests for ‘KAPO CHOC Puces et Larves’  BioGenius  Mo6525 (Interim report)  GLP; Unpublished | Yes | BRUNEL CHIMIE  DERIVES S.A.S. |
| Dr L. Mack | 2019 | Validation of Method MV224: BRU: GC-Determination of Methoprene and Imiprothrin in Aerosols  BioGenius  Mo6620  GLP; Unpublished | Yes | BRUNEL CHIMIE  DERIVES S.A.S. |
| Dr L. Mack | 2019 | Method Validation for Residual Analysis on 3 Surfaces, workup directly after spray application – Table of Results  BioGenius  No GLP; unpublished  Report n°CoA: AQ144-19 – Mo6526 – RT – method validation residues (3 surfaces) | Yes | BRUNEL CHIMIE  DERIVES S.A.S. |
| Dr L. Mack | 2019 | Method Validation for Residual Analysis on glazed tiles, workup directly after spray application – Table of Results  BioGenius  No GLP; unpublished  Report n°CoA: AQ149-19 – Mo6526 – RT – method validation residue (glazed tile) | Yes | BRUNEL CHIMIE  DERIVES S.A.S. |
| Dr L. Mack | 2019 | BRU: GC-MS-Determination of Residues of Methoprene and Imiprothrin on Surfaces  BioGenius  No GLP; unpublished  Report n°AQ115  Version 02 | Yes | BRUNEL CHIMIE  DERIVES S.A.S. |

## Output tables from exposure assessment tools

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## Residue behaviour

To demonstrate the residues concentration of the active substances on the treated surfaces after application of the KAPO CHOC product, the applicant provided the following study : ”*Residue analysis of Methoprene and Imiprothrin on Surfaces for Aerosol ‘Kapo Choc’* ”. This study was aimed at the determination of residues taking into account steps of the possible instructions of use of the product as well as some surface type in order to cover the possible surfaces which could be find in houses of general consumer.

The different time at which the residue level was measured were the following:

1. Directly after application,
2. After 4 hours of treatment and 4 additional hours of ventilation with open doors and windows – natural ventilation,
3. After vaccum cleaning (one wipe per surface) which took place after 4 hours of treatment and 4 hours of natural ventilation of treated room,
4. After dry cleaning with a dry wipe (one wipe per surface) which took place after 4 hours of treatment and 4 hours of natural ventilation of treated room.

The tested surfaces were as described here below:

1. Porous unglazed tillin: in order to imitate porous surface types
2. Carpet: in order to imitate possible carpet or other tissues surfaces
3. Linoleum: in case some housing would have this kind of floor covering, and which was thought to be a non-porous surface on which a large amount of residues could be found after product application
4. Glazed tile: in order to have another non-porous surface in addition of the linoleum and on which a large amount of residues is expected after application.

A surface of 15\*15 cmin size of each surface sample was sprayed with an application rate of 9.1 ml/m² which corresponds to the application of a total amount of 200mL of product in a standard room of 22 m².

Please note the method was validated according to the report “AQ115 BRU: GC-MS-Determination of residues of Methoprene and Imiprothrin on Surfaces” which is developed in the section Method of analysis of the PAR.

As a low recovery of residues percentage was find with the surfaces 1 to 3 as described here above, the additional surface “glazed tile” was added. Indeed, a hogher recovery was obtained with this surface type. This criteria was indeed really important to validate the method.

This first study also showed linoleum was not to considered as a non-porous surface as the product seems to immediately migrates into the polymer ans was not available anymore for post-application treatment as vacuum and dry wiping of the treated surface.

The protocol of the study as well as the results are developed in more details here below.

But please note the worst-case results of residues concentrations were used for Human health and environmental risk assessments. Indeed, the glazed tile is the surface on which there is the most important residues concentrations to which environment or humans can be exposed afterwards.

1. **Protocol:**

The liquid was sprayed with a pump spray flask onto the surfaces.

The quantity applied of approx. 0.2 ml / surface (15 cm x 15 cm) was equivalent to a sprayed quantity of 9 ml/m².

Later, the surfaces were transferred to the test room and analyzed after the treatments as described here above from a to d.

