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 APPLICATION**

(submitted by the competent authority)



**BROS Pršilo proti komarjem za otroke**

Product type 19

Ethyl butylacetylaminopropionate

Case Number in R4BP: BC-CN051010-60

Evaluating Competent Authority: Slovenia

Date: January 2022

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# CONCLUSION

BROS Pršilo proti komarjem za otroke is a ready-for-use liquidbiocidal product in a bottle with pump spray containing ethyl butylacetylaminopropionate (IR3535®) as active substance. The product is used as a repellent by general public (non-professionals)for the control of house mosquitoes, tropical mosquitoes occurring in temperate climate and ticks.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the use as repellent against house mosquitoes, tropical mosquitoes occurring in temperate climate and ticks used by general public (non-professionals), as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

**General**

Detailed information on the intended use of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2.1 of the PAR.

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

A classification according to Regulation (EC) No 1272/20082 is necessary. Detailed information on classification and labelling is provided in section 2.1.3 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

The biocidal product contains non-active substances (so called “co-formulants”) which are considered as substances of concern. The non-active substances considered as substances of concern are ethanol and isopropanol. Use in accordance with the directions for use, as specified in the SPC, does not present an unacceptable risk due to presence of substances of concern. More detailed information on the substances of concern is provided in the confidential annex.

The biocidal product should be considered not to have endocrine-disrupting properties*.*

The biocidal product contains the active substance ethyl butylacetylaminopropionate (IR3535®), which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

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

More information is available in section 2.1.2.6 of the PAR and in the confidential annex.

The biocidal product contains ethyl butylacetylaminopropionate (IR3535®) which does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered as a candidate for substitution. Therefore, a comparative assessment of the biocidal product is not required.

**Composition**

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.3 of the SPC.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product are met. More information is available in sections 2.1.2.1, 2.1.2.3 and 2.1.2.4 of the PAR. The manufacturer of the active substance is listed in section 1.4 of the SPC.

**Conclusions of the assessments for each area**

The intended use as applied for by the applicant has been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 2.2.2 of the PAR.

A physical hazard was identified (Flammable Liquids, Category 2). More information is available in section 2.2.3 of the PAR.

Methods for detection and identification

A validated analytical method for the determination of the concentration of the active substance is available. More information on the analytical method for the active substances is available in section 2.2.4 of the PAR.

Validated analytical method is provided for monitoring of relevant components of the biocidal product and/or residues in soil, air, water, animal and human body fluids, and in food and feeding stuff. More information is available in section 2.2.4 of the PAR.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against house mosquitoes (*Culex* spp.), tropical mosquitoes *(Aedes* spp.)occurring in temperate climate and hard ticks(*Ixodes* sp.) for the intended use. More information is available in section 2.2.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 2.2.6 of the PAR.

Based on the risk assessment, it is unlikely that the intended use causes any unacceptable acute or chronic risk to non-professional users and non-professional bystanders/general public, if the directions for use, as specified in the SPC, are followed.

Dietary risk assessment

Considering the use, food or feed contamination is considered negligible if biocidal product is used as specified in the SPC. No dietary risk assessment has been performed. Risk mitigation measures have been added to avoid any food contamination by the product. More information is available in section 2.2.6 of the PAR.

Risk assessment for animal health

Considering the uses, exposure to animals is not expected. Therefore, no risk assessment for animal health has been performed.

Risk assessment for the environment

A risk assessment for the environment has been carried out for the intended use as applied for by the applicant. More information is available in section 2.2.8 of the PAR.

Ethanol and propan-2-ol are substances of concern in the product as they are active substances in PT 1, 2 and 4 and present in the product with a concentration ≥ 0.1%. However, the risk assessment for the environment is based on ethyl butylacetylaminopropionate (IR3535®) only. Please see section 2.2.8 of the PAR for more details.

Based on the risk assessment, it is unlikely that the intended use causes any unacceptable risk for the environment, if the directions for use, as specified in the SPC, are followed.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| BROS Pršilo proti komarjem za otroke | Slovenia |
| BROS Płyn na komary i kleszcze dla dzieci I | Poland |
| BROS repelent proti komárům pro děti | Czech Republic |
| BROS Kids szúnyogriasztó pumpás aeroszol | Hungary |
| BROS Purškiklis nuo uodų sensitive | Lithuania |
| BROS Līdzeklis pret odiem bērniem | Latvia |
| BROS Sääsetõrjepihusti lastele | Estonia |
| BROS лосион против комари Sensitive | Bulgaria |
| BROS SOLUŢIE ÎMPOTRIVA ŢÂNŢARILOR (ADECVATĂ ŞI PENTRU COPII) | Romania |
| BROS Losion protiv komaraca – za djecu | Croatia |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | BROS Spółka z ograniczoną odpowiedzialnością  |
| **Address** | ul. Karpia 24, 61-619 Poznań, Poland |
| **Authorisation number** |  |
| **Date of the authorisation** |  |
| **Expiry date of the authorisation** |  |

#### Manufacturer of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | BROS Spółka z ograniczoną odpowiedzialnością  |
| **Address of manufacturer** | ul. Karpia 24, 61-619 Poznań, Poland |
| **Location of manufacturing sites** | ul. Karpia 24, 61-619 Poznań, Poland |

#### Manufacturer of the active substance

|  |  |
| --- | --- |
| **Active substance** | Ethyl butylacetylaminopropionate |
| **Name of manufacturer** | Merck KGaA |
| **Address of manufacturer** | Frankfurter Straße 250, 64293 Darmstadt, Germany |
| **Location of manufacturing sites** | Poligono Merck, 08100 Mollet del Vallés, Barcelona, Spain |

### 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 [x]

#### Identity of the active substance

|  |
| --- |
| **Main constituent(s)** |
| **ISO name** | IR3535® |
| **IUPAC or EC name** | 3-(N-acetyl-N-butyl)aminopropionic acid ethyl ester |
| **EC number** | 257-835-0 |
| **CAS number** | 52304-36-6 |
| **Index number in Annex VI of CLP** | - |
| **Minimum purity / content** | >99% w/w |
| **Structural formula** |  |

#### Candidate for substitution

The active substance is not a candidate for substitution.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Ethyl butylacetyl-aminopropio-nate (IR3535®) | 3-(N-acetyl-N-butyl)aminopropionic acid ethyl ester  | Active substance | 52304-36-6 | 257-835-0 | 17.000 (as pure) 17.300 (as technical) |

Full composition is available in the confidential annex.

#### Information on technical equivalence

Not applicable. The manufacturer is the same as included in the Union list of approved active substances.

#### Information on the substances of concern

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Ethanol | Ethanol | Solvent | 64-17-5 | 200-578-6 | 44.054 |
| Isopropanol | Propan-2-ol | Denaturant | 67-63-0 | 200-661-7 | 0.945 |

Please see the confidential annex for further details.

#### Information on endocrine disrupting properties

In reference to toxicity of the mixture, hazard of potential endocrine-disrupting properties should be identified. The active substance is currently not considered as an identified ED substance to have endocrine disrupting properties under Regulation (EU) 528/2012. A step-wise approach for a targeted determination of whether a non-active substance (co-formulant) in a biocidal product is an ED or has indications of ED properties was used in the assessment (Please refer to confidential annex). Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

#### Type of formulation

|  |
| --- |
| AL - Other Liquids to be applied undiluted |

### Hazard and precautionary statements

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

| **Classification** |
| --- |
| Hazard category | Flammable liquid, category 2Eye irritation, category 2 |
| Hazard statement | H225: Highly flammable liquid and vapour.H319: Causes serious eye irritation |
| **Labelling** |
| Signal words | Danger |
| Hazard statements | H225 Highly flammable liquid and vapour.H319 Causes serious eye irritation. |
| Precautionary statements | P101 If medical advice is needed, have product container or label at hand.P102 Keep out of reach of children.  P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.P264 Wash hands thoroughly after handling.P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.P337 + P313 If eye irritation persists: Get medical advice/attention.P501 Dispose of contents/container in accordance with local regulations. |
| Note | Precautionary statement »P233 Keep container tightly closed.« is triggered by H225. Due to the type of closure (pump spray cap) typically used for repellents this statement is not relevant since the bottle is never being opened by the user. |

### Authorised use

#### Use description

Table 1. Use # 1 – House mosquito, tropical mosquito and tick repellent

|  |  |
| --- | --- |
| **Product Type** | PT19 - Repellents and attractants |
| **Where relevant, an exact description of the authorised use** | Repellent |
| **Target organism (including development stage)** | House mosquitoes (*Culex* spp*.)* – adultTropical mosquitoes (*Aedes* spp*.)* – adultTicks (*Ixodes* sp.) - adult |
| **Field of use** | Repellent used on human skin (outdoor and indoor).Product is intended to be used in temperate climate only. |
| **Application method(s)** | Manual spraying |
| **Application rate(s) and frequency** | Rate 0.43 mg/cm2 of skin (0.24 g of the product per forearm) once a day:* Children 1 to < 2 years old - use once a day app. 7 pump-sprays on all uncovered skin areas.
* Children 2 to < 6 years old - use once a day app. 10 pump-sprays on all uncovered skin areas.
* Children 6 to < 12 years old - use once a day app. 13 pump-sprays on all uncovered skin areas.
* Children 12 to < 18 years old - use once a day app. 22 pump-sprays on all uncovered skin areas.
* Adults - use once a day app. 24 pump-sprays on all uncovered skin areas.

Effective against house mosquitoes for 6.5 h (median CPT is 390 ± 51 min for *Culex* spp.).Effective against tropical mosquitoes in temperate climate for 4 h (median CPT is 240 ± 51 min for *Aedes* spp.).Effective against ticks for 5 h. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | See section 2.1.7 for more details |

#### Use-specific instructions for use

|  |
| --- |
| Please see section 2.1.5.1. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Please see section 2.1.5.2. |

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

|  |
| --- |
| Please see section 2.1.5.3. |

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

|  |
| --- |
| Please see section 2.1.5.4. |

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

|  |
| --- |
| Please see section 2.1.5.5. |

### General directions for use

#### Instructions for use

|  |
| --- |
| Apply by spraying evenly on skin from 15 cm distance. Product is to be applied on uncovered human skin (to face, neck, arms, hands, legs and feet only).Do not apply under clothing. Prevent contact of the product with synthetic materials. Before use, test the compatibility of the product with textiles on a hidden part of the garment. Apply once a day to adults and on children.Do not apply on broken or irritated skin.Sunscreens or other cosmetics used after the repellent has been applied considerably lower its effectiveness. |

#### Risk mitigation measures

|  |
| --- |
| Do not use on children under 1 year of age.For children of 1 to 12 years: the repellent must be applied by adults.Do not apply the product directly to face - first, spray it onto palm of the hand, then spread avoiding eyes.Do not apply onto children's hands.Wash hands before handling food.Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed and drinks.To prevent contamination of food, avoid contact of treated skin with food.Do not breathe vapours of the product. Use only outdoors or in well ventilated rooms. Do not use near domestic animals or livestock.Do not apply directly on animals. |

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

|  |
| --- |
| First aid instructions:IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.IF ON SKIN: If symptoms occur, wash skin with water and call a POISON CENTRE or a doctor.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.  |

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

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

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

|  |
| --- |
| Store in a cool, dry, well ventilated place. Shelf life 2 years. |

### Other information

|  |
| --- |
| Not relevant |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging**  | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle | 50 - 300 ml(50 ml, 75 ml, 100 ml, 125 ml, 150 ml, 200 ml, 250 ml, 300 ml) | PE or HDPE or PP or PVC or PET or glass | Pump spray (PP or PE), cap (PP or PE) or trigger (PP or PE)  | Non-professional | Yes |

### Documentation

#### Data submitted in relation to product application

See point 3.1.

#### Access to documentation

Aletter of access of Merck KGaA grants access to data concerning Ethyl butylacetylaminopropionate technical.

