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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT (FAMILY) FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



Mouskito Junior North Europe Lotion

Product type 19

Ethyl butylacetylaminopropionate   
(Further referred to as IR3535®)

Case Number in R4BP: BC-YL020104-40

Evaluating Competent Authority: Belgium

Date: [01/03/2024]

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|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| NA-APP | BE | BC-YL020104-40 | 15/11/2019 | Initial assessment | - |
| NA-MIC | BE | BC-EL062862-34 | 12/05/2021 | Increase/addition of a non-active substance in the product  Change in the shelf life from 2 years to 3 years | - |
| NA-ADC | BE | BC-NN072400-37 | 08/03/2022 | Change of the name of the biocidal product from Mouskito Junior Lotion to Mouskito Junior North Europe Lotion | - |
| NA-AAT | BE | BC-FX092556-02 | 01/03/2024 | Removal of the use against wasps and bees in accordance with the Commission Implementing decision (EU) 2022/1515 | - |

# Conclusion

Mouskito Junior Lotion can be authorised as a ready-to-use repellent (PT19) to be used against flying insects and ticks in temperate areas and also mosquitoes in tropical conditions. It is suitable only for children older than 2 years of age and adults. It should only be applied on exposed skin (face, hands, arms, legs and feet).

In accordance with the Commission Implementing decision (EU) 2022/1515, the use against wasps and bees is no longer approved.

**Remark:**

-This product is not authorised for use on children younger than 2 years of age.

-This product is not authorised for use against target organisms other than those indicated above.

The assessment of the endocrine disrupting (ED) properties of the substances used in the biocidal product Mouskito Junior Lotion was performed according to the Regulation (EU) 528-2012 and Regulation (EU) 2017-2100.

Based on the existing knowledge and the data provided by the applicant, there may be a potential concern regarding the ED properties of one of the substances used in the biocidal product Mouskito Junior Lotion. Pending the final decision regarding the ED properties of this substance, it was not possible to conclude whether the non-active substance should be considered to have ED properties before the expiration of the legal deadline in the BPR and therefore the process will be concluded at the post-authorisation stage (Please refer to section 2.1.2 (34) of CA-March18.Doc.7.b-final).

# Assessment Report

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| Mouskito Junior Lotion | Belgium |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Laboratoria QUALIPHAR N.V./S.A. |
| **Address** | Rijksweg 9 – 2880 Bornem - Belgium |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

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

|  |  |
| --- | --- |
| **Name of manufacturer** | Cosmade BVBA |
| **Address of manufacturer** | Impulsstraat 3A – 2220 Heist-op-den-Berg - Belgium |
| **Location of manufacturing sites** | Belcofill BVBA - Impulsstraat 7 – 2220 Heist-op-den-Berg - Belgium |

|  |  |
| --- | --- |
| **Name of manufacturer** | Fareva - FCA |
| **Address of manufacturer** | Les Iles Freays – 07300 Tournon sur Rhône - France |
| **Location of manufacturing sites** | Les Iles Freays – 07300 Tournon sur Rhône - France |

|  |  |
| --- | --- |
| **Name of manufacturer** | Alcoholes Montplet |
| **Address of manufacturer** | Via Trajana 53-55 – 08020 Barcelona - Spain |
| **Location of manufacturing sites** | Via Trajana 53-55 – 08020 Barcelona - Spain |

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

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

### Product (family) composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | IR3535 |
| **IUPAC or EC name** | ethyl 3-[N-acetyl-N-butyl] aminopropionate |
| **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** | ir3535 |

#### Candidate(s) for substitution

The active substance IR3535 is not a candidate for substitution.

#### Qualitative and quantitative information on the composition of the biocidal product[[2]](#footnote-2)

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| IR3535 | ethyl 3-[N-acetyl-N-butyl] aminopropionate | Active substance | 52304-36-6 | 257-835-0 | 20 |

Full composition is available in the confidential annex.

#### Information on technical equivalence

Not needed, since the manufacturer is the same as included in the Union list of approved active substances.

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

The product does not contain any substance of concern.

However, the substance Hexahydrotetramethylmethanoazulenylethanon (CAS 32388-55-9) **has been flagged** for its potential ED properties. Please refer to section 2.2.9.

#### Type of formulation

|  |
| --- |
| AL any other liquid |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Eye irritation, category 2 |
| Hazard statement | H319: Causes serious eye irritation |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | / |
| Precautionary statements | P102: Keep out of reach of children |
|  | |
| **Note** | GHS07, warning  For reduced labelling (volumes <125ml) art. 29(2) and Annex I pt 1.5.2.1 of Regulation (EC) No 1272/2008 can be followed. |

### Authorised use(s)

#### Use description[[3]](#footnote-3)

|  |  |
| --- | --- |
| **Table 1. Use # 1 – repellent – use in tropical climatic conditions** | |
| **Product Type** | PT 19 – Repellents and attractants |
| **Where relevant, an exact description of the authorised use** | Repellent - to protect human skin from insect bites |
| **Target organism (including development stage)** | Aedes aegypti (adults)  Culex quinquefasciatus (adults)  Anopheles gambiae (adults)  Mouskito Junior Lotion is a ready-to-use insect repellent used to protect humans in areas with tropical climatic conditions against mosquito (*Aedes aegypti, Culex quinquefasciatus, Anopheles gambiae*) bites. |
| **Field of use** | indoors in well ventilated areas and outdoors |
| **Application method(s)** | Manual spreading  Apply the repellent on the skin, only on uncovered parts of the body (face, hands, arms, legs and feet only). Suitable only for children older than 2 years and adults. Do not apply on children’s hands. |
| **Application rate(s) and frequency** | Mouskito Junior Lotion(20 % IR3535) applied on human skin in tropical climatic conditions at a dose of 1 g/ 600 cm² provides a protection time of 7 hours against mosquitoes (*Aedes aegypti, Culex quinquefasciatus, Anopheles gambiae).*  Protects against Anopheles (potential vector of malaria).  Apply a sufficient amount on exposed skin (face, hands, arms, legs and feet only). For application on the face: apply by hand.  Dose per application:  Adults: 15.2 g  *children’s hands are not to be treated*  Children (6-<12y): 8.5 g  Children (2-<6y): 6.2 g  Maximum number of applications per day:  Adults, children >2 years: 1 application/day |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### 

|  |  |
| --- | --- |
| **Table 2. Use # 2 – repellent – use in temperate climatic conditions** | |
| **Product Type** | PT 19 – Repellents and attractants |
| **Where relevant, an exact description of the authorised use** | Repellent - to protect human skin from insect bites |
| **Target organism (including development stage)** | Aedes aegypti (adults)  Culex quinquefasciatus (adults)  Stomoxys calcitrans (adults)  Ixodes ricinus (adults & nymphs)  Mouskito Junior Lotion is a ready-to-use insect repellent used to protect humans in areas with temperate climatic conditions against mosquito bites (*Aedes aegypti, Culex quinquefasciatus*), fly (*Stomoxys calcitrans*) bites and tick (*Ixodes ricinus*) bites. |
| **Field of use** | indoors in well ventilated areas and outdoors |
| **Application method(s)** | Manual spreading  Apply the repellent on the skin, only on uncovered parts of the body (face, hands, arms, legs and feet only). Suitable only for children older than 2 years and adults. Do not apply on children’s hands. |
| **Application rate(s) and frequency** | Mouskito Junior Lotion (20 % IR3535) applied on human skin in temperate climatic conditions at a dose of 1 g/ 600 cm² provides a protection time of 7h30 against mosquitoes (*Aedes aegypti & Culex quinquefasciatus)*, of 8 h against flies (*Stomoxys calcitrans)* and of 2 h against ticks (*Ixodes ricinus*).  Apply a sufficient amount on exposed skin (face, hands, arms, legs and feet only). For application on the face: apply by hand.  Dose per application:  Adults: 15.2 g  *children’s hands are not to be treated*  Children (6-<12y): 8.5 g  Children (2-<6y): 6.2 g  Maximum number of applications per day:  Adults, children >2 years: 1 application/day |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use-specific instructions for use[[4]](#footnote-4)