The surfaces were wiped off with acetone soaked cellulose towels, 15 x 15 cm in size, once in longitudinal direction and once perpendicular to that direction. These towels were extracted in acetone and the content of the active substances was determined according to method BioG AQ115.

1. **Results:**

* Surfaces 1 to 3: the residues percentages are really low (below 12% for S-methoprene and below 1.8% for total Imiprothrin).

In absorbent surfaces, this low residual amounts of active substances assumes that the rest of the active ingredients has already diffused into the material. For the non-porous surface vinyl linoleum, this low amount can be explained by the possible migration of the active substances into the polymer, the active ingredients being not released anymore by the material.

* Surface 4 shows the highest residues concentration for all the surface types.

The post-application of the treated surface globally reduces the active substances residues content on surface after they have been applied, except for vacuum application on glazed tile which does not reduce a lot the S-methoprene available residues, but which is still effective for Imiprothrin.

**Table : Residues (Recoveries) of S-Methoprene on surfaces after above post-application treatment**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Surface | Treatment | Residues  (Recoveries)  [%] | | | Mean  residue  [%] |
| porous unglazed tile | A | 13.0 | 14.2 | 8.8 | 12.0 |
| B | 11.3 | 9.5 | 11.2 | 10.7 |
| C | 3.3 | 3.7 | 5.5 | 4.2 |
| D | 0.0 | 0.0 | 1.1 | 0.4 |
| carpet | A | 7.7 | 5.4 | 10.1 | 7.7 |
| B | 9.9 | 12.2 | 8.8 | 10.3 |
| C | 1.9 | 2.9 | 1.4 | 2.1 |
| D | 6.4 | 7.1 | 0.0 | 4.5 |
| vinyl linoleum | A | 2.9 | 1.1 | 2.3 | 2.1 |
| B | 1.6 | 2.5 | 0.0 | 1.4 |
| C | 0.0 | 0.9 | 0.0 | 0.3 |
| D | 3.3 | 3.2 | 0.0 | 2.2 |
| glazed tile | A | 84.6 | 81.5 | 81.5 | 82.6 |
| B | 61.6 | 52.8 | 64.1 | 59.5 |
| C | 64.7 | 70.6 | 64.2 | 66.5 |
| D | 50.1 | 49.8 | 43.5 | 47.8 |

**Table: Residues (Recoveries) of Imiprothrin (total cis- and trans-Isomers) on surfaces after above post-application treatment**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Surface | Treatment | Residues  (Recoveries) | | | Mean  residue  [%] |
| porous unglazed tile | A | 0.6 | 0.5 | 0.5 | 0.5 |
| B | 0.5 | 0.4 | 0.4 | 0.4 |
| C | 0.1 | 0.3 | 0.4 | 0.3 |
| D | 0.1 | 0.1 | 0.1 | 0.1 |
| carpet | A | 3.6 | 3.4 | 3.8 | 3.6 |
| B | 2.6 | 1.7 | 1.3 | 1.8 |
| C | 1.2 | 1.7 | 1.1 | 1.3 |
| D | 0.8 | 2.5 | 0.8 | 1.4 |
| vinyl linoleum | A | 0.9 | 1.1 | 0.8 | 1.0 |
| B | 0.6 | 0.8 | 0.6 | 0.7 |
| C | 0.7 | 1.0 | 0.6 | 0.8 |
| D | 0.8 | 0.7 | 0.6 | 0.7 |
| glazed tile | A | 75.9 | 77.4 | 75.3 | 76.2 |
| B | 37.9 | 32.8 | 37.7 | 36.2 |
| C | 34.6 | 28.7 | 32.5 | 31.9 |
| D | 31.3 | 27.6 | 24.4 | 27.8 |

1. **Conclusion**

The residual amounts of (S)-Methoprene, and Imiprothrin (cis- and trans-isomers) were investigated after application of the test item on four different kinds of surfaces, i.e. porous unglazed tiles, carpet, vinyl linoleum and glazed tiles and after following treatments of the surfaces: ventilated storage and ventilated storage followed by vacuum cleaning or dry wiping.