## Assessment of the biocidal product

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

Table 2. Intended use #1 – Mosquito and tick repellent

|  |  |
| --- | --- |
| Product Type(s) | PT19 - Repellents and attractants |
| Where relevant, an exact description of the authorised use | Repellent |
| Target organism (including development stage) | Ticks: *Ixodes* sp. (adults)Mosquitoes: *Culex* spp*.* (adults)  *Aedes* spp*.* (adults) |
| Field of use | Outdoor, indoorProduct is intended to be used in temperate climate only. |
| Application method(s) | Manual spraying - hold 15 cm away from skin and then spray the product only on face, neck, arms, hands, legs and feet. Do not apply the product directly to face - first, spray it onto palm of the hand, then spread avoiding eyes. |
| Application rate(s) and frequency | 0.43 mg/cm2 of skin (0.24 g of the product per forearm)Children 1 to < 2 years old - use once a day app. 7 pump-sprays on all uncovered skin areas.Children 2 to < 6 years old - use once a day app. 10 pump-sprays on all uncovered skin areas.Children 6 to < 12 years old - use once a day app. 13 pump-sprays on all uncovered skin areas.Children 12 to < 18 years old - use once a day app. 22 pump-sprays on all uncovered skin areas.\*Adults - use once a day app. 24 pump sprays on all uncovered skin areas. CPT for mosquitoes *Culex* spp*.* is 390 ± 51 min and for *Aedes* spp*.* 240 ± 51 min. |
| Category(ies) of user(s) | Non-professional |
| Pack sizes and packaging material | See section 2.1.7. for more details |
| \* based on 55% of the average body surface in children 12-18 y.o. in RIVM report 090013003/2014 the amount of bp per application is 3.6 g |

### Physical, chemical and technical properties

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| Physical state at 20 °C and 101.3 kPa | Visual/olfactory | Mosquito and Tick Pump Spray for Children IBatch No. Pr.09A - Production 10/9/18 | Colourless translucent liquid with a characteristic odour | Elisabeth Servajean 2019 |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa |
| Acidity / alkalinity | -CIPAC 75.3 -CIPAC MT191 | Mosquito and Tick Pump Spray for Children IBatch No. Pr.09A - Production 10/9/18 | - neat (undiluted) 6.9- measured only upon receipt: 0.003% w/w as H2SO4 | Elisabeth Servajean 2019 |
| Relative density / bulk density | OECD 109 | Mosquito and Tick Pump Spray for Children IBatch No. Pr.09A - Production 10/9/18 | D204 = 0.916Density = 0.915 kg/L | Elisabeth Servajean 2019 |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 | Mosquito and Tick Pump Spray for Children IBatch No. Pr.09A - Production 10/9/18 | The product was stored for 8 weeks at 40 ± 2 °C in the initial sealed containers and mean air moisture %.

|  |  |  |
| --- | --- | --- |
| Parameter | Initial | After 8 weeks at 40 °C |
| IR3535 [g/kg] | 170.9 ± 4.2 | 167.1 ± 4.8 (2.2 % loss) |
| Appearance | Colourless translucent liquid | Colourless translucent liquid |
| Odour | Characteristic | Characteristic |
| Weight change | - | 0.5 – 0.6 % |
| pH, neat | 6.9 | 7.0 |
| Kinematic viscosity at 20 °C  | 5.41 ±0.01 mm2/s | 5.45 ±0.01 mm2/s |
| Kinematic viscosity at 40 °C | 3.06 ±0.00 mm2/s | 3.06 ±0.00 mm2/s |
| Surface tension at 20 °C | 27.6 mN/m | 27.6 mN/m |
| Discharge rate | U1: 0.16g ± 0.01 g/stroke (N=25) U2: 0.16g ± 0.01 g/stroke (N=25) | U1: 0.15g ± 0.01 g/stroke (N=24) U2: 0.16g ± 0.01 g/stroke (N=25) |

The concentration of the active substance decreased by 2.2%. Other parameters changed only slightly. The product was stable for 8 weeks at 40.5 °C. | Elisabeth Servajean 2019 |
| Storage stability test – **long term storage at ambient temperature** |  | Mosquito and Tick Pump Spray for Children IBatch No. Pr.09A - Production 10/9/18 | The product was stored for 24 months at room temperature in the initial sealed containers.

|  |  |  |
| --- | --- | --- |
| Parameter | Initial | After 24 months at ambient temperature |
| IR3535 [g/kg] | 170.9 ± 4.2 | 167.0 ± 1.6 (2.3 % loss) |
| Appearance | Colourless translucent liquid | Colourless translucent liquid |
| Odour | Characteristic | Characteristic |
| Weight change | - | 0.3 – 0.4 % |
| pH, neat | 6.9 | 7.2 |
| Free acidity | 0.003 % w/w H2SO4 | 0.003 % w/w H2SO4 |
| Kinematic viscosity at 20 °C  | 5.41 ±0.01 mm2/s | 5.75 ±0.00 mm2/s |
| Kinematic viscosity at 40 °C | 3.06 ±0.00 mm2/s | 3.11 ±0.00 mm2/s |
| Surface tension at 20 °C | 27.6 mN/m | 27.6 mN/m |
| Discharge rate | U1: 0.16g ± 0.01 g/stroke (N=25) U2: 0.16g ± 0.01 g/stroke (N=25) | U1: 0.15g ± 0.01 g/stroke (N=25) U2: 0.16g ± 0.01 g/stroke (N=25) |

The concentration of the active substance decreased by 2.3 %. Other parameters changed only slightly. The product was stable for 24 months at ambient temperature. | Elisabeth Servajean 2019Elisabeth Servajean 2020 |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT39.3 | Mosquito and Mosquito and Tick Pump Spray for Children IBatch No. Pr.09A - Production 10/9/18 | The product was stored for 7 days at 0 ± 2 °C in the initial sealed containers.

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| Parameter | Initial | After 7 days at 0 °C |
| IR3535 [g/kg] | 170.9 ± 4.2 | 167.5 ± 6.6 (2.0 % loss) |
| Appearance | Colourless translucent liquid | Colourless translucent liquid |
| Odour | Characteristic | Characteristic |
| pH, neat | 6.9 | 7.3 |
| Discharge rate | U1: 0.16g ± 0.01 g/stroke (N=25) U2: 0.16g ± 0.01 g/stroke (N=25) | U1: 0.15g ± 0.01 g/stroke (N=24) U2: 0.16g ± 0.01 g/stroke (N=25) |

The concentration of the active substance decreased by 2.0%. Other parameters changed only slightly. The product was stable for 7 days weeks at 0 °C. | Elisabeth Servajean 2019 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Waived | - | The package precludes the effect of light to be considered. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Organoleptic | Mosquito and Tick Pump Spray for Children IBatch No. Pr.09A - Production 10/9/18 | The package is tightly closed, therefore there are no effects on the a.s. content due to humidity.Regarding the temperature stability, the effect is described above.  | Elisabeth Servajean 2019 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Organoleptic | Mosquito and Tick Pump Spray for Children IBatch No. Pr.09A - Production 10/9/18 | No indication of decomposition (e.g. leaking, breaking, clogging or damage) was observed. | Elisabeth Servajean 2019 |
| Wettability | Waived | - | Not relevant, the product is a liquid formulation. |  |
| Suspensibility, spontaneity and dispersion stability | Waived | - | Not relevant, the product is not a suspension. |  |
| Wet sieve analysis and dry sieve test | Waived | - | Not relevant, the product is liquid formulation. |  |
| Emulsifiability, re-emulsifiability and emulsion stability | Waived | - | Not relevant, the product is not an emulsion. |  |
| Disintegration time | Waived | - | Not relevant, the product is not a tablet, not relevant. |  |
| Particle size distribution, content of dust/fines, attrition, friability | CIPAC MT187 | Mosquito and Tick Pump Spray for Children IBatch No. Pr.09A - Production 10/9/18 | Dv(10)µm: 35.01Dv(16)µm: 39.90Dv(50)µm: 62.14Dv(84)µm: 93.98Dv(90)µm: 104.70Dv(99)µm: 143.40D[3,2] µm: 52.80D[4,3] µm: 66.30%V < 15 µm: 1.61%V < 10 µm: 1.60%V < 5 µm: 0.00 %V < 1 µm: 0.00 | Marzena Włodarczak 2018 |
| Persistent foaming | Waived | - | The product is not intended to be diluted with water. |  |
| Flowability/Pourability/ Dustability | Waived | - | Not relevant, the product is not a solid. |  |
| Burning rate — smoke generators | Waived | - | Not relevant, the product is not a smoke generator. |  |
| Burning completeness — smoke generators | Waived | - | Not relevant, the product is not a smoke generator. |  |
| Composition of smoke — smoke generators | Waived | - | Not relevant, the product is not a smoke generator. |  |
| Spraying pattern — aerosols | Waived  | - | Not relevant, the product is not an aerosol. |  |
| Physical compatibility | Waived  | - | The product is not intended to be mixed with other products. |  |
| Chemical compatibility | Waived  | - | The product is not intended to be mixed with other products. |  |
| Degree of dissolution and dilution stability | Waived | - | The product is not intended to be diluted with water or any other solvents. |  |
| Surface tension | OECD 115 | Mosquito and Tick Pump Spray for Children IBatch No. Production 10/9/18 | At 20 °C = 27.6 mN/m | Elisabeth Servajean 2019 |
| Viscosity | OECD 114 | Mosquito and Tick Pump Spray for Children IBatch No. Production 10/9/18 | Kinematic Viscosity:- at 20 °C: 5.41 ± 0.01 mm2/s- at 40 °C: 3.06 ± 0.00 mm2/s | Elisabeth Servajean 2019 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| BROS Pršilo proti komarjem za otroke is a ready-to-use liquid (AL) formulation type. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w))** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | Waived | - | None of the formulants are classified/reported to be explosive. Furthermore, formulation contains no oxidisers, no strong reducing agents. Over 99% of the composition are substances well tested and well-known to have no explosive properties and there is no chemical reaction possible between these components and thus it cannot form other substances that are possibly explosive. In this case the formulation will not possess explosive effects. Based on CLP criteria, point 2.1.4.2. substances that are considered as explosives must contain functional groups, such as: C-C unsaturated, C-Metal, N-Metal, azides, azo, diazo, hydrazines (any N-N bonds), peroxides, ozonides (any O-O bonds), N-O groups (nitrates, nitro, oxides, oxazoles etc), N-halogen, O-halogen. Based on the structure of each co-formulant, which does not contain any of the above functional groups as well as the CLP criteria point 2.1.4.2., where a substances or a mixture contained none of the aforementioned groups, the product is not classified as explosive. Additionally to some of the compounds the calculated oxygen balance showed values below -200, which reflects non-classification as explosive. Moreover, the SDS of each co-formulant suggests the non-explosive properties. |  |
| Flammable gases | Waived | - | Not relevant, the formulation does not contain any gaseous ingredients. |  |
| Flammable aerosols | Waived | - | Not relevant the product is not an aerosol. |  |
| Oxidising gases | Waived | - | Not relevant the product does not contain gases. |  |
| Gases under pressure | Waived | - | Not relevant the product does not contain any gases under pressure. |  |
| Flammable liquids | Abel closed-up methodEC A.2 / OECD No. 103 | Mosquito and Tick Pump Spray for Children IBatch No. Production 10/9/18 | Flash Point: 21.0 ± 1.0 °C. Classification: Flammable LiquidBoiling Point: 91.6 ± 0.6 °C Classification: Flammable Liquid, category 2 | Paulina Flasińska 2018J. Kalbarczyk, 2021 |
| Flammable solids | Waived | - | Not relevant the product is not a solid. |  |
| Self-reactive substances and mixtures | Waived | - | Not relevant, the formulation does not contain any components and mixtures that are self-reactive. The mixture is not classified as explosive, which means it does not contain any specified functional groups in all co-formulants listed in the Confidential Annex. Additionally, none of the co-formulants are oxidising and does not contain any peroxides. |  |
| Pyrophoric liquids | Waived | - | Not relevant the formulation does not contain any components that are reactive towards air, or any other components/substances therefore are not pyrophoric. |  |
| Pyrophoric solids | Waived | - | Not relevant the product is not a solid. |  |
| Self-heating substances and mixtures | Waived | - | Not relevant the product is not a solid. Additionally, none of the components are classified/reported as self-heating. Additionally, none of the co-formulants, listed in the Confidential Annex, are oxidising and does not contain any peroxides. |  |
| Substances and mixtures which in contact with water emit flammable gases | Waived | - | The product is not intended to be diluted with water nor contains any water reactive ingredients. |  |
| Oxidising liquids | Waived | - | The formulation does not contain any oxidising components nor such chemical structures. |  |
| Oxidising solids | Waived | - | Not relevant the product is not a solid. |  |
| Organic peroxides | Waived | - | Not relevant the product does not contain any organic peroxides. |  |
| Corrosive to metals | Waived | - | The biocidal product fulfils all required criteria described in the Technical Agreements for Biocides Released on August 2018. The tests are not required when the product is:- halogen-free - no acid- no base- no complexing agents- pH-neutraltherefore, the biocidal product fulfils all criteria mentioned above. Hence the test is not required. Based on Point 2.16. of the CLP criteria no tests are needed when there are no substances that possess strong acidic or strong basic character that could reflect the pH value of the biocidal product and consequently initiate the corrosion process. In our mixture we do not have any strong acids nor strong bases and not even any halogen atoms or salts- all chemical structures are pictured in the Confidential Annex proving this justification. Neither the structure contain any halogen-carbon bonds. Each structure of the substances showed that they are rather neutral then acidic or basic and it reflects the almost neutral pH of the biocidal product. All criteria mentioned in the Technical Agreements for Biocides Released on August 2018 and CLP, Point 2.16. are fulfilled and no testing needs to be conducted for this biocidal product. |  |
| Auto-ignition temperatures of products (liquids and gases) | EC A15 auto-ignition temp (l & g) | Pump Spray Formula | Auto-ignition temperature: 415.0 °C | Paulina Flasińska 2018 |
| Relative self-ignition temperature for solids | Waived | - | Not relevant the product is not a solid. |  |
| Dust explosion hazard | Waived | - | Not relevant the product is not a solid. |  |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| Based on the assessment of the product, the product is classified as Flammable liquid, Category 2. **Implications for labelling:** Flammable Liquids, Category 2.  |