|  |
| --- |
| See §2.1.5.1 |

#### Use-specific risk mitigation measures

|  |
| --- |
| See §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

|  |
| --- |
| See §2.1.5.3 |

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

|  |
| --- |
| See §2.1.5.4 |

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

|  |
| --- |
| See §2.1.5.5 |

### General directions for use

#### Instructions for use[[5]](#footnote-5)

|  |
| --- |
| Use repellents safely. Always read the label and product information before use and follow the instructions provided.  Respect the recommended application doses.  Apply the product evenly onto exposed skin and distribute the applied lotion on the skin by hand.  The product should be applied on a dry skin.  Do not apply over cuts, wounds, freshly shaven or irritated skin. Only for external use.  The protection time is only indicative. The protection time will be modified by environmental factors (e.g. high temperature, wind velocity) and in case of swimming, excessive transpiration, …  Mechanical protection (clothing, mosquito nets) is to be preferred at all times. Cover untreated parts of the body by clothing.  Applying sun care products or cosmetic formulations after repellent use will decrease the efficacy of the repellent considerably.  The use of the product with other repellent products is not recommended.  The product is not intended for use on animals/pets.  Inform the registration holder if the treatment is ineffective. |

#### Risk mitigation measures

|  |
| --- |
| Suitable only for children older than 2 years and adults.  Keep out of reach of children.  Use only outdoors or in a well-ventilated area.  ONLY apply to uncovered parts of the body, limited to arms, hands, legs, feet and face. Do not use on children’s hands. Do not use under clothing.  Avoid contact with the eyes, mouth and mucous membranes. Do not apply to eye area. For treatment of the face, the product should be applied to the hand and spread carefully on the face. Take care to protect the eyes.  For children below 12 years of age: the repellent must be applied by adults.  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.  Adults and children >2 years: max. 1 application per day. Not suitable for children younger than 2 years old. |

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

|  |
| --- |
| In case of ingestion: Rinse mouth thoroughly with water. Get medical advice/attention. Eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. When in doubt or if symptoms are observed, get medical advice. |

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

|  |
| --- |
| Avoid release to the environment. |

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

|  |
| --- |
| Shelf life: 2 years  The product must not be stored at temperatures ≤0°C.  Storage conditions: Observe label precautions. Keep container tightly closed in a dry and well-ventilated place.  Recommended storage temperature: ambient temperature  Environmental exposure controls: Do not let product enter drains. |

### Other information

|  |
| --- |
| The authorization holder is allowed to apply reduced labelling in accordance with art. 29(2) and Annex I pt 1.5.2.1 of Regulation (EC) No 1272/2008. |

### 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 | 75 ml | PP | PP cap with PE flow reducer insert | General public (non-professional) | yes |

### Documentation

#### Data submitted in relation to product application

Please see §3.1 list of studies for the biocidal product.

Specific data were provided of the identification of the product, the physico-chemical properties and analytical methods. Efficacy studies have been performed on the product.

The following toxicological studies have been performed on a product with similar composition (trade name Moustifluid lotion répulsive jeunes enfants): skin irritation, eye irritation, skin sensitisation, acute oral toxicity, acute dermal toxicity. A detailed comparison between both formulas can be found in the relevant IUCLID sections and in section 1 of the confidential part of the PAR.

Dermal absorption was tested on a formula (Mouskito Roller) with identical composition to the product under evaluation.

None of the non-active ingredients have an influence on the ecotoxicological classification and labelling of the final product in the concentration that they are present in the formula. Therefore, none of the non-active ingredients was considered to be a substance of concern regarding eco-toxicology and no further additional data are required. All eco-toxicological data can thus be derived from the dossier of the active ingredient.

#### Access to documentation

A letter of access to the dossiers of the active substance IR3535® was submitted. This letter of access covers all data used for including IR3535® in the Union list of approved active substances under the BPR.

## Assessment of the biocidal product

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

|  |  |
| --- | --- |
| **Table 1. Use # 1 – name of the use[[6]](#footnote-6)** | |
| **Product Type** | PT 19 – Repellents and attractants |
| **Where relevant, an exact description of the authorised use** | Protects in tropical areas against mosquitoes (Aedes aegypti, Culex quinquefasciatus, Anopheles gambiae). Protects in areas with moderate climate against mosquitoes (Aedes aegypti, Culex quinquefasciatus), flies (Stomoxys calcitrans), bees (Apis mellifera), wasps (Vespula vulgaris) and ticks (Ixodes ricinus) .  Apply to the uncovered skin. Children older than 3 months and adults. |
| **Target organism (including development stage)** | Aedes aegypti (adults)  Culex quinquefasciatus (adults)  Anopheles gambiae (adults)  Stomoxys calcitrans (adults)  Apis mellifera (adults)  Vespula vulgaris (adults)  Ixodes ricinus (adults) |
| **Field of use** | Use on skin |
| **Application method(s)** | spreading |
| **Application rate(s) and frequency** | Max. 4 applications per day |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | 75 ml PP bottle with PP cap and PE flow reducer insert |