Fairly low residual amounts of the active substances were found on the absorbent surfaces (porous tiles, carpet) and on the linoleum directly after application. For Imiprothrin these were ≤ 1% of the total applied amount on porous tiles and linoleum and 3.6 % on the carpet. For (S)-Methoprene these were 12.0 % on porous tiles, 7.7 % on carpet and 2.1 % on linoleum, only.

In case of the absorbent materials it is assumed that the rest of the active substance has already diffused into the material directly after application, in case of the linoleum it is assumed that the active substances have migrated into the polymer immediately and are not available anymore for possible future exposure.

On the non-absorbent glazed tiles high recoveries of 82.6 % of the applied (S)-Methoprene and 76.2% of the total Imiprothrin were obtained directly after application. This is an internal validation of the wiping procedure and the method of analysis. The loss to 100 % can be explained by spraying loss.

In general, all treatments significantly reduced the residual amounts of active substances on all four surfaces compared to the starting values.

This residue study is used in order to refine the Human Health Risk Assessment and the Environmental Risk Assessment. The results finally show that the natural ventilation of the treated room is sufficient to guarantee a safe exposure of humans and environment to the product. However, in order to show the post-application treatment can also lead to a better health protection, the different exposure to residues after dry wiping were also chosen in higher tier approach.

These post-applications instructions are in line with instructions of use of this one -shot aerosol insecticide, which guarantee a sufficient level of protection.

## Summaries of the efficacy studies

See UICLID dossier.

## Confidential annex

See separated confidential annex.

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
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3. Gray L, Florez SD, Barreiro AM, Valdillo-Sánchez J, González-Olvera G, Lenhart A, et al. Experimental evaluation of the impact of household aerosolized insecticides on pyrethroid resistance *Aedes aegypti*. Sci Rep. 2018;8:12535. [↑](#footnote-ref-4)
4. Lau, K.W., Chen, C.D., Lee, H.L., Norma-Rashid, Y., and Sofian-Azirun, M. (2015). Evaluation of Insect Growth Regulators Against Field-Collected *Aedes aegypti* and *Aedes albopictus* (Diptera: Culicidae) from Malaysia. Journal of Medical Entomology 1-8. [↑](#footnote-ref-5)
5. Vasquez, M.I., Violaris, M., Hadjivassilis, A., and Wirth, M.C. (2009). Susceptibility of *Culex pipiens* Field Populations in Cyprus to Conventional Organic Insecticides, Bacillus thuringiensis subsp. israelensis, and Methoprene. Journal of Medical Entomology, 46 881-887. [↑](#footnote-ref-6)
6. Minkoff III, C., and T.G. Wilson. (1992). The Competitive Ability and Fitness Components of the Methoprene-Tolerant (Met) Drosophila Mutant Resistant to Juvenile Hormone Analog Insecticides. Genetics, 131 91-97. [↑](#footnote-ref-7)
7. Kristensen M., and Jespersen J. B. (2003). Larvicide Resistance in *Musca domestica* (Diptera: Muscidae) Populations in Denmark and Establishment of Resistant Laboratory Strains. Journal of Economic Entomology, 96 (4) 1300-1306. [↑](#footnote-ref-8)
8. Study No. Mo6527, Dr Lienhard Mack, 2019, Residue analysis of methoprene and imiprothrin on surfaces for aerosol ‘Kapo choc’ [↑](#footnote-ref-9)
9. EFSA Scientific Committee; Guidance on selected default values to be used by the EFSA Scientific

   Committee, Scientific Panels and Units in the absence of actual measured data. EFSA Journal 2012;10(3):2579. [32 pp.] doi:10.2903/j.efsa.2012.2579. Available online: www.efsa.europa.eu [↑](#footnote-ref-10)
10. Study No. Mo6527, Dr Lienhard Mack, 2019, Residue analysis of methoprene and imiprothrin on surfaces for aerosol ‘Kapo choc’ [↑](#footnote-ref-11)
11. Guidance on the BPR : Volume III Parts B+C. December 2017. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses. [↑](#footnote-ref-12)
12. https://www.rivm.nl/en/consexpo#Fact\_sheets [↑](#footnote-ref-13)