### Methods for detection and identification

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|  **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 |
| IR3535® | GC method with FID detector. The identity of the IR3535® was established by comparison with the reference material retention time as an external standard.The working solutions were prepared using accurately weighed 95-105 mg of the test item and the volumes were made to 20 mL with acetone. The working solutions were then diluted 1/20 v/v in acetone for further GC-FID determination. The specificity of the method was obtained by using SUPELCO SLB-5ms column with a total time run of 17.0 min. The carrier gas (He) was used in a constant pressure at 20 psi head. | The regression was considered as valid over 6.4 – 213.6 mg/L: the measured concentrations did not deviate by more than 6% from the nominal values.144.8 g/kg162.7 g/kg173.5 g/kg189.7 g/kg(2 measurements for each spiked level) | r2=99.94%log(IR3535*®*) = 0.933logA-0.803 mg/Ln=6Range: 6.41 – 213.6 mg/Lcalibration points = 6single repetition | YES - Analytical grade IR3535® eluted as a single peak area at 7.9 min.Blank determination of acetone had no interfering peak area at the retention time of IR3535®.The blank matrix without IR3535® had no interfering peak area at the retention time of IR3535®. | 98-102.41) 98.1 - 100.62) 98.8-98.73) 98.0-99.14) 99.0-102.4 | 99.371) 99.42) 98.83) 98.64) 100.7 | <1.7 | - LOD 2.1mg/L- LOQ 6.4mg/L | Elisabeth Servajean 2019 |

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| **Analytical methods for monitoring** |
| **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 |  |  |
| Refer to the individual compartments below. |

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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 |
| Refer to Letter of Access obtained from the manufacturer of the active substance. Waived in the CAR for the active substance. |

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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 |
| Refer to Letter of Access obtained from the manufacturer of the active substance. Waived in the CAR for the active substance. |

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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 |
| Refer to Letter of Access obtained from the manufacturer of the active substance. HpLC-MS method can be found in the CAR for the active substance. |

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| **Analytical methods for animal and human body fluids and tissues** |
| **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 |
| Refer to Letter of Access obtained from the manufacturer of the active substance. Waived in the CAR for the active substance. |

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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 |
| Refer to Letter of Access obtained from the manufacturer of the active substance. Assessed in CAR for the active substance. |

According to Technical Agreements for Biocides Version 2.0 Released on February 2020 the analytical methods are not required for SoC that cannot be formed during the storage and their concentration remains unchanged. Hence, the analytical methods for ethanol and propan-2-ol are not submitted because they are added as a solvent to the formulation and the concentration is not being changed during the storage period.

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| **Conclusion on the methods for detection and identification of the product** |
| An analytical method for the determination of IR3535® in the biocidal product is available. Specificity, linearity, accuracy and precision were checked and found acceptable. Methods for the detection of IR3535® in soil, air, water, and animal and human body fluids and tissues were provided and deemed acceptable at EU level. No other data is required. |

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### Efficacy against target organisms

#### Function and field of use

Main group 03: Pest Control

Product type 19: Repellents and attractants

Biocidal product BROS Pršilo proti komarjem za otroke is a ready-for-use liquid in a bottle with pump spray to be applied on uncovered human skin (to face, neck, arms, hands, legs and feet only) to protect humans against insects by repelling them. Product effectively repels house mosquitoes (*Culex* spp.) up to 6.5 h and tropical mosquitoes (*Aedes* spp.) occurring in temperate climate up to 4 h. The product also repels hard ticks (*Ixodes* sp.) up to 5 h. Product is intended to be used in temperate climate only.

The product is intended to be used by the general public (non-professional) for children over 1 year old and for adults.

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

The target organisms to be controlled with BROS Pršilo proti komarjem za otroke are biting and blood sucking insects and arachnids:

* House mosquitoes (*Culex* spp*.,* adults)
* Tropical mosquitoes (*Aedes* spp*.,* adults)in temperate climate
* Hard ticks (*Ixodes* sp*.,* adults)

The product will protect humans, children over 1 year old and adults.

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

BROS Pršilo proti komarjem za otroke is intended to repel certain species of mosquitoes and ticks. Since target organisms are mosquitoes and ticks, unacceptable suffering is not considered relevant.

#### Mode of action, including time delay

Mode of action is described in CAR of IR3535®.

The mode of action of IR3535® is not a passive masking of an attracting odour of a victim, but an active repellent effect as insects avoid entering regions with IR3535® vapours. The exact biochemical mode of action of IR3535® on insects is not well known yet, but it is most self-evident to assume that IR3535® has an olfactory-based effect. The repelling biocidal active substance IR3535® works by interfering with the olfactory perception of insects, which makes it impossible to locate the victim. Insects search for the target of their attack, sensing lactic acid, which is a component of human sweat. The use of a repellents hides the insect attractors.

It evaporates from the skin surface into the air surrounding the skin. The target organisms sense the repellent and refrain from landing onto the skin and biting.

#### Efficacy data

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| **Experimental data on the efficacy of the biocidal product against target organism(s)** |
| **Function and field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method / Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| PT 19 - Repellent to be applied on uncovered human skin | BROS Pršilo proti komarjem za otroke (IR3535® 17% w/w) | Mosquitoes: *Culex pipiens* (adult stage) | Arm-in-cage simulated-use study -conducted in accordance with the Guidance on the Biocidal Products Regulation - Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 and GUIDELINES FOR EFFICACY TESTING OF MOSQUITO REPELLENTS FOR HUMAN SKIN - WHO/HTM/NTD/WHOPES/2009.4.Test lasted for 7 hours post application for tested product and for 7.5 hours for standard product (positive control).Out of 15 volunteers (8 women: 25-61 years and 7 men: 20-64 years) 10 volunteers (5 women and 5 men) had one forearm covered with tested repellent product and the other arm not covered with the product as negative control. Remaining 5 volunteers had one forearm covered with 20% DEET in ethanol (positive control) and the other not treated for a negative control. The volunteers were informed on all relevant items concerning the test and on avoiding tobacco for 24 hours before and during the test.Before each test, skin on both hands of each volunteer was washed with unscented soap, rinsed with water, and then rinsed with a solution of 70% ethanol and dried with a towel.Each cage (35cm x 38cm x 38cm) dedicated to one exposure contained over 200 female mosquitoes, at the age of 5-7 days, starved for preceding 12h of the test. The biting activity of mosquitoes was recorded. In the case of inactivity of mosquitoes, they were exchanged for new ones in both cages. The treated forearm was placed in the cage with mosquitoes for 3 min exposure directly after the product and the standard has dried after application, and then every 30 minutes until the first confirmed bite (one bite in an exposure followed by at least one bite in the next exposure) or at least two bites in a single exposure. After the trial test mosquitoes were provided with a 10% sugar solution and maintained within the test cage (with constant conditions of temp. 27 ± 2 °C, humidity 60 ± 10%) to observe any insecticidal effects of repellent product. Mortality was recorded after 24 hours. Test conditions:- temperature: 26.1 – 28.6 °C- relative humidity 56.2 – 65.1%- photoperiod 12:12 h (L:D)The applied dose of:- product was 0.24 g per forearm, which is equivalent to 0.43 mg/cm2 of skin. - standard (positive control) was 0.50 g per forearm which is equivalent to 0.90 mg/cm2 of skin. | Test result was presented as median CPT (Complete Protection Time) calculated using the Kaplan-Meier survival analysis. Product BROS Pršilo proti komarjem za otroke was effective repellent against *C. pipiens* mosquitoes for a period of 6.5 h.Positive control (DEET) showed 7 h of protection against mosquitoes *Culex* spp. The calculated median CPT of tested product is 390 ± 51 min (6.5 h), and for positive control is 420 ± 72 min (7 h).Test is considered valid and showed sufficient biting activity:* 10 bites within 4 to 13 sec maximum in cages of volunteers testing the product
* 10 bites between 4 and 14 sec in cages of volunteers testing the positive control

Mortality of mosquitoes after 24 h was <2% similar to the control (1.4%).No adverse effect on skin or skin irritation of volunteers was observed. | Łukasz Zygrykalis (2021) |
| PT 19 - Repellent to be applied on uncovered human skin | BROS Pršilo proti komarjem za otroke (IR3535® 17% w/w) | Mosquitoes: *Aedes aegypti*(adult stage) | Arm-in-cage simulated-use study -conducted in accordance with the Guidance on the Biocidal Products Regulation - Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 and GUIDELINES FOR EFFICACY TESTING OF MOSQUITO REPELLENTS FOR HUMAN SKIN - WHO/HTM/NTD/WHOPES/2009.4.Test lasted for 4.5 hours post application for tested product and for 7 hours for standard product (positive control).Out of 15 volunteers (8 women: 23-63 years and 7 men: 28-61 years) 10 volunteers (5 women and 5 men) had one forearm covered with tested repellent product and the other arm not covered with the product as negative control. Remaining 5 volunteers had one forearm covered with 20% DEET in ethanol (positive control) and the other not treated for a negative control.In each cage (35cm x 38cm x 38cm) dedicated to one exposure there were over 200 female mosquitoes at the age of 5-7 days, starved for preceding 12h before the start of the study. The biting activity of mosquitoes was recorded. In the case of inactivity of mosquitoes, they were exchanged for new ones in both cages. The treated forearm was placed in the cage with mosquitoes for 3 min exposure directly after the product and the standard has dried after application, and then every 30 minutes until the first confirmed bite (one bite in an exposure followed by at least one bite in the next exposure) or at least two bites in a single exposure.After the trial test mosquitoes were provided with a 10% sugar solution and maintained within the test cage (with constant conditions of temp. 27 ± 2 °C, humidity 60 ± 10%) to observe any insecticidal effects of repellent product. Mortality was recorded 24 hours after first exposure. Test conditions:- temperature: 25.8 – 28.1 °C- relative humidity 52.3 – 63.6 %- photoperiod 12:12 h (L:D)The applied dose of:- product was 0.24 g per forearm, which is equivalent to 0.43 mg/cm2 of skin. - positive control was 0.50 g per forearm which is equivalent to 0.90 mg/cm2 of skin. | Test result was presented as median CPT (Complete Protection Time) calculated using the Kaplan-Meier survival analysis. Product BROS Pršilo proti komarjem za otroke was effective repellent against *A. aegypti* mosquitoes for a period of 4 h.Positive control (DEET) showed 5.5 h of protection against mosquitoes *Aedes* spp.The calculated median CPT of tested product is 240 ± 51 min (4 h), and for positive control is 330 ± 72 min (5.5 h).Test is considered valid and showed sufficient biting activity:* 10 bites within 5 to 13 sec maximum in cages of volunteers testing the product
* 10 bites between 4 and 14 sec in cages of volunteers testing the positive control

Mortality of mosquitoes after 24 h was <2% similar to the control (1.1%).No adverse effect on skin or skin irritation of volunteers was observed.  | Łukasz Zygrykalis (2021) |
| PT 19 - Repellent to be applied on uncovered human skin | BROS Pršilo proti komarjem za otroke (IR3535® 17% w/w) | Ticks: *Ixodes ricinus*(adult stage) | Laboratory test in accordance with the Guidance on the Biocidal Products Regulation - Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 Test lasted for 5.5 hours post application.10 volunteers (5 women aged 22-59 and 5 men aged 31-64 years). The volunteers refrained from tobacco use and avoided using fragrance or another repellent product for 12 hours before testing.The repelling activity was evaluated with a test based on the negative geotropism of ticks. Only ticks showing negative geotropism were considered active and used in experiment. Activity was tested for 10 ticks each time. Non-fed, pathogen-free laboratory ticks *(Ixodes ricinus)* of both genders were used in the study.6 ticks both genders (3 males and 3 females) were put on the outer side of the palm of the forearm. The line of product application starts 3 cm above the wrist. An effective repellent does not allow the ticks to enter the protected skin area or it results in the tick falling off the arm during 5-minute exposure. Unprotected arm of volunteer was a control. Test conditions:- temperature: 23.7 – 26.2 °C- relative humidity 64.3 – 69.7% RHThe applied dose of product was 0.24 g per forearm, which is equivalent to 0.43 mg/cm2 of skin.  | The result was presented as a percentage of repellence of the product in relation to the number of ticks involved in test.BROS Pršilo proti komarjem za otroke showed 100% repellence against ticks for 5 hours from its application for all 10 volunteers. Average 88.3% repellence was calculated for 5.5 h after the application of product.The number of ticks showing activity on untreated arm of volunteers per 10 tested ticks, before each exposure, was always 7 ticks or more.No skin irritation or other adverse effects on skin of volunteers was observed. | Magdalena Zygrykalis (2021) |

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| **Conclusion on the efficacy of the product** |
| Overall, 3 studies with the product BROS Pršilo proti komarjem za otroke were submitted. Two studies were AIC simulated use tests to demonstrate the repellent activity against *Culex* and *Aedes* mosquitoes and one study was a laboratory test to show the repellence against ticks (*Ixodes* sp.). To eliminate the risk of disease transmission to volunteers in field settings and due to ethical reasons, field trials are not required for authorisation of products applied on human skin to repel insects.The results summarized in the table Experimental data on the efficacy of the biocidal product against target organism(s) confirmed that the product BROS Pršilo proti komarjem za otroke with 17% IR3535® active substance will be effective for the intended use.We conclude that the product BROS Pršilo proti komarjem za otroke will effectively repel house mosquitoes (*Culex* spp*.)* up to 6.5 h and tropical mosquitoes (*Aedes* spp*.)* occurring in temperate climate up to 4 h. Product BROS Pršilo proti komarjem za otroke will also effectively repel adult ticks (*Ixodes* sp.) from human skin for up to 5 h.Product BROS Pršilo proti komarjem za otroke will be effective for the intended use when applied by spraying with a rate of 0.43 mg/cm2 of human skin (which is equivalent to 0.24 g of the product per forearm) once a day as instructed in the instructions of use. |

#### Occurrence of resistance and resistance management

There are no reported cases of target insects developing resistance to IR3535® in the literature up to date.