### 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 | Organoleptic | Mouskito junior lotion 20% IR3535 | Liquid  [at ambient temperature (±20°C) and atmospheric pressure (±101.3 kPa)] | Van Diest, M., 2015. Laboratoria Qualiphar |
| Colour at 20 °C and 101.3 kPa | Organoleptic | Mouskito junior lotion 20% IR3535 | Clear to slightly turbid, colourless solution  [at ambient temperature (±20°C) and atmospheric pressure (±101.3 kPa)] | Van Diest, M., 2015. Laboratoria Qualiphar |
| Odour at 20 °C and 101.3 kPa | Organoleptic | Mouskito junior lotion 20% IR3535 | Characteristic  [at ambient temperature (±20°C) and atmospheric pressure (±101.3 kPa)] | Van Diest, M., 2015. Laboratoria Qualiphar |
| Acidity / alkalinity | CIPAC MT 75.3  [using METROHM 914 pH meter] | READ-ACROSS  Mouskito Roller 20% IR3535  (20.28 ± 0.84 % w/w) | 4.71 ± 0.01  [at 20°C] | 24050, de Ryckel, B., 2015. Laboratoria Qualiphar |
| Relative density / bulk density | EU method A.3  [using Mettler Toledo DE 40 Density Meter] | READ-ACROSS  Mouskito Roller 20% IR3535  (20.28 ± 0.84 % w/w) | 1.0197 ± 0.0001  [At 20 ± 0.5°C] | 24050, de Ryckel, B., 2015. Laboratoria Qualiphar |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  Organoleptic  [GC-FID, Agilent Technologies 6890 series using a capillary column fused silica, 25 m x 0.32 mm i.d. coated with CP-Sil 5 CB, 1.2 μm film thickness] | Mouskito junior lotion 20% IR3535 | - No change in overall appearance, pH, or relative density.  - No change in packaging appearance.  - Change in A.S.: 20.2% -> 20.0%  (= 1% change)  [**8 weeks** at 40°C. Humidity: **Dry**  Packaging: 75ml PP bottle with PP cap and PE insert]  - Change in A.S.: 20.2% -> 20.0%  (= 1% change)  [**8 weeks** at 40°C. Humidity: **75%**  Packaging: 75ml PP bottle with PP cap and PE insert]  - Change in A.S.: 20.2% -> 18.3%  (= 9.4% change)  [**6 months** at 40°C. Humidity: **75%**  Packaging: 75ml PP bottle with PP cap and PE insert] | Van Diest, M., 2015. Laboratoria Qualiphar |
| Storage stability test – **long term storage at ambient temperature** | ICH  Organoleptic  CIPAC method 667/TC/M/3  Directive 96/46/EC  SANCO/3030/99, rev.4  [GC-FID, Agilent Technologies 6890 series using a capillary column fused silica, 25 m x 0.32 mm i.d. coated with CP-Sil 5 CB, 1.2 μm film thickness] | Mouskito junior lotion 20% IR3535 | - No change in overall appearance or relative density.  - No change in packaging appearance.  - Change in pH: 5 -> 4  - Change in A.S.: 20.2% -> 18.9%  (= 6.4 % change)  [**2 years** year at 25°C. Humidity: **60%**  Packaging: 75ml PP bottle with PP cap and PE insert] | Van Diest, M., 2016. Laboratoria Qualiphar  Clincke, L., 2017.  Laboratoria Qualiphar |
| Storage stability test – **low temperature stability test for liquids** | Waived | - | The product must not be stored or applied ≤ 0°C. This should be stated on label. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | ICH Q1B  [GC-FID, Agilent Technologies 6890 series using a capillary column fused silica, 25 m x 0.32 mm i.d. coated with CP-Sil 5 CB, 1.2 μm film thickness] | Mouskito junior lotion 20% IR3535 | - Change in A.S.: 20.2% -> 20.1%  (= 0.5% change)  [**5 days** at 25°C. Humidity: **60%**  1.2 million lux hours + UV 200W h/sq. m] | Van Diest, M., 2015. Laboratoria Qualiphar |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | (See above storage stability test data) | (See above storage stability test data) | (See above storage stability test data) | (See above storage stability test data) |
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | (See above storage stability test data) | (See above storage stability test data) | (See above storage stability test data) | (See above storage stability test data) |
| Wettability | Waived | - | Not applicable since biocidal product is not a solid preparations to be dispersed in water. | - |
| Suspensibility, spontaneity and dispersion stability | Waived | - | Not applicable since biocidal product does not need to be diluted. | - |
| Wet sieve analysis and dry sieve test | Waived | - | Not applicable since biocidal product is a ready to use liquid. | - |
| Emulsifiability, re-emulsifiability and emulsion stability | Waived | - | Not applicable since biocidal product does not need to be emulsified. | - |
| Disintegration time | Waived | - | Not applicable since biocidal product is not a tablet and is not used in a water soluble bag. | - |
| Particle size distribution, content of dust/fines, attrition, friability | Waived | - | Not applicable since biocidal product is not a granule or tablet. | - |
| Persistent foaming | Waived | - | Not applicable since biocidal product is a ready for use product. | - |
| Flowability/Pourability/Dustability | Waived | - | Not applicable since biocidal product is not granular/a suspension. | - |
| Burning rate — smoke generators | Waived | - | Not applicable since the biocidal product is no smoke generator. | - |
| Burning completeness — smoke generators | Waived | - | Not applicable since the biocidal product is no smoke generator. | - |
| Composition of smoke — smoke generators | Waived | - | Not applicable since the biocidal product is no smoke generator. | - |
| Spraying pattern — aerosols | Waived | - | Not applicable since the biocidal product is no aerosol. | - |
| Physical compatibility | Waived | - | The biocidal product is not intended to be added or mixed with any other products. | - |
| Chemical compatibility | Waived | - | The biocidal product is not intended to be added or mixed with any other products. | - |
| Degree of dissolution and dilution stability | Waived | - | The biocidal product is not intended to be added or mixed with any other products. | - |
| Surface tension | PA-U10-METTENS, equivalent to EEC A.5  [using Tensiometer K10ST KRÜSS.] | READ-ACROSS  Mouskito Roller 20% IR3535  (20.28 ± 0.84 % w/w) | 23.0 ± 0.6 mN/m  [undiluted, at 25 ± 0.5°C] | 24050, de Ryckel, B., 2015. Laboratoria Qualiphar |
| Viscosity | ASTM D445, based on OECD 114  [using Ubbelhode tube viscometer] | READ-ACROSS  Mouskito Roller 20% IR3535  (20.28 ± 0.84 % w/w) | Ubbelhode tube n° 0C: 7.1929 ± 0.0026 cSt  Ubbelhode tube n° 1: 7.2666 cSt  [At **20** ± 0.5°C]  Ubbelhode tube n° 0C: 3.5172 ± 0.0013 cSt  Ubbelhode tube n° 1: 3.5963 cSt  [At **40** ± 0.5°C] | 24050, de Ryckel, B., 2015. Laboratoria Qualiphar |

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| Conclusion on the physical, chemical and technical properties of the product |
| The Mouskito junior lotion, as manufactured, is a clear to slightly turbid, colourless liquid with a characteristic odour. Based on read-across, the relative density of the product is expected to be 1.0197 and the respective pH value is expected to be 4.71. The product has a proven stability of 2 years in its commercial packaging. The product must not be stored or applied ≤ 0°C. The different influences of light, temperature and humidity on the content of the active substance are minor. Based on read-across, the surface tension is expected to be 23.0 mN/m and the viscosity at 20°C is expected to be between 7.1929 and 7.2666 cST. At 40°C, the viscosity expected to be between 3.5172 and 3.5963 cST. Physical and chemical compatibility with other products are not relevant. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | Waived | - | None of the ingredients of the product is classified as explosive. | - |
| Flammable gases | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Flammable aerosols | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Oxidising gases | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Gases under pressure | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Flammable liquids | EEC A.9  [using Tag closed tester, closed cup] | READ-ACROSS  Mouskito Roller 20% IR3535  (20.28 ± 0.84 % w/w) | Flash point: >93°C  [At 101kPa] | 24050, de Ryckel, B., 2015. Laboratoria Qualiphar |
| Flammable solids | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Self-reactive substances and mixtures | Waived | - | The mixture does not contain any substances known to self-react or with chemical groups present in their molecules that are associated with explosive or self-reactive properties. | - |
| Pyrophoric liquids | Waived | - | The mixture does not contain any substances known to react with air so the mixture is no pyrophoric liquid. | - |
| Pyrophoric solids | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Self-heating substances and mixtures | Waived | - | The mixture is not self-heating since it is a liquid at room temperature. Since the liquid will also not be absorbed onto powder particles thus generating a large surface, no self-heating must be considered. | - |
| Substances and mixtures which in contact with water emit flammable gases | Waived | - | Not applicable since biocidal product is a ready to use liquid. | - |
| Oxidising liquids | Waived | - | None of the ingredients of the product is classified as oxidising. | - |
| Oxidising solids | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Organic peroxides | Waived | - | Not applicable since biocidal product does not contain any organic peroxide. | - |
| Corrosive to metals | Waived | - | None of the ingredients in the mixture is classified as corrosive or suspected from a chemical point of view to be able to react with metals and thus, the mixture is also not corrosive to metal. | - |
| Auto-ignition temperatures of products (liquids and gases) | Waived | - | None of the ingredients of the product is classified as autoflammable. | - |
| Relative self-ignition temperature for solids | Waived | - | Not applicable since biocidal product is a liquid. | - |
| Dust explosion hazard | Waived | - | Not applicable since biocidal product is a liquid. | - |

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| Conclusion on the physical hazards and respective characteristics of the product |
| The product is not oxidizing, nor explosive. It is not able to react with metals and is not corrosive. The product has no self-reacting properties, does not react with air and is not self-heating since it is a liquid at room temperature. The flash point has been determined to be >93°C, hence the product is considered non-flammable. |

### Methods for detection and identification

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

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| READ-ACROSS  Mouskito Roller 20% IR3535 | GC-FID  [Agilent Technologies 6890 series using a capillary column fused silica, 25 m x 0.32 mm i.d. coated with CP-Sil 5 CB, 1.2 μm film thickness; CIPAC method 667/TC/M/3, adapted and validated in compliance with Directive 96/46/EC and SANCO/3030/99, rev.4, 11 July 2000, as general base.] | 3 levels (11.24%, 20.87%, and 31.04% (w/w))  3 replicates/level | Linear in the range 8.3 – 12.7 mg/mL, with r²=0.9988 and correlation coefficient r =0.9994 | The retention times of IR 3535 and of internal standard from sample solution do not deviate by more than 1 % compared to the calibration solution. | 100.3-102.0 | 101.1 | 0.62 | 11.0% w/w | 23906, de Ryckel, B., 2015. CRA-W |

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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 |
| See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 |

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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 |
| See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 |

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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 |
| See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 |

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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 |
| See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 |

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| **Analytical methods for animal and human body fluids and tisues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 |

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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 |
| See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 | See AR IR3535 |

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| **Conclusion on the methods for detection and identification of the product** |
| The IR3535 content can be determined in the product using a validated GC-FID method consisting of a gas chromatograph with a capillary column fused silica, 25 m x 0.32 mm i.d. coated with CP-Sil 5 CB, 1.2 μm film thickness, a flame ionisation detector (FID) and an automatic liquid sampler. The identity of the analyte is confirmed by comparison of the retention times. The standard regression is linear and the method is repeatable. The mean recovery rates at each spiking level are in the range of 100.3 - 102.0%. Repeated injection of the samples resulted in a coefficient of variation which was 0.62 %. The limit of quantification (LOQ) is 11%. The overall mean recovery rate for IR3535 was 101.1%. |

### Efficacy against target organisms

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

MG03: pest control

PT19: Repellents

***Mouskito Junior Lotion*** is a ready-to-use product containing 20% IR3535 (i.e. Ethyl 3-[N-acetyl-N-butyl] aminopropionate with N°CAS 52304-36-6) applied by spreading.