The active substance IR3535® is a repellent and possesses no killing effect. Hence, it does not give a rise to selection pressure and resistance is less likely to be developed.

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

- Always read the label or leaflet before use and follow all the instructions provided.

- Respect the recommended application doses.

#### Known limitations

Age of children is a limitation to consider for BROS Pršilo proti komarjem za otroke – product is intended only for 1 year old and above.

#### Evaluation of the label claims

The label claims for the product which are supported by the efficacy data package are:

Product BROS Pršilo proti komarjem za otroke effectively repels:

- house mosquitoes (*Culex* spp.) up to 6.5 h

- tropical mosquitoes (*Aedes* spp.) when occurring in temperate climate up to 4 h

- hard ticks (*Ixodes* sp.) up to 5 h

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

Product BROS Pršilo proti komarjem za otroke is not intended for use in combination with other biocidal products.

### Risk assessment for human health

The toxicological properties of the active substance in BROS Pršilo proti komarjem za otroke, IR3535®, are summarised in the respective CA report (RMS BE, 2014).

Acute toxicity tests as well as tests for skin or eye irritation and skin sensitisation have not

been performed. The criteria for the classification of mixtures according to the Regulation 1272/2008 (CLP) were followed.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

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| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | Not irritating to skin. |
| Justification for the value/conclusion | A skin irritation study with BROS Pršilo proti komarjem za otroke has not been conducted. None of the ingredients classified for skin irritation/corrosion are present above the generic cut-off limit of 1%. According to Regulation EC 1272/2008, BROS Pršilo proti komarjem za otroke does not need to be classified for skin corrosion/irritation. |
| Classification of the product according to CLP and DSD | According to CLP, no classification for skin irritation/corrosion is necessary. |

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| **Data waiving** |
| Information requirement | Skin irritation/corrosion (IUCLID Section 8.1.1) |
| Justification | Study scientifically not necessary / other information available. The toxicity of active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).  |

***Eye irritation***

|  |
| --- |
| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | The biocidal product has to be classified as an eye irritant according to (EU) No 1272/2008 (Eye Irrit. 2, H319) |
| Justification for the value/conclusion | No studies on eye irritation are available for biocidal product. The concentration of active substance is 17%, leading to the classification as Eye Irrit. 2 (H319). None of the co-formulants classified as Eye Irrit. 2 (H319) is present above the generic cut-off limit of 1%. There are no co-formulants classified as Eye Dam. 1 (H318).  |
| Classification of the product according to CLP and DSD | Eye irritation cat 2, H319 |

|  |
| --- |
| **Data waiving** |
| Information requirement | Eye irritation (IUCLID Section 8.1.2)  |
| Justification | Study scientifically unjustified. Since the eye irritation of BROS Pršilo proti komarjem za otroke can be assessed on the basis of the properties of the ingredients, the performance of eye irritation study with the biocidal product is scientifically not justified. There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Based on a consideration of the composition of the formulation the biocidal product meets the criteria for classification for eye irritation. |

***Respiratory tract irritation***

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| --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** |
| Value/conclusion | Not irritating to the respiratory tract. |
| Justification for the conclusion | No experimental data on respiratory irritation of BROS Pršilo proti komarjem za otroke is available. None of the ingredients in BROS Pršilo proti komarjem za otroke are classified for Specific target organ toxicity – Single exposure Cat 3 for respiratory tract irritation (H335). Therefore, the product does not need to be classified as STOT SE3 (H335) |
| Classification of the product according to CLP and DSD | According to CLP, no classification for respiratory tract irritation is necessary. |

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| --- |
| **Data waiving** |
| Information requirement | Respiratory tract irritation  |
| Justification | Study scientifically not necessary / other information available. The toxicity of active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). |

***Skin sensitization***

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| --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | Not sensitising. |
| Justification for the value/conclusion | A skin sensitisation study with BROS Pršilo proti komarjem za otroke has not been conducted. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). There is no co-formulant classified for skin sensitisation present above generic concentration limit for skin sensitisation or above concentration limit for elicitation. See confidential annex for further explanation. |
| Classification of the product according to CLP and DSD | According to CLP, no classification for skin sensitization is necessary. |

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| --- |
| **Data waiving** |
| Information requirement | Skin sensitisation (IUCLID Section 8.3.1) |
| Justification | The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). |

***Respiratory sensitization (ADS)***

|  |
| --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** |
| Value/conclusion | Not sensitising. |
| Justification for the value/conclusion | No data on respiratory sensitisation of BROS Pršilo proti komarjem za otroke is available. None of the components in BROS Pršilo proti komarjem za otroke is classified for respiratory sensitisation Category 1 (H334). |
| Classification of the product according to CLP and DSD | According to CLP, no classification for respiratory sensitisation is necessary. |

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| --- |
| **Data waiving** |
| Information requirement | Respiratory sensitisation (IUCLID Section 8.3.2) |
| Justification | Study scientifically unjustified. The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). |

***Acute toxicity***

*Acute toxicity by oral route*

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| --- |
| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value | Not acutely toxic via oral route |
| Justification for the selected value | Acute toxicity studies with BROS Pršilo proti komarjem za otroke have not been conducted. None of the ingredients classified for acute oral toxicity (H302) are present above the generic cut-off limit of 1%. According to Regulation EC 1272/2008, BROS Pršilo proti komarjem za otroke does not need to be classified for acute oral toxicity. |
| Classification of the product according to CLP and DSD | According to CLP, no classification for acute oral toxicity is necessary. |

|  |
| --- |
| **Data waiving** |
| Information requirement | Acute toxicity: oral (IUCLID Section 8.5.1) |
| Justification | Study scientifically unjustified. The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). |

*Acute toxicity by inhalation*

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| --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** |
| Value | Not acutely toxic via inhalation route |
| Justification for the selected value | Acute toxicity studies with BROS Pršilo proti komarjem za otroke have not been conducted. None of the ingredients classified for acute inhalation toxicity (H332) are present above the generic cut-off limit of 1%. According to Regulation EC 1272/2008, BROS Pršilo proti komarjem za otroke does not need to be classified for acute inhalation toxicity. |
| Classification of the product according to CLP and DSD | According to CLP, no classification for acute inhalation toxicity is necessary. |

|  |
| --- |
| **Data waiving** |
| Information requirement | Acute inhalation toxicity (IUCLID Section 8.5.2) |
| Justification | Study scientifically unjustified. The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). |

*Acute toxicity by dermal route*

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| --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value | Not acutely toxic via dermal route |
| Justification for the selected value | Acute toxicity studies with BROS Pršilo proti komarjem za otroke have not been conducted. None of the ingredients of BROS Pršilo proti komarjem za otroke are classified for dermal toxicity. According to Regulation EC 1272/2008, BROS Pršilo proti komarjem za otroke does not need to be classified for acute dermal toxicity. |
| Classification of the product according to CLP and DSD | According to CLP, no classification for acute dermal toxicity is necessary. |

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| --- |
| **Data waiving** |
| Information requirement | Acute toxicity: dermal (IUCLID Section 8.5.2) |
| Justification | Study scientifically unjustified. The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). |

***Information on dermal absorption***

|  |
| --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** |
| Substance | IR3535® |
| Value(s) | 25% |
| Justification for the selected value(s) | According to the EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873) a default value of 25% for concentrates of organic solutions can be used. |

|  |
| --- |
| **Data waiving** |
| Information requirement | Information on dermal absorption (IUCLID Section 8.6) |
| Justification | The default dermal absorption value from the EFSA Guidance on dermal absorption (2017) can be applied for exposure and risk assessment. |

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

There are valid data available on each of the components of the product, sufficient to allow its classification according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

In this biocidal product two substances of concern have been identified in accordance with the EU guidance (CA-Nov14-Doc.5.11): ethanol and isopropanol.

Ethanol should be considered as a substance of concern, since it is responsible for the classification of the biocidal product as a flammable liquid. However, from a toxicological point of view, ethanol is not considered relevant. Based on its harmonized classification, ethanol is not classified for any human health hazard. Consequently, no risk assessment was performed for ethanol.

Ethanol used in the product is denaturated with isopropanol, which is also considered SoC as a compound authorised for use as a biocidal active substance. Isopropanol is classified as Flam. Liq. 2, Eye Irrit. 2 and STOT SE 3 (CNS). Concentration of isopropanol (propan-2-ol) in the product is ca. 0.945%. However, such amount of isopropanol does not influence the predicted hazards based on the calculation method related to exposure to the biocidal product. The banding approach does not have to be applied since the eye irritation can be caused by the presence of the active substance IR3535® itself and the additive toxicity method does not change the final classification. The product is labelled accordingly - Eye irritation cat 2, H319. Moreover, during application or release of the product both ethanol and isopropanol evaporate rapidly and dissipate in the air, considerably reducing any potential health risks, including the STOT SE 3 risk related to drowsiness or dizziness. This is additionally addressed in the label by statements: “Do not breathe vapours of the product.” and "Use only outdoors or in well ventilated rooms.”.

Please see confidential annex for details.

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

There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

***Other***

Not applicable.

***Available toxicological data relating to endocrine disruption***

For the assessment of endocrine-disrupting properties of (the) non-active substances, refer to the respective section of the Confidential Annex.

The biocidal product does not contain any active substances having endocrine-disrupting properties. The biocidal product contains the active substance ethyl butylacetylaminopropionate (IR3535®), which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

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

#### Exposure assessment

The active substance contained in the product BROS Pršilo proti komarjem za otroke is the same as evaluated in the CAR for IR3535® and therefore no new data/information on the active substance is required. The composition of the representative product from the CAR is not identical to that of BROS Pršilo proti komarjem za otroke. However, the intended use is identical for both products.

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

| **Summary table: relevant paths of human exposure** |
| --- |
| **Exposure path** | **Primary (direct) exposure**  | **Secondary (indirect) exposure**  |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | n.a. | n.a. | Yes | n.a. | n.a. | Yes | n.a. |
| Dermal | n.a. | n.a. | Yes | n.a. | n.a. | Yes | n.a. |
| Oral | n.a. | n.a. | n.a. | n.a. | n.a. | Yes | n.a. |

For primary exposure, the most relevant route of exposure is the dermal route. During the application phase, inhalation exposure is possible resulting from respiring aerosols after spraying. It was considered that the respirable particles will be absorbed via the lower airways and that the non-respirable particles will precipitate in the upper airways and be taken in orally. Direct oral exposure is not considered to be relevant because of the form of the product (accidental consumption is highly likely), relatively small single dose, repelling taste (bad palatability) of the active substance and presence of taste deterrent denatonium benzoate.

For secondary exposure, dermal exposure is possible for adults treating or handling children. However, this scenario is fully covered by primary adult dermal exposure. Hand to mouth transfer is also possible for adults and children; nonetheless, the biocidal product is not intended to be applied on children’s hands which reduces potential oral uptake of the dermally applied active substance. For inhalation exposure, the inhalation of volatilized residues after application is also relevant.

**General information**

General default values for exposure assessment

| **Default value considering age groups1** |
| --- |
| **Age groups** | **Body weight [kg]** | **Respiration rate** **[m³/air/hour]** | **Total body surface area [cm²]** |
| **ADULT irrespective of gender**  | 60 | 1.25 | 16600 |
| **CHILD (6 to <12 years old)**  | 23.9 | 1.32 | 9200 |
| **CHILD (2 to <6 years old)**  | 15.6 | 1.26 | 6800 |
| **TODDLER (1 to <2 years old)**  | 10 | 1.26 | 4800 |

1 Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017)

Treated surface, applied amount of biocidal product and number of applications per day:

**Treated surface:**

According to Recommendation no. 11 of the BPC Ad hoc Working Group on Human Exposure Proposal for harmonising the assessment of human exposure to repellents (PT19) January 2018 the uncovered body surface area corresponds to 55% of the total body surface***.*** This corresponds to the situation when normal outdoor clothing (short-sleeved shirt (i.e. T-shirt) and shorts) are worn. This type of clothing leaves the following body parts exposed: head, neck, hands (palms and backs), lower arms, lower legs, feet and 70% of upper arms and thighs. It is assumed that for mid-term scenarios, which are those relevant for exposure to insect repellents, the normal outdoor clothing will be worn.

Hence the treated surface will amount to 9130 cm2, 5060 cm2, 3740 cm2 and 2640 cm2 for an adult, a child over 6 y.o., a child 2-6 y.o. and a toddler, respectively.

**Amount of biocidal product:**

Based on the efficacy studies done for this product, the efficient dose is 0.43 mg product/cm2 skin. Considering the treated surface, the application rate would be approximately 3.926 g per application for an adult, 2.176 g/app. for a child over 6 y.o., 1.608 g/app. for a child 2-6 y.o., and 1.135 g/app. for a toddler.

***Number of applications per day:***

BROS Pršilo proti komarjem za otroke can be applied 1 time a day for adults and children between the age of 1 and 12 years.

| **Summary: Amount of product used per application for the different age groups, treated****surface and number of applications per day** |
| --- |
| Age groups | Amount of product used per application [g] | Treated surface [cm²] | number of application per day |
| **ADULT irrespective of gender**  | 3.926 g | 9130 | 1 application/day |
| **CHILD (6 to <12 years old)** | 2.176 g | 5060 | 1 application/day |
| **CHILD (2 to <6 years old)** | 1.608 g | 3740 | 1 application/day |
| **TODDLER (1 to <2 years old)** | 1.135 g | 2640 | 1 application/day |

Dermal, inhalation and oral absorption:

- Inhalation absorption: 100%

- Dermal absorption: 25%

- Oral absorption: 100%

***List of scenarios***

Insect Repellent BROS Pršilo proti komarjem za otroke is used by the general public. The primary route of exposure is dermal.

Oral exposure by hand-to-mouth transfer is not considered to be a significant route of primary exposure, because of the repellent taste (bad palatability) of the active substance, thus, preventing repeated mouthing of IR3535® by children and infants. Furthermore, the biocidal product is not intended to be applied by children younger than 12 years which makes an oral uptake of the dermally applied active substance inconsiderable.

A potential inhalation exposure is only possible during the application phase via spraying. After application, no inhalation exposure risk is anticipated due to the low vapour pressure of IR3535®. Moreover, it has to be taken into account that the exposure time to the spray is extremely short and that it is not recommended to spray the biocidal product directly on the face.

Dermal secondary exposure is possible for adults treating or handling children. However, this scenario is fully covered by primary adult dermal exposure. A parent applying (spraying) the product on children and herself/himself has been taken into account for inhalation secondary exposure.

| **Summary table: scenarios** |
| --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure** **Description of scenario** | **Exposed group** |
| 1. | Application phase | Primary exposure: Dermal exposure assessment for adults, children and toddlers. | Non-professionals |
| 2. | Application phase | Primary exposure: Inhalation exposure assessment for adults, children and toddlers. | Non-professionals |
| 3. | Post-application phase | Secondary exposure (indirect exposure as a result of use): Hand-mouth transfer reverse reference scenario (oral exposure)  | General public |
| 4. | Post-application phase | Inhalation of volatilised residues after application (inhalation exposure) | General public |

Hand to mouth transfer has been developed consistently with the DEET dossier. It was proposed to use a reverse scenario to estimate this exposure.

Inhalation of volatilized residues after application is relevant based on the HEEG opinion on Assessment of Inhalation Exposure of Volatilized Biocide Active Substance. The exposure to volatilised residues indoors was calculated using ConsExpo model.

***Industrial exposure***

Not applicable as for non-professional use only.

***Professional exposure***

Not applicable as for non-professional use only.

***Non-professional exposure***

Scenario 1: Primary exposure: Dermal exposure assessment for adults, children and toddlers.

| **Description of Scenario 1** |
| --- |
| This scenario is based on the one available in the CAR of IR3535®. It has been updated with the document Recommendation no. 11 of the BPC Ad hoc Working Group on Human Exposure Proposal for harmonising the assessment of human exposure to repellents (PT19) January 2018.**Dermal systemic exposure:** Number of application/day x amount b.p./application x percent of a.s. in b.p. x percent of dermal absorption/ body weight |
| **Tier 1** | **Parameters** | **Value** |
| Efficacy application rate [mg biocidal product/cm²]1 | 0.43 |
| Number of applications/ day1 | 1 |
| Amount of product used per application [g]2 | Adult | 3.926 |
| Child (6 to <12 years old) | 2.176 |
| Child (2 to <6 years old) | 1.608 |
| Toddler | 1.135 |
| % of active substance in biocidal product1 | 17 |
| Dermal absorption3 | 25% |
| Body weight [kg]4 | Adult | 60  |
| Child (6 to <12 years old) | 23.9 |
| Child (2 to <6 years old) | 15.6 |
| Toddler | 10 |

1 Product related data

2 See Summary table above: Amount of product used per application for the different age groups, treated surface and number of applications per day, p. 41

3 The EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873), a default value for concentrates of organic solutions

4 Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017)

**Calculations for Scenario 1**

| **Summary table: systemic exposure for Dermal Primary exposure** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated dermal uptake [mg/kg bw/day]** |
| Scenario 1 – ADULT 1 application/day | Tier 1 / no PPE | 2.78 |
| Scenario 1 – CHILD (6 to <12 years old) 1 application/day | Tier 1 / no PPE | 3.87 |
| Scenario 1 – CHILD (2 to <6 years old) 1 application/day | Tier 1 / no PPE | 4.38 |
| Scenario 1 – TODDLER 1 application/day | Tier 1 / no PPE | 4.82 |

Scenario 2: Primary exposure: Inhalation exposure assessment for adults, children and toddlers.

| **Description of Scenario 2** |
| --- |
| This scenario is based on the one available in the CAR of IR3535®. It has been updated with the documents: Recommendation no. 11 of the BPC Ad hoc Working Group on Human Exposure Proposal for harmonising the assessment of human exposure to repellents (PT19) January 2018, Biocide Human Health Exposure Methodology (Oct 2015) and Guidance on the biocidal products Regulation (volume III Human Health – Parts B+C Assessment & Evaluation, Dec 2017).Model used: “Consumer spraying and dusting model 2 - Hand-held trigger spray” from Biocide Human Health Exposure Methodology, p. 220Inhaled product = Inhalation rate x number of application/day x spray duration (min.) / 60 min. x indicative value for inhalation Inhaled active substance = Inhaled product x percent of a.s. in the b.p.Particle size distribution will determine the respirable fraction of the product released. Regarding the cut-off value for respirable droplet size, different sources are available. The BPR guidance III part B+C states that particles below 15 µm may reach the alveolar region of the respiratory tract. According to the Biocides Human Health Exposure Methodology, particles larger than 20 µm are all non-respirable and particles smaller than 5 µm are respirable for about 35%. The Proposal for harmonising the assessment of human exposure to repellents (PT19) states that in general, the cut-off for the respirable fraction is 10 µm, and refers to ConsExpo 4.1 for the assessment of inhalation exposure. In ConsExpo 4.1, the default cut-off for the respirable fraction has been set at 15 µm. For the present assessment, a cut-off value of 10 µm for the respirable fraction has been chosen.According to the study for the distribution of particles and their size 1.6% (V) of the released biocidal product has a diameter below 10 µm. The rest is regarded as non-respirable and is assumed to be taken in orally.Inhalation systemic exposure: 1.6 % x inhaled a.s x inhalation absorption / body weight Oral systemic exposure: 98.4 % x inhaled a.s. x oral absorption/ body weight |
| **Tier 1**  | **Parameters** | **Value** |
| Indicative value for inhalation1 [mg/m3] | 10.5  |
| % of active substance in biocidal product2 | 1 |
| Number of applications/ day2 | 1 |
| Spray duration3 [min] | 4 |
| Inhalation rate [m3/air/hour]4 | Adult | 1.25  |
|  | Child (6 to <12 years old) | 1.32 |
| Child (2 to <6 years old) | 1.26 |
| Toddler | 1.26 |
| Body weight [kg]4 | Adult | 60 |
| Child (6 to <12 years old) | 23.9 |  |
| Child (2 to <6 years old) | 15.6 |  |
| Toddler | 10 |  |

1 “Consumer spraying and dusting model 2 - Hand-held trigger spray” from Biocide Human Health Exposure Methodology, p. 220

2 Product related data

3 CAR of IR3535® (expert judgement)

4 Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017)

**Calculations for Scenario 2**

| **Summary table: systemic exposure for Inhalation Primary exposure** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated oral uptake****[mg/kg bw/day]** |
| Scenario 2 – ADULT1 application/day | Tier 1 / no PPE | 3.97 ∙ 10-5 | 2.44 ∙ 10-3 |
| Scenario 2 – CHILD (6 to <12 years old)1 application/day | Tier 1 / no PPE | 1.05 ∙ 10-4 | 6.47 ∙ 10-3 |
| Scenario 2 – CHILD (2 to <6 years old)1 application/day | Tier 1 / no PPE | 1.54 ∙ 10-4 | 9.46 ∙ 10-3 |
| Scenario 2 - TODDLER1 application/day | Tier 1 / no PPE | 2.40 ∙ 10-4 | 1.48 ∙ 10-2 |

Scenario 3: Secondary exposure (indirect exposure as a result of use): Hand-mouth transfer reverse reference scenario (oral exposure)

| **Description of Scenario 3** |
| --- |
| This scenario is based on the one available in the CAR of IR3535®. It has been updated with the documents: Recommendation no. 11 of the BPC Ad hoc Working Group on Human Exposure Proposal for harmonising the assessment of human exposure to repellents (PT19) January 2018.Hand to mouth transfer might be possible for small children. However, this scenario is not considered to be a significant route of exposure because of bad palatability (bitterness) preventing repeated mouthing by small children and you may not apply to children’s hand.At TM IV 2010, it was agreed to develop the scenario “hand-mouth transfer” consistently with the DEET dossier evaluated by SE and to be discussed with HEEG and TM agreed not to sum up the two routes (oral and dermal) in small children. Reverse reference scenario is included to show how much IR3535® anyone can be exposed to after oral exposure, without exceeding reference dose (AEL for IR3535® is 5 mg/kg bw/d).**External dermal amount of a.s. per application:** Amount of b.p./application x percent of a.s. in b.p. / body weight **Oral systemic exposure via hand-mouth transfer is:** External dermal amount of a.s. per application x Factor for oral intake by hand-mouth transfer x oral absorption **Number of times of application b.p. before exceeding the AEL via hand-mouth** **transfer:** AEL / Oral systemic exposure via hand-mouth transfer |
|  | **Parameters** | **Value** |
| **Tier 1** | Oral absorption [%] | 100 |
| % of active substance in biocidal product1 | 17 |
| Factor for oral intake by hand-mouth transfer2 [%] | Adult | 4 |
| Child (6 to <12 years old) | 8 |
| Child (2 to <6 years old) | 8 |
| Toddler | 8 |
| Amount of biocidal product/ application [g]3 | Adult | 3.926  |
| Child (6 to <12 years old) | 2.176  |
| Child (2 to <6 years old) | 1.608  |
| Toddler | 1.135 |
| Body weight [kg]4 | Adult | 60 |
| Child (6 to <12 years old) | 23.9 |
| Child (2 to <6 years old) | 15.6 |
| Toddler | 10 |

1 Product related data

2 Recommendation no. 11 of the BPC Ad hoc Working Group on Human Exposure Proposal for harmonising the assessment of human exposure to repellents (PT19) (Agreed at the Human Health Working Group III on 25 May 2016, revision agreed at Human Health Working Group V on 22 November 2017)

3 See Summary table above: Amount of product used per application for the different age groups, treated surface and number of applications per day, p. 41

4 Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017)

**Calculations for Scenario 3**

| **Summary table: estimated exposure for Hand-mouth transfer reverse reference scenario (oral exposure)** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Calculated exposure to IR3535®** |
| Scenario 3 – ADULT1 applications/day | Tier 1 / no PPE | Adult up to 11.24 applications |
| Scenario 3 – CHILD (6 to <12 years old)1 application/day | Tier 1 / no PPE | Child up to 4.04 applications |
| Scenario 3 – CHILD (2 to <6 years old)1 application/day | Tier 1 / no PPE | Child up to 3.57 applications |
| Scenario 3 - TODDLER1 application/day | Tier 1 / no PPE | Toddler up to 3.25 applications |

Scenario 4: Inhalation of volatilised residues after application (inhalation exposure)

| **Description of Scenario 4** |
| --- |
| Considering HEEG opinion 13 (Assessment of Inhalation Exposure of Volatilized Biocide Active Substance), the inhalation of volatilised residues after application has to be taken into account for this product. The spray repellent can be used by a non-professional consumer in both indoors and outdoors. According to the intended uses an adult can apply the product once a day. The product can be applied to a child once a day. The exposure was assessed using ConsExpo 4.1 (inhalation of vapour, instantaneous release as a worst case).Inhalation of volatilized residues after application is relevant considering the HEEG opinion on Assessment of Inhalation Exposure of Volatilized Biocide Active Substance: The result of this equation is superior to 1 which means that the inhalation exposure couldn’t be considered as negligible. So, this exposure was assessed using ConsExpo – exposure to vapour – instantaneous release. **General inputs to the model:** Exposure duration: 24 hours (all day, in line with HEEG opinion on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance) Weight fraction compound: 17% (biocidal product information) Room volume: 20 m3 (default value of ConsExpo) Ventilation rate: 2.5/h (default value of ConsExpo for bedrooms with opened windows, ConsExpo General Fact Sheet, 2014)Vapour pressure: 0.15 Pa (at 20°C) (active substance information) Molecular weight: 215.29 g/mol (active substance information) Temperature: 25°C (ambient temperature) |
|  | **Parameters** | **Value** |
| **Tier 1** | % of active substance in biocidal product1 [%] | 17 |
| Amount of biocidal product/ application [g]2 | Adult | 3.926  |
| Child (6 to <12 years old) | 2.176  |
| Child (2 to <6 years old) | 1.608  |
| Toddler | 1.135 |
| Body weight [kg]3 | Adult | 60 |
| Child (6 to <12 years old) | 23.9 |
| Child (2 to <6 years old) | 15.6 |
| Toddler | 10 |
| Inhalation rate [m3/air/hour]3 | Adult | 1.25  |
| Child (6 to <12 years old) | 1.32 |
| Child (2 to <6 years old) | 1.26 |
| Toddler | 1.26 |

1 Product related data

2 See Summary table above: Amount of product used per application for the different age groups, treated surface and number of applications per day, p. 41

3 Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017)

**Calculations for Scenario 4**

| **Summary table: estimated exposure for inhalation of volatilised residues after application (inhalation exposure)** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake of volatilised residues after application****[mg/kg bw/day]** |
| Scenario 4 – ADULT | Tier 1 / no PPE | 2.78 ∙ 10-1 |
| Scenario 4 – CHILD (6 to <12 years old) | Tier 1 / no PPE | 4.09 ∙ 10-1 |
| Scenario 4 – CHILD (2 to <6 years old) | Tier 1 / no PPE | 4.42 ∙ 10-1 |
| Scenario 4 - TODDLER | Tier 1 / no PPE | 4.86 ∙ 10-1 |

Combined scenarios: Total primary exposure, combination of scenario 1 and 2

| **Summary table: estimated exposure for combined scenarios 1+2** |
| --- |
| **Scenarios combined** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** |
| Scenario 1+2 – ADULT 1 app/day | 2.78 | 3.97 ∙ 10-5 | 2.44 ∙ 10-3 | 2.78 |
| Scenario 1+2 – CHILD (6 to <12 years old) 1 app/day | 3.87  | 1.05 ∙ 10-4 | 6.47 ∙ 10-3 | 3.88 |
| Scenario 1+2 – CHILD (2 to <6 years old) 1 app/day | 4.38  | 1.54 ∙ 10-4 | 9.46 ∙ 10-3 | 4.39  |
| Scenario 1+2 - TODDLER 1 app/day | 4.82 | 2.40 ∙ 10-4 | 1.48 ∙ 10-2 | 4.84 |

The exposure of inhalation of volatilised residues after application and the combined inhalation and oral exposure of a parent treating two children are negligible compared to primary (dermal) exposure.