This product is intended to be used by general public to repel flying insects and ticks in temperate areas and also mosquitoes in tropical conditions.

This product should be use maximum once per day on the uncovered skin (face, hands, arms and legs) by adults and children of more than 2 years. The product should not be applied to children's hands.

Additional information:

The time of protection is reduced by: bathing, excessive sweating and applying insufficient amount of product.

Applying sun care products or cosmetic formulations after repellent use will decrease the efficacy of the repellent considerably.

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

The target species to be controlled are mosquitoes (*Culex quinquefasciatus, Aedes aegypti & Anopheles gambiae)* in temperate and tropical conditions;flies (*Stomoxys calcitrans*)*,*wasps (*Vespula vulgaris*), bees (*Apis mellifera*) and ticks (*Ixodes ricinus*) in temperate conditions.

The aim of the use is avoid bites of mosquitoes, flies, wasps, bees and ticks on the human uncovered skin.

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

The effect on the target organisms is repellent effect. This reaction is most likely caused by an olfactory sensitivity towards this substance. So, the insects avoid contact with the treated area and the immediate surroundings .

The insects are repelled but not killed. The animal suffering is not relevant/applicable.

#### **Mode of action, including time delay**

The mode of action of IR3535 is described in the CAR. «This 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.»

#### **Efficacy data**

To support the claim, 7 studies have been submitted to prove the efficacy (repellent effect) of the product against the target organisms.

* A simulated-use test (**arm-in-cage**) performed on the product Mouskito Roller (batch RD 2834 F2) conducted with 5 human volunteers and 3 replicates on ***Anopheles gambiae*** in tropical conditions. (Report 1832q- MTRRD2834F2/0914R / 2015-07-27 / T.E.C. Laboratory)
* The test system was based on MS 1497 (2000) and WHO/HTM/NTD/WHOPES/2009.4; GUIDELINES FOR EFFICACY TESTING OF MOSQUITO REPELLENTS FOR HUMAN SKIN.

These methods are part of the Appendix of approved methodologies for Biocides registration, in the “DRAFT Guideline to replace part of Appendices to chapter 7 (page 187 to 200) from TNsG on Product evaluation”.

The trial is conducted in accordance with the procedures required to conduct Officially Recognised Trials (EOR), from the European directive 91/414/CE, according to the laboratory agreement by the French Ministry of Agriculture.

* The persistence of the efficacy was assessed every hour until inefficacy and under “tropical” climatic conditions (30+/-1°C; 80+/-5% RH).
* The biting and landing are recorded every 2 hours or every hour (depending on the landing data of the previous assessment) until 8 hours (or stopped in case of inefficacy) by introducing the treated forearms in new cages of fresh insects
* End of protection = time until there is a first bite followed by a second one.
* Density of the organisms : 1/320 cm³ ( 200 insects released in a cage of 64000cm³)
* Dose of application of the product: 1 g on 600 cm² (dosage required by the method).
* Duration of exposure of the forearms in the cage: 3 minutes

**Conclusion: results validated**

The test method (arm-in-cage) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19. However, the forearm was exposed to test mosquitoes in the cage for 3 minutes compared to 5 minutes recommended in the TNsG. This lower time of exposure should not affect the quality of the results.

According to this simulated-use test, the results obtained on the product Mouskito Rollerwhen used at a dose of 1 g/600 cm² on the skin, seems to demonstrate a time of protection of 7 hours (repellent effect) against mosquito (*Anopheles gambiae)* in “tropical” climatic conditions.

Considering that the test method used is conform to the requirements mentioned in the TNsG and that the field tests are not mandatory. That 3 genera of tropical mosquitoes were tested but only 5 volunteers were used, the results are validated with a reliability of 2.

* A simulated-use test (**arm-in-cage**) performed on the product Mouskito Roller (batch RD 2834 F2) conducted with 5 human volunteers and 3 replicates on ***Aedes aegypti, Culex quinquefasciatus*** in tropical conditions. (Report 1832p- MTRRD2834F2/0914R / 2015-07-27 / T.E.C. Laboratory)
* The test system was based on MS 1497 (2000) and WHO/HTM/NTD/WHOPES/2009.4; GUIDELINES FOR EFFICACY TESTING OF MOSQUITO REPELLENTS FOR HUMAN SKIN.

These methods are part of the Appendix of approved methodologies for Biocides registration, in the “DRAFT Guideline to replace part of Appendices to chapter 7 (page 187 to 200) from TNsG on Product evaluation”.

The trial is conducted in accordance with the procedures required to conduct Officially Recognised Trials (EOR), from the European directive 91/414/CE, according to the laboratory agreement by the French Ministry of Agriculture.

* The persistence of the efficacy was assessed every hour until inefficacy and under “tropical” climatic conditions (30+/-1°C; 80+/-5% RH).
* The biting and landing are recorded every 2 hours or every hour (depending on the landing data of the previous assessment) until 8 hours (or stopped in case of inefficacy) by introducing the treated forearms in new cages of fresh insects
* End of protection = time until there is a first bite followed by a second one.
* Density of the organisms : 1/320 cm³ ( 200 insects released in a cage of 64000cm³)
* Dose of application of the product: 1 g on 600 cm² (dosage required by the method).
* Duration of exposure of the forearms in the cage: 3 minutes

**Conclusion: results validated**

The test method (arm-in-cage) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19. However, the forearm was exposed to test mosquitoes in the cage for 3 minutes compared to 5 minutes recommended in the TNsG. This time to lower exposure should not affect the quality of the results.

According to this simulated-use test, the results obtained on the product Mouskito Rollerwhen used at a dose of 1 g/600 cm² on the skin, seems to demonstrate a time of protection of 7 hours 30 minutes (repellent effect) against mosquitoes (*Aedes aegypti, Culex quinquefasciatus)* in “tropical” climatic conditions.

Considering that the test method used is conform to the requirements mentioned in the TNsG and that the field tests are not mandatory. That 3 genera of tropical mosquitoes were tested but only 5 volunteers were used, the results are validated with a reliability of 2.

* A simulated-use test (**arm-in-cage**) performed on the product Mouskito Roller (batch RD 2834 F2) conducted with 5 human volunteers and 3 replicates on ***Aedes aegypti, Culex quinquefasciatus*** in “normal” climatic conditions. (Report 1832o- MTRRD2834F2/0914R / 2015-07-27 / T.E.C. Laboratory)
* The test system was based on MS 1497 (2000) and WHO/HTM/NTD/WHOPES/2009.4; GUIDELINES FOR EFFICACY TESTING OF MOSQUITO REPELLENTS FOR HUMAN SKIN.

These methods are part of the Appendix of approved methodologies for Biocides registration, in the “DRAFT Guideline to replace part of Appendices to chapter 7 (page 187 to 200) from TNsG on Product evaluation”.

The trial is conducted in accordance with the procedures required to conduct Officially Recognised Trials (EOR), from the European directive 91/414/CE, according to the laboratory agreement by the French Ministry of Agriculture.