***Exposure of the general public***

Exposure of the general public is covered by the secondary exposure of non-professional.

***Monitoring data***

Not applicable.

***Dietary exposure***

Considering the fact that the amount in scenario 3 (hand to mouth transfer) will be superior to the amount on the fingers of the hands (possible contact surface for transfer of residue to food) and finally considering that the biocidal product is not used for and/or during food production, or in rooms where food is produced processed or stored, the dietary risk would be covered by the scenario 3.

In order to avoid indirect contact of ethyl butylacetylaminopropionate to food or feeding stuff following label restrictions are proposed:

* For children of 1 to 12 years: the repellent must be applied by adults.
* Do not apply onto children’s hands.
* Wash hands before handling food.
* Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed and drinks.
* To prevent contamination of food, avoid contact of treated skin with food.

The above RMM should be sufficient to minimize the risk of a transfer of residues of IR3535® from hand to food.

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

The modelling of exposures and subsequent risk characterisation during production and formulation of BROS Pršilo proti komarjem za otroke is addressed under EU legislation (e.g. Directive 98/24/EC) and is not required under BPR. Therefore, no exposure from production of the biocidal product is further considered.

***Aggregated exposure***

Not applicable.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** |
| --- |
| **Scenario number** | **Exposed group****(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake** |
| 1. | Non-professionals, adult  | Tier 1, no PPE, dermal, 1 applications/day | 2.78 mg/kg/day |
| Non-professionals, child (6 to <12 years old) | Tier 1, no PPE, dermal, 1 application/day | 3.87 mg/kg/day |
| Non-professionals, child (2 to <6 years old) | Tier 1, no PPE, dermal, 1 application/day | 4.38 mg/kg/day |
| Non-professionals, toddler  | Tier 1, no PPE, dermal, 1 application/day | 4.82 mg/kg/day |
| 2. | Non-professionals, adult  | Tier 1, no PPE, inhal+oral, 1 application/day | 2.48 ∙ 10-3 mg/kg/day  |
| Non-professionals, child (6 to <12 years old) | Tier 1, no PPE, inhal+oral, 1 application/day | 6.57 ∙ 10-3 mg/kg/day  |
| Non-professionals, child (2 to <6 years old) | Tier 1, no PPE, inhal+oral, 1 application/day | 9.61 ∙ 10-3 mg/kg/day  |
| Non-professionals, toddler  | Tier 1, no PPE, inhal+oral, 1 application/day | 1.50 ∙ 10-2 mg/kg/day  |
| 3. | Non-professionals, adult  | Tier 1, no PPE, Hand-mouth transfer reverse reference scenario, oral | 11.24 app. |
| Non-professionals, child (6 to <12 years old) | Tier 1, no PPE, Hand-mouth transfer reverse reference scenario, oral | 4.04 app. |
| Non-professionals, child (2 to <6 years old) | Tier 1, no PPE, Hand-mouth transfer reverse reference scenario, oral | 3.57 app. |
| Non-professionals, toddler  | Tier 1, no PPE, Hand-mouth transfer reverse reference scenario, oral | 3.25 app. |
| 4. | Non-professionals, adult  | Tier 1 / no PPE  | 2.78 ∙ 10-1 mg/kg bw/day |
| Non-professionals, child (6 to <12 years old) | Tier 1 / no PPE  | 4.09 ∙ 10-1 mg/kg bw/day |
| Non-professionals, child (2 to <6 years old) | Tier 1 / no PPE  | 4.42 ∙ 10-1 mg/kg bw/day |
| Non-professionals, toddler  | Tier 1 / no PPE  | 4.86 ∙ 10-1 mg/kg bw/day |

#### Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference**  | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | Rabbit, oral, 28-days toxicity study Rabbit, oral, developmental study | 500 (1500) mg/kg bw/d 300 (600) mg/kg bw/d | 100 | 100% | 5 mg/kg bw/d |
| AELmedium-term | Rabbit, oral, 28-days toxicity study Rabbit, oral, developmental study | 500 (1500) mg/kg bw/d 300 (600) mg/kg bw/d | 100 | 100% | 5 mg/kg bw/d |
| AELlong-term | Rabbit, oral, 28-days toxicity study Rabbit, oral, developmental study | 500 (1500) mg/kg bw/d 300 (600) mg/kg bw/d | 100 | 100% | 5 mg/kg bw/d |
| ARfD | n.a | n.a |  |  | not applicable, no residues in food or feed occur |
| ADI | n.a | n.a |  |  | not applicable, no residues in food or feed occur |

1 Reason for assessment factor: factor 10 for both intra-species and interspecies differences. No extrapolation factor for duration is needed, as the overall NOAEL is derived from a repeated 28d-oral toxicity study and a teratogenicity study.

***Risk for industrial users***

Not applicable.

***Risk for professional users***

Not applicable.

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

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****[mg/kg bw/d]** | **AEL****mg/kg bw/d** | **Estimated uptake** | **Estimated uptake/ AEL (%)** | **Acceptable****(yes/no)** |
| Scenario 1, dermal, adult | 1 | 500 | 5 | 2.78 mg/kg bw /day | 55.6 | yes |
| Scenario 1, dermal, child(6 to <12 years old) | 1 | 500 | 5 | 3.87 mg/kg bw /day | 77.4 | yes |
| Scenario 1, dermal, child(2 to <6 years old) | 1 | 500 | 5 | 4.38 mg/kg bw /day | 87.6 | yes |
| Scenario 1, dermal, toddler | 1 | 500 | 5 | 4.82 mg/kg bw /day | 96.5 | yes |
| Scenario 2, Inhal+oral, adult | 1 | 500 | 5 | 2.48 ∙ 10-3 mg/kg bw/day | 0.05 | yes |
| Scenario 2, Inhal+oral, child(6 to <12 years old) | 1 | 500 | 5 | 6.57 ∙ 10-3 mg/kg bw/day | 0.13 | yes |
| Scenario 2, Inhal+oral, child(2 to <6 years old) | 1 | 500 | 5 | 9.61 ∙ 10-3 mg/kg bw/day | 0.19 | yes |
| Scenario 2, Inhal+oral, toddler | 1 | 500 | 5 | 1.50 ∙ 10-2 mg/kg bw/day | 0.30 | yes |
| Scenario 3, hand-mouth transfer, adult | 1 | 500 | 5 | up to 11.24 applications | n.a. | Reverse reference scenario |
| Scenario 3, hand-mouth transfer, child(6 to <12 years old) | 1 | 500 | 5 | up to 4.04 applications | n.a. | Reverse reference scenario |
| Scenario 3, hand-mouth transfer, child(2 to <6 years old) | 1 | 500 | 5 | up to 3.57 applications | n.a. | Reverse reference scenario |
| Scenario 3, hand-mouth transfer, toddler | 1 | 500 | 5 | up to 3.25 applications | n.a. | Reverse reference scenario |
| Scenario 4, inhal, adult | 1 | 500 | 5 | 2.78 ∙ 10-1 mg/kg bw/day | 5.56 | yes |
| Scenario 4, inhal, child (6 to <12 years old) | 1 | 500 | 5 | 4.09 ∙ 10-1 mg/kg bw/day | 8.18 | yes |
| Scenario 4, inhal, Child (2 to <6 years old) | 1 | 500 | 5 | 4.42 ∙ 10-1 mg/kg bw/day | 8.84 | yes |
| Scenario 4, inhal, toddler | 1 | 500 | 5 | 4.86 ∙ 10-1 mg/kg bw/day | 9.72 | yes |

**Combined scenarios**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Scenarios 1+2 – ADULT 1 app/d | 1 | 500 | 5 | 2.78 | 55.7 | yes |
| Scenario 1+2 – CHILD (6 to <12 years old) 1 app/day | 1 | 500 | 5 | 3.88  | 77.5 | yes |
| Scenario 1+2 – CHILD (2 to <6 years old) 1 app/day | 1 | 500 | 5 | 4.39 | 87.8 | yes |
| Scenarios 1+2 – TODDLER 1 app/d | 1 | 500 | 5 | 4.84 | 96.8 | yes |

**Local effects**

The biocidal product is classified as eye irritation cat 2, H319. However, appropriate risk mitigation measures will be imposed and taken up on the label.

|  |  |  |
| --- | --- | --- |
| **Hazard** | **Exposure** | **Risk** |
| Hazard Cat.  | Local effects in terms of C&L  | Exposed groups | Tasks, uses, processes  | Potential exposure route  | Frequency and duration of potential exposure  | Rough degree of exposure | Relevant RMM & PPE | Conclusion on risk |
| Low | H319 Eye irritation | non-professionals - adults | - application to own skin- application to children’s skin | accidental transfer to eyes from fingers during or after handling the product | 1 application/ day for adultsand 1 application/ day on 2 children;seasonal application | *per analogiam* with hand-to-mouth transfer (b.p. application rate x a.s. concentration x area of treated body x transfer factor – fingers only):41 mg a.s.(the amount is overestimated since all fingers are considered as a potential source of transfer to eyes) | - no PPE- labelling as eye irritant- application of P-statement:P102P264P305+P351+P338P337+ P313- additional provisions: “Do not apply the product directly to face - first, spray it onto your hand, then spread avoiding eyes.” | Acceptable:- the product is intended for dermal application only- eye irritation can occur during unintended transfer: by rubbing eyes with hands or accidental spraying- product is used only when the presence of insects is expected (low frequency of use), for a short period of time (applying on uncovered parts of body) - the effect is reversible (Eye Irrit 2) - the product is in a ready-to-use form and has a protective cap which reduces the probability of unintended spraying |
| Low | H319 Eye irritation | non-professionals / general public - children (6-12 y.o.)- children (2-6 y.o.)- toddlers | - application of product to children’s skin by adult | accidental transfer to eyes from fingers during or after application of the product | 1 application/ day by adult;seasonal application | *per analogiam* with hand-to-mouth transfer (b.p. application rate x a.s. concentration x area of treated body x transfer factor – fingers only):43 mg, 32 mg and 23 mg a.s., respectively(the amount is overestimated since all fingers are considered as a potential source of transfer to eyes)  | - no PPE- labelling as eye irritant- application of P-statement: P102P264P305+P351+P338P337+ P313- additional provisions: “For children of 1 to 12 years: the repellent must be applied by adults. “, „Do not apply the product directly to face - first, spray it onto hand, then spread avoiding eyes.“, „Do not apply onto children's hands.” |

Risk related to local effects which may be caused by BROS Pršilo proti komarjem za otroke is considered low based on above mentioned aspects of exposure.

***Risk for the general public***

Exposure of the general public is covered by the secondary exposure of non-professional.

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

Not applicable.

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

Not applicable.

### Risk assessment for animal health

Exposure of animals is unlikely if the biocidal product is used as intended (direct application to human skin). Thus, a corresponding exposure and risk assessment is not required. However, similar biocidal products for use on animals exist. Therefore, an advice not to treat animals is required for the label. The following RMMs are proposed:

-“Do not use near domestic animals or livestock.”

-“Do not apply directly on animals.”

Secondary exposure (e.g. by dermal and inhalation exposure to residues) is covered by human secondary exposure and risk assessment.

### Risk assessment for the environment

The biocidal product BROS Pršilo proti komarjem za otroke contains the active substance ethyl butylacetylaminopropionate (IR3535®), that was approved for use as a repellent (PT19) in November 2014. The applicant provided a full letter of access for the active substance dossier. No new data were submitted by the applicant for the authorisation of the biocidal product, therefore the environmental risk assessment is based on the information given in the CAR for the active substance IR3535® (CAS: 52304-36-6).