* The persistence of the efficacy was assessed every hour until inefficacy and under “normal” climatic conditions (20+/-1°C; 60+/-5% RH).
* The biting and landing are recorded every 2 hours or every hour (depending on the landing data of the previous assessment) until 8 hours (or stopped in case of inefficacy) by introducing the treated forearms in new cages of fresh insects
* End of protection = time until there is a first bite followed by a second one.
* Density of the organisms : 1/320 cm³ ( 200 insects released in a cage of 64000cm³)
* Dose of application of the product: 1 g on 600 cm² (dosage required by the method).
* Duration of exposure of the forearms in the cage: 3 minutes

**Conclusion: results validated**

The test method (arm-in-cage) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19. However, the forearm was exposed to test mosquitoes in the cage for 3 minutes compared to 5 minutes recommended in the TNsG. This time to lower exposure should not affect the quality of the results.

According to this simulated-use test, the results obtained on the product Mouskito Rollerwhen used at a dose of 1 g/600 cm² on the skin, seems to demonstrate a time of protection of 7 hours 30 minutes (repellent effect) against mosquitoes (*Aedes aegypti, Culex quinquefasciatus)* in “normal” climatic conditions.

Considering that the test method used is conform to the requirements mentioned in the TNsG and that the field tests are not mandatory. That 3 genera of tropical mosquitoes were tested but only 5 volunteers were used, the results are validated with a reliability of 2.

* A simulated-use test (**arm-in-cage**) performed on the product Mouskito Roller (batch RD 2834 F2) conducted with 5 human volunteers and 3 replicates on ***Stomoxys calcitrans*** in “normal” climatic conditions. (Report 1832n-MSRD2837B2/0914 / 2015-07-27 / T.E.C. Laboratory
* The test system was based on MS 1497 (2000) and WHO/HTM/NTD/WHOPES/2009.4; GUIDELINES FOR EFFICACY TESTING OF MOSQUITO REPELLENTS FOR HUMAN SKIN.

These methods are part of the Appendix of approved methodologies for Biocides registration, in the “DRAFT Guideline to replace part of Appendices to chapter 7 (page 187 to 200) from TNsG on Product evaluation”.

The trial is conducted in accordance with the procedures required to conduct Officially Recognised Trials (EOR), from the European directive 91/414/CE.

* The persistence of the efficacy was assessed every hour until inefficacy and under “normal” climatic conditions (20+/-1°C; 60+/-5% RH).
* The biting and landing are recorded every 2 hours or every hour (depending on the landing data of the previous assessment) until 8 hours (or stopped in case of inefficacy) by introducing the treated forearms in new cages of fresh insects
* End of protection = time until there is a first bite followed by a second one.
* Density of the organisms : 1/1280cm³ ( 50 insects released in a cage of 64000cm³)
* Dose of application of the product: 1 g on 600 cm² (dosage required by the method).
* Duration of exposure of the forearms in the cage: 3 minutes

**Conclusion: results validated**

For product with a repellent effect against flies no agreed protocols are available. The tests should be designed to mimic the practical use situation.

The test method (arm-in-cage) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19.

According to this simulated-use test, the results obtained on the product Mouskito Roller when used at a dose of 1 g/600 cm² on the skin, appear to demonstrate/suggest a time of protection of 8 hours (repellent effect) against flies (Stomoxys calcitrans) in “normal” climatic conditions.

Considering that the test method used is conform to the requirements mentioned in the TNsG, but only 5 volunteers were used, the results are validated with a reliability of 2.

* A Laboratory test (**spatial repellency assay/ *2 glass cylinders***) performed on the product Mouskito Roller(batch RD 2834 F2) conducted with mouse and 4 replicates on ***Ixodes ricinus*** in temperate climatic conditions. (Report 1832m-MTRRD2834F2/0914R / 2015-07-27 / T.E.C. Laboratory
* The test system was based on Manual for the Authorization of Pesticides - EU part – Biocides - Chapter 7 Efficacy - version 1.1; January 2013

The trial is conducted in accordance with the procedures required to conduct Officially Recognised Trials (EOR), from the European directive 91/414/CE, according to the laboratory agreement by the French Ministry of Agriculture.

* The persistence of the efficacy was assessed every hour until inefficacy and under “normal” climatic conditions (20+/-1°C; 60+/-5% RH).
* The biting and landing are recorded every 2 hours or every hour (depending on the landing data of the previous assessment) until 8 hours (or stopped in case of inefficacy) by introducing the same treated mouse.
* End of protection = time until there is a first bite followed by a second one.
* Density of the organisms : 1/1978cm³ (25 ticks released in the first cylinder)
* Dose of application of the product: 1 g on 600 cm² (dosage required by the method).
* Duration of exposure: 15 minutes.

**Conclusion: results Validated**

According to this simulated-use test, the results obtained on the product Mouskito Roller when used at a dose of 1 g/600 cm² on the skin, seems to demonstrate a time of protection of 6 hours (repellent effect) against ticks adults (Ixodes ricinus) in “normal” climatic conditions.

* A simulated-use test (**Trapping insects, treated and untreated trap**) performed on the product Mouskito Roller (batch RD 2834 F2) conducted in field and 6 plots on ***Vespula vulgaris*** and ***Apis mellifera*** in “normal” climatic conditions. (Report 1832r-MTRRD2834F2/0914R / 2015-07-27 / T.E.C. Laboratory
* In the absence of specific methodology, the repellent effectiveness based on the comparison of insects’ catches in trapping devices with treatment or not with the formula to be tested.
* Trapping devices with attractant solution. 6 plots with 4 unit traps (1 trap untreated and three traps treated)
* The percentage of repellent efficacy is calculated by comparing the number of insects trapped in the untreated and treated traps.
* Record of the trapped insect number every day and during 10 days after setup.
* Conditions: July and August in South west of France (T° mean : 21°C)
* Dose: 1 g of product on 600cm² two times per day applied on the surface of the trap.

**Conclusion: results NOT Validated**

For product with a repellent effect against wasps and bees no agreed protocols are available. The tests should be designed to mimic the practical use situation.

According to this simulated-use test, the results obtained on the product Mouskito Roller when used at a dose of 1 g/600 cm² on the trap, seems to demonstrate a repellent effect of more of 90 % against wasps and bees (Vespula vulgaris, Apis mellifera) in “normal” climatic conditions, when applied on a trapping device. However, the test does not demonstrate efficacy when the product is applied on human skin-like surfaces, and therefore, no protection times can be derived.

* A Laboratory test (**human forearms-wrist to elbow**) performed on the product Mouskito junior lotion conducted with 10 volunteers on ***Ixodes ricinus*** in temperate climatic conditions. (report *Mouskito junior lotion\_efficy report\_ticks*/ 2017-05-12 / i2LResearch Ltd)
* The test system was based on the transitional guidance on efficacy PT18 and PT19 (2016).
* The persistence of the efficacy was assessed every hour until 8 hours under “normal” climatic conditions (25-26°C; >50% RH).
* Ten volunteers (7 males and 3 females) – 5 fresh ticks for each exposure
* A tick that crossed at least 3 cm into the treated area (overcoming the crossing line towards the elbow) or remained anywhere in the treated area for at least one minute was reported as ‘not repelled’.
* Dose of application of the product: 1 g on 600 cm².

**Conclusion: results validated**

According to this simulated-use test, the results obtained on the product Mouskito junior lotion when used at a dose of 1 g/600 cm² on the skin, seems to demonstrate a time of protection of 4 hours (repellent effect) against ticks (Ixodes ricinus) in “normal” climatic conditions.

#### **Efficacy data table**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| *PT19*  *Repellent* | *liquid solution*  *ready-to-use (roller)*  *applied on uncovered human skin*  *non-professional user/consumer*  *to repel mosquitoes (Anopheles gambiae) in tropical areas* | *MOUSKITO Roller\* (*batch RD 2834 F2)  *\* The formula of* ***Mouskito Junior Lotion*** *is identical to the formula of* ***Mouskito Roller****. The only difference is the packaging material, but*  *this has no influence on the outcome of the test.* | **Mosquitoes**  ♀ 5-7 days  *Anopheles gambiae* | Simulated-use test (arm-in-cage) | *Arm-in-cage with 5 volunteers and 3 replicates in tropical conditions (30°C±1 and RH 80%±5).*  *3 minutes of exposure of the forearms in the cage with 1 g of product on 600cm².*  *Record of landing and biting every 2 hours or every hour*  *until 8 hours* | *Time of protection:*  *A.gambiae*  *:7 hrs.*  *in tropical conditions* | *Report 1832q-*  *MTRRD2834F2/0914R*  *2015-07-27*  *T.E.C. Laboratory*  *Laboratory*  *assessment*  *of a personal*  *skin repellent*  *against mosquitoes*  *-Anopheles gambiae*  Reliability: 2 |
| *PT19*  *Repellent* | *liquid solution*  *ready-to-use (roller)*  *applied on uncovered human skin*  *non-professional user/consumer*  *to repel mosquitoes (Aedes aegypti, Culex quinquefasciatus) in tropical areas* | *MOUSKITO Roller (*batch RD 2834 F2) | **Mosquitoes**  ♀ 5-7 days  *Aedes aegypti,*  *Culex quinquefasciatus* | Simulated-use test (arm-in-cage) | *Arm-in-cage with 5 volunteers and 3 replicates in tropical conditions (30°C±1 and RH 80%±5).*  *3 minutes of exposure of the forearms in the cage with 1 g of product on 600cm².*  *Record of landing and biting every 2 hours or every hour*  *until 8 hours* | *Time of protection:*  *A.aegypti*  *:7 hrs 30 minutes*  *C.quinquefasciatus*  *:7 hrs 30 minutes*  *in tropical conditions* | *Report 1832p-*  *MTRRD2834F2/0914R*  *2015-07-27*  *T.E.C. Laboratory*  *Laboratory*  *assessment*  *of a personal*  *skin repellent*  *against mosquitoes*  *-Aedes + culex*  *Trial in tropical climatic conditions*  Reliability: 2 |
| *PT19*  *Repellent* | *liquid solution*  *ready-to-use (roller)*  *applied on uncovered human skin*  *non-professional user/consumer*  *to repel mosquitoes (Aedes aegypti, Culex quinquefasciatus) in temperate areas* | *MOUSKITO Roller (*batch RD 2834 F2) | **Mosquitoes**  ♀ 5-7 days  *Aedes aegypti,*  *Culex quinquefasciatus* | Simulated-use test (arm-in-cage) | *Arm-in-cage with 5 volunteers and 3 replicates in tropical conditions (20°C±1 and RH 60%±5).*  *3 minutes of exposure of the forearms in the cage with 1 g of product on 600cm².*  *Record of landing and biting every 2 hours or every hour*  *until 8 hours* | *Time of protection:*  *A.aegypti*  *:7 hrs 30 minutes*  *C.quinquefascatus*  *:7 hrs 30 minutes*  *in temperate conditions* | *Report 1832o-*  *MTRRD2834F2/0914R*  *2015-07-27*  *T.E.C. Laboratory*  *Laboratory*  *assessment*  *of a personal*  *skin repellent*  *against mosquitoes*  *-Aedes + culex*  Reliability: 2 |
| *PT19*  *Repellent* | *liquid solution*  *ready-to-use (roller)*  *applied on uncovered human skin*  *non-professional user/consumer*  *to repel flies (Stomoxys calcitrans) in “normal” climatic conditions* | *MOUSKITO Roller (batch RD 2834 F2)* | **Flies**  *Adult mixed sex captured 4-6 days*  *Stomoxys calcitrans* | Simulated-use test (arm-in-cage) | *Arm-in-cage with 5 volunteers and 3 replicates in “normal” climaticl conditions (20°C±1 and RH 60%±5).*  *3 minutes of exposure of the forearms in the*  *cage with 1 g of product on 600cm².*  *Record of landing and biting every 2 hours or every hour*  *until 8 hours* | *Time of protection:*  *S. calcitrans*  *:8 hrs*  *in “normal” climatic conditions* | *Report 1832n-*  *MSRD2837B2/0914*  *2015-07-27*  *Laboratory assessment of a*  *Personal skin repellent*  *against Stomoxys biting flies*  Reliability: 2 |
| *PT19*  *Repellent* | *liquid solution*  *ready-to-use (roller)*  *applied on uncovered human skin*  *non-professional user/consumer*  *to repel ticks (Ixodes ricinus) in “normal” climatic conditions* | *MOUSKITO Roller*  *(Batch: ch RD 2834 F2)* | **Ticks**  *Adult mixed sex 1-2 weeks*  *Ixodes ricinus* | *Laboratory test*  *(choice-test)* | *2 glass cylinders with mouse.*  *The 25 ticks (\*4 replicates) are released in the cylinder 1, and the product is applied on the bite target (mouse) which is placed in the cylinder 2 during 15 minutes.*  *record of the location of ticks, biting and landing every minute from 0 to 15 minutes and redone every 2 hours or every hour*  *Conditions: 20°C±1 and RH 60%±5*  *Dose: 1 g of product on 600cm²* | *Time of protection:*  *I.ricinus*  *:6hrs*  *in “normal” climatic conditions*  **Not sufficient to validate the target organism** | *Report 1832m-*  *MTRRD2884F2/0914R*  *2015-07-27*  *Laboratory assessment of a*  *Personal skin repellent*  *against tick*  Reliability: 3 |
| *PT19*  *Repellent* | *liquid solution*  *ready-to-use (spray)*  *applied on uncovered human skin*  *non-professional user/consumer*  *to repel wasps and bees (Vespula vulgaris, Apis mellifera) in “normal” climatic conditions* | *MOUSKITO Roller (batch RD 2834 F2)* | **Wasps and bees**  Wild insects  *Vespula vulgaris*  *Apis mellifera* | *Field test*  *(choice-test)* | *Trapping devices with attractant solution.*  *6 plots with 4 unit traps (1 trap untreated)*  *The percentage of repellent efficacy is calculated by comparing the number of insects trapped in the untreated and in the treated traps.*  *Record of the trapped insect number every day and during 10 days after setup.*  *Conditions: July and August in South west of France (T° mean : 21°C)*  *Dose: 1 g of product on 600cm²*  *two times a day* | *% of reduction of trapping: > 90 %*  *Vespula vulgaris*  *Apis mellifera*  *In “normal” climatic condition*  **The test demonstrates repellent effect against wasps and bees when applied on trapping device. However, no repellent effect on human skin-like surfaces (to mimic practical conditions) was demonstrated. Therefore, no protection time can be derived.** | *Report 1832r-*  *MTRRD2834F2/0914*  *2015-07-27*  *Assessment of the repellency of a personal skin repellent*  *against wasps and bees* |
| *PT19*  *Repellent* | *liquid solution*  *Mouskito junior lotion (20 % IR3535*  *applied on uncovered human skin*  *non-professional user/consumer*  *to repel ticks (Ixodes ricinus) in “normal” climatic conditions* | *MOUSKITO junior lotion*  *(Lot number 6320)* | **Ticks**  *(Nymphs)*  *Ixodes ricinus* | *Simulated-use test (wrist to elbow)* | *Human forearms*  *Ten replicates/ volunteers with 5 fresh ticks for each exposure.*  *+Negative control*  *Assessment of efficacy every hours until 8 hours*    *Conditions: 25-26°C and RH >50%*  *Dose: 1 g of product on 600cm²* | *Time of protection: I.ricinus*  *: until 2 hrs*  *in “normal” climatic conditions*  *% of protection (mean)( n=10)*  *60 min : 90 %*  *120 min: 88 %*  *180 min : 78 %*  *240 min : 70 %*  *300 min : 62 %*  *% of protection (mean) (n=8)*  *Without best and worst results:*  *60 min : 92.5 %*  *120 min: 92.5 %*  *180 min : 82.5 %*  *240 min : 75 %*  *300 min : 65 %* | *Mouskito junior lotion\_efficy report\_ticks*2017-05-12 *I2LResearch Ltd*  *Laboratory study to determine the efficacy of a repellent product against ticks Ixodes ricinus*  Reliability: 1 |