Ethanol and propan-2-ol are substances of concern in the product as they are active substances in PT 1, 2 and 4 and present in the product with a concentration ≥ 0.1%. These substances are solvents which will quickly evaporate from treated skin. The main emission route for the environment will be to air and no emission to the sewer is expected.

Considering that the substances are diluted in the air and moreover degraded quickly once deposited on surface water and soil, concentrations above environmental risks limits are not expected and the accompanied risks are considered acceptable. Furthermore, the substances are resistant to hydrolysis, but readily biodegradable. The degradation products of these substances are water and carbon dioxide and are not considered relevant for the environmental risk assessment as these are natural occurring compounds. Therefore, the risk assessment is carried out for the active substance only.

#### Effects assessment on the environment

No new endpoint studies have been submitted since the approval of the active substance. The risk assessment is entirely based on the list of endpoints as published in the assessment report (Assessment report for ethyl butylacetylaminopropionate, PT19, 13/03/2014) for which BE was the rapporteur member state.

The PNECs applied in the environmental risk assessment are summarised in the table below.

|  |
| --- |
| **Summary of PNEC values for the active substance**  |
| **Compartment** | **PNEC value** |
| Surface water | PNECwater > 0.1 mg/L |
| Aquatic micro-organisms (STP)  | PNECmicro-organisms (STP) = 100 mg/L |
| Sediment | PNECsediment > 1.11 mg/kgwwt |
| Soil | PNECsoil > 0.851 mg/kgwwt |

***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***

There are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected. Thus, ecotoxicological properties and classification has been deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

The product does not contain any substance at such a concentration that has an effect on the environmental classification of the product. No additional information on the biocidal product is required.

***Further Ecotoxicological studies***

No data is available

|  |
| --- |
| **Data waiving** |
| Information requirement | Further Ecotoxicological studies |
| Justification | No further studies used, other than the ones included in the CAR for the active substance. |

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

Not relevant

|  |
| --- |
| **Data waiving** |
| Information requirement | Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk |
| Justification | Not required for PT19 |

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

Not relevant

|  |
| --- |
| **Data waiving** |
| Information requirement | Supervised trials to assess risks to non-target organisms under field conditions |
| Justification | Not required because the biocidal product is not in the form of bait or granules. |

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

Not relevant

|  |
| --- |
| **Data waiving** |
| Information requirement | Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk |
| Justification | Not required because the biocidal product is not in the form of bait or granules. |

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

Secondary ecological effect studies may be required when a habitat such as a water body, wetland, forest or field is treated. No testing on secondary ecological effect is needed, as product will not be applied to large proportions of a specific habitat.

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

The product is to be used by general public, indoors and outdoors as insect repellent to protect humans from insects by application on skin.

Emissions to the environment occur during application of the product to skin via spray drift to the ground and during the removal phase. However, according to ESD PT19, emissions during the application step are of minor importance since it is unlikely that applications occur above the same limited surface area repeatedly. Therefore, only emissions due to removal of the product are considered in the following exposure assessment.

The main emissions to the environment resulting from the application of the product on human skin occur during the removal phase of the insect repellent:

* Through showering and bathing of humans who have used an insect repellent: Sewage Treatment Plants (STP) are the primary compartment for emissions, whereas surface water (including sediment) and soil (including groundwater) are secondary exposed compartments for remnants via STP effluents and sewage sludge applications, respectively.
* Through direct release to surface water if people with treated skin go swimming in outdoor surface waters.

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

No data is available

|  |
| --- |
| **Data waiving** |
| Information requirement | Further studies on fate and behaviour in the environment |
| Justification | No further studies used, other than the ones included in the CAR for the active substance. |

***Leaching behaviour (ADS)***

No studies on the degradation behaviour of IR3535® in soil are available since soil is not a directly exposed compartment. Consequently, leaching behaviour is also not relevant for the considered product.

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

No additional data is available for distribution and dissipation in soil.

|  |
| --- |
| **Data waiving** |
| Information requirement | Testing for distribution and dissipation in soil |
| Justification | No further studies used, other than the ones included in the CAR for the active substance. |

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

No additional data is available for distribution and dissipation in water and sediment.

|  |
| --- |
| **Data waiving** |
| Information requirement | Testing for distribution and dissipation in water and sediment |
| Justification | No further studies used, other than the ones included in the CAR for the active substance. |

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

No additional data is available for distribution and dissipation in air.

|  |
| --- |
| **Data waiving** |
| Information requirement | Testing for distribution and dissipation in air |
| Justification | No further studies used, other than the ones included in the CAR for the active substance. |

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

No new data was submitted or is required.

***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)***

No new data was submitted or is required.

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT19 |
| Assessed scenarios | Scenario 1: Removal through showering and bathing of humansScenario 2: Release to surface water bodies through swimming |
| ESD(s) used | Emission Scenario Document for Product Type 19: Repellents and attractants (ECHA, 2015) |
| Approach | Average-consumption |
| Distribution in the environment | Calculated based on Guidance on the Biocidal Products Regulation, vol. IV – Parts B + C (2017) |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | All scenariosProduction: NoFormulation: NoUse: YesService life: No |
| Remarks | None |

**Emission estimation**

**Scenario 1: Removal through showering and bathing of humans**

The main emissions of this scenario to the environment occur during the removal phase of the insect repellent. Removal of the product from human skin takes place through showering or bathing of humans who have used an insect repellent. Sewage treatment plants are the primary compartment for emissions.

Modelling has been taken from the ESD PT19 covering repellents and attractants: Table 3-6, based upon the post-consumer release prediction model taken from ESD PT1 (according to Van der Aa and Balk, 2004). Where indicated, default values have been taken from the ESD PT19, and specific values for IR3535® taken from the AR have been applied where it is relevant to do so:

* Value for Finh of 0.2 for the fraction of inhabitants using the product (default).
	+ Value for Fpenetr of 0.5 for the market share of products applied for this purpose (default).
* Whilst it has been shown in the Doc II-A of the CAR (for a.s. used in PT19 products) that up to 30% of applied IR3535® can be absorbed by the human skin, no refinement of the environmental risk assessment to discount this fraction has been undertaken. Many of the reported HH studies use unrepresentative formulations and identify significant dermal adsorption measured 10 - 24 h after topical application. As such, they cannot be reliably used as refinement in emissions assessment when products may have been removed by washing or swimming after a much shorter period of time. As a worst case protective approach, Fskin will be considered as zero and therefore a value of Fwater of 1 will be used in ESD models.
	+ As indicated in ENV 172 of TAB 2.1 (2019) the value used in modelling for treated skin area should be as in the Recommendation no. 11 of the BPC Ad hoc Working Group on Human exposure, i.e. 9130 cm2, which represents 55% of total body area (16600 cm2), since this could be considered as a mean value taking into account the different skin areas for women, men and children.

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Nomenclature** | **Value**  | **Unit** | **Remarks** |
| Scenario: Removal through showering and bathing of humans (ESD 3.1.4.1) |
| Number of inhabitants feeding one STP | Nlocal | 10000 | cap | Default ESD PT19 |
| Application rate of biocidal product  | Qformappl | 0.43 | mg/cm² | *c.f.* 2.2.1 |
| Concentration of active substance in the product  | Cformweight | 170 | g/kg | 17% (w/w) |
| Number of applications per day  | Nappl | 1 | day-1 | Product label |
| Treated area of human skin  | AREAskin | 9130 | cm² | ENV 172 (TAB 2.1) |
| Fraction released to air | Fair | 0 | - | Default ESD PT19 |
| Fraction dermally absorbed | Fskin | 0 | - | Default ESD PT19 |
| Fraction released to wastewater  | Fwater | 1 | - | Default ESD PT19D |
| Fraction of inhabitants using a repellent product  | Finh | 0.2 | - | ESD PT19, Table 3-5 |
| Market share of products applied for this purpose  | Fpenetr | 0.5 | - | Default ESD PT19D |

Calculations for Scenario 1



| **Resulting local emission to relevant environmental compartments** |
| --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 0.6674E+00 | Local emission rate to wastewater (STP) from human skin treated with repellent following showering/bathing or washing |

**Scenario 2: Release to surface water bodies through swimming**

The main emissions of this scenario to the environment occur through direct release to surface water if people with treated skin go swimming in outdoor surface waters. Humans treated with a repellent, can swim in coastal areas as well as in inland waters (rivers and lakes). To represent a realistic worst case scenario, the release of repellents from the skin of treated humans into ponds, lakes or reservoirs during swimming is evaluated. Due to dilution effects, neither coastal areas nor rivers will be considered (according to ESD PT19). Thus, surface water bodies like ponds, lakes or reservoirs are the receiving compartments for emissions.

Assessment of emissions reaching the surface water bodies in Scenario 2 will be based upon a number of assumptions:

* Based upon the approach outlined in the ENV 172 of TAB 2.1 (2019), application to 9130 cm2 of skin is assumed.
	+ For emissions to surface water bodies, the number of swimmers (Nswimmer = 1500), fraction of swimmers using the repellent (Fswim = 0.1 for product level assessment), number of applications per day (Nappl = 1) and fraction released to surface water body (Fwaterbody = 1) are ESD default values.

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Nomenclature** | **Value**  | **Unit** | **Remarks** |
| Scenario 2: Release to surface water bodies through swimming (ESD 3.1.4.2) |
| Daily number of swimmers  | Nswimmer | 1500 | - | Default ESD PT19 |
| Fraction of swimmers using the repellent product  | Fswim | 0.1 | - | Default ESD PT19 |
| Number of applications per day  | Nappl | 1 | day-1 | Default ESD PT19 |
| Fraction released to surface water body  | Fwaterbody | 1 | - | Default ESD PT19 |
| Application rate of biocidal product  | Qformappl | 0.43 | mg/cm² | *c.f.* 2.2.1 |
| Concentration of active substance in the product  | Cformweight | 170 | g/kg | 17% (w/w) |
| Treated area of human skin or garments | AREAskin | 9130 | cm² | ENV 172 (TAB 2.1) |

Calculations for Scenario 2



| **Resulting local emission to relevant environmental compartments** |
| --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Surface water | 1 E-01 | Local emission rate to surface water from swimmers using the repellent product |

In the above calculation a local daily emission to the surface water body due to swimmers treated with the repellent, was calculated. In order to assess the impact of this emission on the aquatic life in this waterbody, the actual concentration of the active substance in this waterbody should be calculated. As a first tier approach, concentrations are calculated for emission periods of 1 day and 91 days, representing the worst case situation as no degradation processes in the water body are considered.

|  |
| --- |
| **Input parameters for calculating surface water concentration** |
| **Input**  | **Nomenclature** | **Value**  | **Unit** | **Remarks** |
| Scenario 2: Release to surface water bodies through swimming  |
| Local emission to surface water body  | Elocalwater | 1E-01 | kg/d | Calculated |
| Volume of water body  | Vwaterbody | 435000 | m3 | Default ESD PT19 |
| Number of emission days  | Temission,1d | 1 | d | Default ESD PT19 |
| Number of emission days  | Temission,91d | 91 | d | Default ESD PT19 |



| **Resulting local concentrations in the waterbody** |
| --- |
| **Compartment** | **Local concentration (Clocalcompartment) [mg/L]** | **Remarks** |
| Surface water – after 1 day | 2.29E-04 | / |
| Surface water – after 91 days | 2.09E-02 | Without considering possible degradation |

**Fate and distribution in exposed environmental compartments**

|  |
| --- |
| **Identification of relevant receiving compartments based on the exposure pathway** |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1 | Yes | Yes | Yes | Yes | Yes | NR | Yes | Yes | No |
| Scenario 2 | Yes | Yes | Yes | Yes | NR | NR | NR | NR | No |

|  |
| --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** |
| **Input**  | **Value** | **Unit** | **Remarks** |
| Molecular weight | 215.29 | g/mol |  |
| Melting point | -90 | °C | Test substance is liquid at room temperature |
| Boiling point | 300 | °C | Metastable boiling point |
| Vapour pressure (at 20 °C) | 0.15 ± 0.01 | Pa |  |
| Water solubility (at 20 °C) | 7.0E+04 | mg/L |  |
| Log octanol/water partition coefficient | 1.7 | Log Pow | HPLC method |
| Organic carbon/water partition coefficient (Koc) | 475.25 | L/kg | Value obtained from adsorption/desorption test |
| Henry’s Law Constant (at 20 °C) | 4.613E-04 | Pa m3/mol |  |
| Biodegradability | Not Readily biodegradable |  | IR3535® failed on the ready biodegradability tests. However an STP simulation test showed elimination of 99% after 28 days, indicating that the substance is biodegradable in the STP. |

In terms of distribution in the STP, values have been provided for Simple Treat 4.0 but emission models for this product will use those values predicted within the IR3535® CAR, which takes into account data from the STP simulation test (Doc. No.: 713-002, Doc. IIIA, Section A7.1.2.1.1/01). This approach assumes that 99% removal of a.s. by mineralisation takes place within the STP and any remaining active substance (predicted to be 1%) will be released into surface waters. The terrestrial compartment (including groundwater) and air will not be exposed.

|  |
| --- |
| **Calculated fate and distribution in the STP**  |
| Compartment | Percentage [%] | Percentage [%] |
| Scenario 1(Simple Treat 4.0) | Scenario 1(IR3535® CAR) |
| Air | 1.06E-03 | 0 |
| Water | 94.21 | 1 |
| Sludge | 5.784 | 0 |
| Degraded in STP | 0 | 99 |

**Calculated PEC values**

The compartmental PEC values were determined using the equations and default values taken from the Guidance on the Biocidal Products Regulation, vol. IV – Parts B + C (2017) and Emission Scenario Document for Product Type 19 (2015).