In the light of the results and the knowledges about a similar products based on this active substance, the efficacy experts consider that the low number of volunteers should not discredit the studies, even if a minimum of 10 volunteers ensures more robust and consolidated results.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| *N.B.: The formula of* ***Mouskito Junior Lotion*** *is identical to the formula of* ***Mouskito Roller****. The only difference is the packaging material, but this has no influence on the outcome of the test.*  According to the studies submitted, the ***Mouskito Junior Lotion***(20 % IR3535) applied on human skin in tropical climatic conditions at a dose of 1 g/ 600 cm² does provide a protection time of 7 hours against mosquitoes (*Aedes aegypti, Culex quinquefasciatus, Anopheles gambiae).*  In temperate climatic conditions, the ***Mouskito Junior Lotion***(20 % IR3535) applied on human skin at a dose of 1 g/ 600 cm² does provide a protection time of 7h30 against mosquitoes (*Aedes aegypti & Culex quinquefasciatus)*, of 8 h against flies (*Stomoxys calcitrans)* and of 2 h against ticks (*Ixodes ricinus*).  Since no agreed protocol is available to assess the repellent efficacy against bees *(Apis mellifera)* and wasps *(Vespula vulgaris)*,  According to the test provided (performed with trapping devices), the product ***Mouskito Junior Lotion***(20 % IR3535) is considered effective to repel wasps and bees (*Apis melifera)* and *(Vespula vulgaris)* when applied on trapping devices. However no protection time can be reported and the efficacy against wasp/bee bites is not proven. Due to lack of data on representative surfaces for human skin, demonstrating the repellent efficacy, the claim against wasp and bees cannot be validated.  The results obtained prove the efficacy of the product to avoid biting from mosquitoes, flies and ticks. These trials are conducted in accordance with recommendations of the TNsG except the time of exposure. The BE eCA is of the opinion that the lower time of exposure (i.e. 3 min) should not affect the quality of the results. |

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

« Development of resistance is not known. Due to the repellent action of IR3535®, insects are repelled, but not killed.

Resistance is typically developed if there is a selection pressure on a population of species, in such a way that individuals that are more tolerant against the substance in question do not die and can therefore reproduce. Unlike insecticides, IR3535® is not used to kill insects, but only to hinder them from entering areas where IR3535® has been applied. Generally, a repellent applied on human or animal skin hinders, e.g. blood sucking insects, from biting. One could argue that this effect constitutes a positive selection pressure, in such a way that the repelled insects may die of starvation and would therefore be removed from the population, so that insects, which are more tolerant, i.e. which are less repelled, would have a feeding advantage and would therefore be in favour for reproduction. Such a scenario would only be of relevance if the majority of potential hosts in a habitat of a population of insects was treated with an insect repellent, so that the insects would have severe problems to find hosts which are not treated with the repellent. Such a scenario is extremely unlikely, as the occurrence of insect repellent treated hosts in a habitat of a population of insects is only sporadic. In other words, the amount of blood not available for the insects, due to the protection by a repellent, is negligible compared to the overall amount of blood available from other sources.

Therefore there is no selection pressure and no resistance can be developed. It is then considered unnecessary to take actions to prevent development of resistance by target organisms”.

#### **Known limitations**

The time of protection is reduced by: bathing, excessive sweating and applying insufficient amount of product.

Applying sun care products or cosmetic formulations after repellent use will decrease the efficacy of the repellent considerably.

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

According to the label provided by the Applicant, the product **Mouskito Junior Lotion** is intended to provide a good protection against mosquitoes bites (organisms mentioned) during 7h30, 8h against flies bites (organism mentioned) and against wasp/bee bites in temperate climatic areas. In tropical areas, the product **Mouskito Junior Lotion** is intended to provide a good protection against mosquitoes bites (organisms mentioned) during 7h.

Based on the efficacy tests submitted and validated, the BE eCA also agreed to accept a protection time of 7h for the product **Mouskito Junior Lotion** (intended to be used on human uncovered skin, in **tropical** climatic conditions, applied at 1 g/600 cm²) against mosquitoes bites.

Based on the efficacy tests submitted and validated, the BE eCA agreed to accept a protection time of 7h30 for the product **Mouskito Junior Lotion** (intended to be used on human uncovered skin, in **temperate** climatic conditions, applied at 1 g/600 cm²) against mosquitoes bitesof 8 hours against flies bites and of 2h against ticks bites.

No agreed protocol for test of repellent effect of products applied on human skin are available. There is an agreement that tests provided should demonstrate in conditions that mimic the practical situation. The product application on trapping devices does not reflect an application on human skin, and therefore, the claim against wasps and bees is not validated.

The label must be modified in order to :

* Mention the application dose for the consumer:

The BE eCA thinks that it’s necessary to inform the user in an easily understandable form how much of the biocidal product he should use. We do not consider that Application Rate indicated in g/cm2 is an instruction clear and easy enough for the general public to follow.

* As the consequence, the Applicant must add on the label an advice which clearly describes in easily understandable form the amount, which can be used per application and for each user group (adult, child, toddler etc).
* To achieve a safe and effective treatment, the instructions should include a specification of which body parts (specified for each user category) that can be treated.
* Replace the mention *Culex pipiens* by *Culex quinquefasciatus*
* Wasps and bees should be removed from the label, since there is no test available demonstrating the efficacy of the product when it is applied on human skin-like surfaces.

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

None

### Risk assessment for human health

#### Assessment of effects on Human Health

Acute oral and dermal toxicity, skin and eye irritation and sensitising properties were assessed using formula Moustifluid lotion repulsive jeunes enfants. The test substance can be regarded as representative for the product under evaluation. The main differences between the 2 formulas are (1) the presence of 2 additional components in the tested formula, (2) the replacement of the perfume by another perfume, and (3) a small increase in amount of water in order to compensate for the changes in composition. These changes have no impact on the results of the tests and the classification of the product. For details, see relevant IUCLID sections and confidential part of the PAR.

##### Skin corrosion and irritation

| **Summary table of animal studies on skin corrosion /irritation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method,Guideline,**  **GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks *(e.g. major deviations)*** | **Reference** |
| OECD 404,  GLP, reliable without restriction | New Zealand albino rabbits, 3 males | Moustifluid lotion répulsive jeunes enfants, no vehicle, 0,5 ml, 4 hours | No erythema was observed. No oedema was observed. | Test performed with formula similar to the product under evaluation | Acute dermal irritation/corrosion test in the rabbit – Tn 077/07-0352, P. Gomond 2007 |

No *in vitro* or human data are available for skin corrosion/irritation.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Mouskito Roller is not irritating for the skin. |
| Justification for the value/conclusion | The potential for skin irritation was assessed based on a GLP study according to the OECD guideline No. 404 |
| Classification of the product according to CLP and DSD | / |

##### Eye Irritation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table of animal studies on serious eye damage and eye irritation** | | | | | |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance,Dose levels, Duration of exposure** | **Results**  ***Average score (24, 48, 72h)/***  ***observations and time point of onset, reversibility*** | **Remarks *(e.g. major deviations)*** | **Reference** |
| OECD 405,  GLP, reliable without restriction | New Zealand albino rabbits, 3 males | Moustifluid lotion répulsive jeunes enfants, 0,1 ml, single application | Chemosis score  Animal 1 :1.0  Animal 2 : 1.0  Animal 3 : 0.7  Fully reversible in all animals  - Conjunctivae score  Animal 1 :2.0  Animal 2 : 2.3  Animal 3 : 2.3  Fully reversible in all animals  - Iris score  Animal 1 :1.0  Animal 2 : 0.3  Animal 3 : 0.0  Fully reversible in all animals  - Cornea score  Animal 1 :2.0  Animal 2 : 1.7  Animal 3 : 1.7  Fully reversible in all animals | Test performed with formula similar to the product under evaluation | Acute eye irritation/corrosion test in the rabbit – rapport Tn078/07-0352, P. Gomond 2007 |