**PECsediment:** As no toxicological studies with sediment organisms were provided, the PNECsediment presented in the CAR was based on the PNECwater using the equilibrium partitioning method (EPM) and therefore the ratio PEC/PNEC for freshwater covers that of sediment as well. Calculation of PECsediment is therefore not included in the current risk assessment.

**PECseawater and PECseasediment:** The aquatic compartment is exposed by repellent products both directly and indirectly via STP. Emissions to freshwater bodies are expected to be the worst case scenario compared to seawater considering the higher dilution factor in seawater. Therefore, only emissions to freshwater are taken into account in the following assessment.

**PECair:** As the major route of exposure of IR3535® to the environment for Scenario 1 is considered to be via STP, the worst case unrefined value taken from Simple Treat 4.0 for the fraction of emission directed to air from STP should be considered. This value of
1.06E-03% represents the highest proportion directed to air as a protective approach but would still suggest that any exposure to air via this route is likely to be negligible. Moreover, STP simulation data submitted at a.s. review indicates that 99% of a.s. would degrade and the remaining 1% was accepted as being directed solely to surface water. No assessment of risks to air is therefore necessary.

In the case of Scenario 2, direct emissions to air by use of the product are expected to be negligible because of the low vapour pressure of IR3535® being 0.15 Pa at 20 °C. Furthermore, the half-life of the active substance was calculated to be about 0.5482 days or 13.16 hours due to reaction with OH-radicals (24-h day). Thus, accumulation of IR3535® in air and long range transport is unlikely. Moreover, it is expected that any repellent product will be formulated to ensure that active components remain on the skin and thus maintain effectiveness against target organisms.

Hence PECair will not be considered any further as emissions would likely be negligible.

|  |
| --- |
| **Summary table on calculated PEC values** |
|  | **PECSTP** | **PECwater** | **PECsoil** | **PECGW** |
|  | [mg/L] | [mg/L] | [mg/kgwwt] | [μg/L] |
| Scenario 1 | 3.34E-03 | 3.33E-04 | \* | \* |
| Scenario 2 | - | 2.09E-02 | - | - |
| \* Although the SimpleTreat model used in the CAR predicted negligible levels of IR3535® being released in sludge (with an Fstpsludge of 0), this is not true for SimpleTreat 4.0 where 5.784% of a.s. is predicted to be directed to sludge. However, provision of reliable STP simulation data at review led to an accepted approach in the CAR that 99% of a.s. can be degraded within STP, with the remaining 1% being directed only to surface waters. As a consequence of this refinement in the CAR, there will be no exposure of the terrestrial compartment (including groundwater).  |

The worst case PEC value for the risk assessment for the aquatic compartment for scenario 2 corresponds to the Clocalwater,91d value.

**Primary and secondary poisoning**

Primary poisoning

The direct intake of the biocidal product by non-target organisms is not considered as likely, therefore primary poisoning is not further considered.

Secondary poisoning

IR3535® released by use of BROS Pršilo proti komarjem za otroke is unlikely to bioaccumulate in the aquatic or terrestrial environment. The active substance has a low log Kow (1.7), which is below the relevant trigger value of 3. The low accumulation potential is supported also by low BCFfish of 5.6 L/kg and BMFearthworm of 1.44 kg/kg. No further assessment of secondary exposure via the food chain is therefore considered necessary.

#### Risk characterisation

***Atmosphere***

No air concentrations have been calculated as the level of risk to this compartment is expected to be negligible.

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

|  |
| --- |
| **Summary table on calculated PEC/PNEC values** |
|  | **PEC/PNECSTP** |
| Scenario 1 | 3.34E-05 |
| Scenario 2 | Not relevant |

Conclusion: An acceptable level of risk to microorganisms at STP has been identified for Scenario 1, as the PEC/PNEC ratio is less than 1.

Assessment for Scenario 2 is not relevant, as no release to drains can be expected.

***Aquatic compartment***

|  |
| --- |
| **Summary table on calculated PEC/PNEC values** |
|  | **PEC/PNECwater** | **PEC/PNECsediment** |
| Scenario 1 | 3.33E-03 | Same as aquatic compartment |
| Scenario 2 | 2.09E-01 | Same as aquatic compartment |

Conclusion: No risk to surface water and sediment has been identified, as PEC/PNEC ratio is less than 1 for both compartments.

***Terrestrial compartment***

In Scenario 1, release of IR3535® via the application of sewage sludge to agricultural land (grassland and/or arable land) is not expected in the Tier 2 refinement undertaken in the a.s. review based upon STP simulation data. Study results in Doc II-A of the CAR indicate that 99% of a.s. can be considered as degraded and the remaining 1% is concluded to be released only to surface waters. No exposure of the terrestrial compartment is therefore expected.

No assessment is relevant in Scenario 2 as release to drains is not expected.

Conclusion: No risk has been identified for the terrestrial compartment.

***Groundwater***

In Scenario 1, IR3535® is expected to degrade almost completely whilst at STP (based upon simulation data) and the remaining 1% is expected to be released only to surface waters. With no exposure to the terrestrial compartment, then groundwater cannot be contaminated with a.s. and no assessment is required.

No assessment is required in Scenario 2, as no exposure of the terrestrial compartment is expected.

***Primary and secondary poisoning***

Primary poisoning

The direct intake of the biocidal product by non-target organisms is not considered as likely, therefore primary poisoning is not further considered.

Secondary poisoning

As the bioaccumulation potential and the potential of accumulation in the food chain of the active substance IR3535® is negligible, secondary poisoning is not further considered.

***Mixture toxicity***

*Screening step*

Screening Step 1: Identification of the concerned environmental compartments

The environmental compartments that are to be exposed are (i) sewage treatment plants (and subsequently surface water bodies including sediment as well as the soil compartment including groundwater) and (ii) surface water bodies.

Screening Step 2: Identification of relevant substances

The product contains IR3535® as the active substance and two substances of concern (SoC), i.e. ethanol and propan-2-ol. However, please see the argument on the ecotoxicological relevance of these substances in the section Risk assessment for the environment.

Screening Step 3: Screen on synergistic interactions

|  |
| --- |
| **Screening step** |
| 1 | Significant exposure of environmental compartments? | Yes |
| 2 | Number of relevant substances >1? | No |
| 3 | Indication for synergistic effects for the product or its constituents in the literature? | No |

Conclusion: The environmental risk assessment is solely based on the active substance and a mixture toxicity assessment is not necessary.

***Endocrine-disrupting properties***

In reference to toxicity of the mixture hazard of potential endocrine-disrupting properties should be identified. The active substance is currently not considered classified as an identified ED substance to have endocrine disrupting properties under Regulation (EU) 528/2012. A step-wise approach for a targeted determination of whether a non-active substance (co-formulant) in a biocidal product is an ED or has indications of ED properties was used in the assessment. Based on the state of the art the components of the biocidal product do not exhibit ED properties. Please refer to the confidential annex for a detailed analysis.

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

Although the product, BROS Pršilo proti komarjem za otroke, is assessed in two different scenarios (release to the STP from showering and bathing and release to surface water if people with treated skin go swimming in outdoor surface waters), no summation of risk quotients has been considered necessary. It is extremely unlikely that losses to surface waters from discharge of treated wastewater at STP would ever reach swimming lakes such that cumulative effects on aquatic organisms can be ignored.

However, even if predicted risks to surface water from both scenarios were aggregated, risk to aquatic systems (aquatic and sediment compartments) would be acceptable.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The product BROS Pršilo proti komarjem za otroke contains the active substance IR3535® at 17% (w/w). It is a repellent under PT19 for use against biting insects and is applied directly to the skin.According to the ESD PT19 the main emissions from this use to the environment occur during the removal phase of the insect repellent. Removal of the product from human skin can either take place:* + Scenario 1: Through showering or bathing of humans who have used an insect repellent. Sewage treatment plants are the primary compartment for emissions whereas surface water bodies (including sediment) as well as the soil compartment (including groundwater) are secondary exposed compartments for remnants via sewage treatment plant effluents and sewage sludge applications, respectively.
	+ Scenario 2: Through direct release to surface water if people with treated skin go swimming in outdoor surface waters.

STP simulation data provided in Doc II-A of the CAR for IR3535® indicated that a refined approach to emissions assessment could be undertaken, whereby 99% of a.s. is removed by degradation in the STP and the remaining 1% is released to surface waters. This refined approach has been followed in this PAR.Overall, the use of the biocidal product does not induce risk for any of the environmental compartments.  |

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

Please see §2.1.4 and §2.1.5 above.

### Assessment of a combination of biocidal products

Not applicable.

### Comparative assessment

Not applicable.

# Annexes

## List of studies for the biocidal product

| **List of studies for the BROS Pršilo proti komarjem za otroke**  |
| --- |
| **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)**  | **Date of first submission** |
| Elisabeth Servajean | 2019 | Physical-chemical properties, stability and shelf-life ofMosquito and Tick Pump Spray for Children IPart 1: Physical-chemical properties upon receipt, after cold storageand after accelerated storageStudy Number: 18-99-061ESGLP: Yes | YES | BROS Sp.z o.o.Sp.k |  |
| Marzena Włodarczak | 2019 | Determination of the particle size of the test item in the package with the atomizerStudy Number: 0001/0187/FAGLP: Yes | YES | BROS Sp.z o.o.Sp.k |  |
| Paulina Flasińska | 2018 | Determination of flash-point and auto-ignition temperatureStudy Number: BC-107/18GLP: Yes | YES | BROS Sp.z o.o.Sp.k |  |
| Elisabeth Servajean | 2020 | Physical-chemical properties, stability and shelf-life ofMosquito and Tick Pump Spray for Children IPart 3: Physical-chemical properties after 24 months of storage room temperatureStudy Number: 18-99-061-ESGLP: Yes | YES | BROS Sp.z o.o.Sp.k |  |
| Joanna Kalbarczyk | 2021 | Determination of the boiling pointStudy number: BF-15/21GLP: Yes | YES | BROS Sp.z o.o.Sp.k |  |
| Magdalena Zygrykalis | 2021 | Final Report: Repellent efficacy test of liquid product PT19 on ticks.Product: BROS Pršilo proti komarjem za otrokeReport no.: LZ/ AD17LQ-Ixr/ 15-19032021GLP: No | YES | BROS Sp.z o.o.Sp.k |  |
| Łukasz Zygrykalis | 2021 | Final Report: Repellent efficacy test of BROS Płyn na komary i kleszcze dla dzieci I on *Culex* spp. mosquitoes (PT19).Product: BROS Pršilo proti komarjem za otrokeReport no.: LZ/ AD17LQ-Cp/ 15-19032021GLP: No | YES | BROS Sp.z o.o.Sp.k |  |
| Łukasz Zygrykalis | 2021 | Final Report: Repellent efficacy test of BROS Płyn na komary i kleszcze dla dzieci I on *Aedes* spp. mosquitoes (PT19).Product: BROS Pršilo proti komarjem za otrokeReport no.: LZ/ AD17LQ-Aa/ 15-19032021GLP: No | YES | BROS Sp.z o.o.Sp.k |  |

## Output tables from exposure assessment tools

Risk assessment for human health

*Scenario 2*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario 2 - Inhalation exposure** |  |  |  |  |
| **TIER 1 : 1 application/day** |  |  |  |  |
| **User category** | **ADULT** | **CHILD ( 6-12y)** | **CHILD (2-6y)** | **Toddler**  |
| **Indicative value for inhalation (mg/m3)** | **10.5** | **10.5** | **10.5** | **10.5** |
| **inhalation rate** | **1.25** | **1.32** | **1.26** | **1.26** |
| **% of active substance in the product** | **17** | **17** | **17** | **17** |
| **Number of application /day** | **1** | **1** | **1** | **1** |
| **Spray duration (hour)**  | **0.06666667** | **0.066666667** | **0.066666667** | **0.066666667** |
| **Inhalation absorption (%)** | **100** | **100** | **100** | **100** |
| **Oral absorption (%)** | **100** | **100** | **100** | **100** |
| **% of inhalation fraction** | **1.6** | **1.6** | **1.6** | **1.6** |
| **% of oral fraction** | **98.4** | **98.4** | **98.4** | **98.4** |
| **Body Weight (kg)**  | **60** | **23,9** | **15,6** | **10** |
|  |  |  |  |  |
| **Inhaled active substances (mg/day-**  | **0.14875** | **0.15708** | **0.14994** | **0.14994** |
| **inhalation systemic exposure** | **3.9667E-05** | **0.000105158** | **0.000153785** | **0.000239904** |
| **oral systemic exposure** | **0.0024395** | **0.006467227** | **0.009457754** | **0.014754096** |
| **totat systemic exposure** | **0.00247917** | **0.006572385** | **0.009611538** | **0.014994** |

## New information on the active substance

Not applicable.

## Residue behaviour

Not applicable.

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

Not relevant, IUCLID file available.

## Confidential annex

Please see the respective file.

## Other

None