No human data available

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Irritating to eyes (cat. 2) according to EC No. 1272/2008 |
| Justification for the value/conclusion | The potential for eye irritation of the product was assessed based on a GLP study according to the OECD guideline No 405 |
| Classification of the product according to CLP and DSD | DSD: /  CLP: eye irritation 2, warning, H319 |

##### Respiratory tract irritation

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | . |
| Classification of the product according to CLP and DSD | / |

/

##### Skin sensitization

| **Summary table of animal studies on skin sensitisation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline, GLP status, . Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Vehicle,**  **Dose levels,  duration of exposure Route of exposure *(topical/intradermal, if relevant)*** | **Results**  ***(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*** | **Remarks**  ***(e.g. major deviations)*** | **Reference** |
| OECD 406, GLP, reliable without restriction | Hartley albino guinea pigs, male and female, 11 treated and 5 control | Moustifluid lotion répulsive jeunes enfants, water  Challenge phase: test item diluted at 25% (MNIC) and 12.5%, 24h, 48h or 72h  Route of induction exposure: intradermal and epicutaneous  Route of challenge exposure: epicutaneous, occlusive | Percentage of reactive treated animals: 0%  Percentage of reactive control animals: 0% | Test performed with formula similar to the product under evaluation | Skin sensitation in the guinea pig – report rn 079/07-0352, P. Gomond 2007 |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Mouskito Roller is not skin sensitising |
| Justification for the value/conclusion | The potential for skin sensitisation was assessed based on a GLP study according to the OECD guideline No. 406 |
| Classification of the product according to CLP and DSD | / |

##### Respiratory sensitization (ADS)

Since none of the components are classified as respiratory sensitizer and no synergistic effects are

expected, no testing is required.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Mouskito Roller is not respiratory sensitising |
| Justification for the value/conclusion | Since none of the components are classified as respiratory sensitizer and no synergistic effects are expected, no testing is required. |
| Classification of the product according to CLP and DSD | / |

##### Acute toxicity

###### Acute toxicity by oral route

| **Summary table of animal studies on acute oral toxicity** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Method Guideline**  **GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance**  **Dose levels Type of administration** *(gavage, in diet, other)* | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **Value LD50** | **Remarks** *(e.g. major deviations****)*** | **Reference** |
| OECD 423, GLP, reliable without restriction | Sprague-Dawley albino rats, 6 females (3 per group) | Moustifluid lotion répulsive jeunes enfants,  2000 mg/kg bw,  Gavage | No mortality occured during the study. A slight piloerection was noted after treatment and after 30min on the first day of the test. The animals recovered a normal behaviour at 1h post-dose. The body weight of the animals remained normal throughout the study. The macroscopical examination of the animals at the end of the study did not reveal treatment related changes. | > 2000 mg/kg | Test performed with formula similar to the product under evaluation | Acute oral toxicity test in the rat - Acute toxic class method, report Tn 080/07-0352, P. Gomond 2007 |

No human data available

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | The LD50 of the test item is higher than 2000 mg/kg. |
| Justification for the selected value | The potential for acute oral toxicity of the product was assessed based on a GLP study according to the OECD guideline No 423 |
| Classification of the product according to CLP and DSD | DSD: hazard category 5  CLP: / |

###### Acute toxicity by inhalation

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement |  |
| Justification | According to the ECHA Guidance on information requirements, in addition to the oral route of administration, for substances other than gases, the information mentioned under 8.5.2 to 8.5.3 shall be provided for at least one other route of administration. The choice for the second route will depend on the nature of the substance and the likely route of human exposure. Therefore, we chose for the dermal route (product is put on the skin) |

###### Acute toxicity by dermal route

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table of animal studies on acute dermal toxicity** | | | | | | |
| **Method, Guideline,**  **GLP status,**  **Reliability** | **Species, strain, Sex, No/group** | **Test substance, Vehicle, Dose levels, Surface area** | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **LD50** | **Remarks** *(e.g. major deviations)* | **Reference** |
| OECD 402, GLP, reliable without restriction | Sprague-Dawley albino rats, 5 males and 5 females | Moustifluid lotion répulsive jeunes enfants, no vehicle, 2000 mg/kg body weight, min. 10% of total body surface | No mortality occured during the study. Neither cutaneous reactions nor systemic clinical signs related to the administration of the test item were observed. The body weight of the animals remained normal throughout the study. The macroscopical examination of the animals at the end of the study did not reveal treatment related changes. | >2000 mg/kg bw | Test performed with formula similar to the product under evaluation | Acute dermal toxicity test in the rat - Acute toxic class method, report Tn 081/07-0352, P. Gomond 2007 |

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | The LD50 of the test item is higher than 2000 mg/kg body weight by dermal route in the rat. |
| Justification for the selected value | The potential for acute dermal toxicity of the product was assessed based on a GLP study according to the OECD guideline No 402 |
| Classification of the product according to CLP and DSD | / |

##### Information on dermal absorption

| **Summary table of in vitro studies on dermal absorption** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Number of skin samples tested per dose, Other relevant information about the study** | **Test substance, Doses** | **Absorption data for each compartment and final absorption value** | **Remarks** *(e.g. major deviations)* | **Reference** |
| OECD 428, GLP, reliable without restriction | Human, 6 discs from 3 different donors, exposure time of 8h | Mouskito Roller (203 mg IR3535/g).  , 10μl on 1cm2 | * Mean recovery percentage: 95 ± 1% * In vitro dermal absorption of IR3535: 4 ± 2% * In vitro maximum flux of IR3535 through human skin:26 ± 15 μg/cm2\*h | Mouskito Roller (same composition) | Determination of the dermal absorption of ethyl butylacetylaminopropionate (IR3535) in different formulations through human skin in vitro, J.C.W. Rijk, 2015 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | | | |
| Substance | Mouskito Roller |  |  |
| Value(s)\* | Dermal absorption: 4±2 % (203 mg IR3535/g) |  |  |
| Justification for the selected value(s) | The dermal absorption of the product was assessed based on a GLP study according to the OECD guideline No 428 |  |  |

\* please include the concentration range(s) the values are applicable for, if relevant

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

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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

##### 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 Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

#### Exposure assessment

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

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | n.a. | n.a. | n.a. | n.a. | n.a. | Yes | n.a. |
| Dermal | yes | 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. Applying a lotion would not give significant inhalative exposure. For these reasons the inhalative exposure during application was not taken into account. Direct oral exposure is not considered to be relevant because of the repellent taste (bad palatability) of the active substance and because the biocidal product should not be self-applied by children younger than 12 years.

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. The inhalation of volatilized residues after application is also relevant.

| **Summary : Amount of product used per application for the different age groups, treated surface and number of application per day** | | | |
| --- | --- | --- | --- |
| **Age groups** | **Amount of product used per application (g)** | **Treated surface**  **[cm²]**  **Uncovered parts of the body** | **number of application per day** |
| ADULT irrespective of gender (based on female 30 to <40 years old) | **1G/600 CM²** | 16 600 \* 55% = 9130 | 4 applications/day |
| CHILD irrespective of gender (based on female 6 to <11 years old) | **1G/600 CM²** | 5060 | 4 applications/day |
| CHILD irrespective of gender (based on female 2-6 years old) | **1G/600 CM²** | 3740 | 4 application/day |
| TODDLER irrespective of gender (based on female 1-2 years old) | **1G/600 CM²** | 2640 | 4 application/day |
| INFANT irrespective of gender (based on female 6 to <12 months old) | **1G/600 CM²** | 2255 | 4 application/day |

###### Dermal, inhalatory and oral absorption:

* Inhalatory absorption : 100 %
* Dermal absorption : 4 % ±2%; value used for RA = 6%[[7]](#footnote-7)
* Oral absorption : 100 %

Amount of biocidal product:

There are different default values existing for the application rate of a lotion/roller repellent. There are currently discussions about harmonizing the exposure scenario for PT19.

Based on the efficacy studies done for this product, the efficient dose would be **1g product/600 cm² skin.**

***Treated surface:***

The treated surface is assumed to be the uncovered parts of the body, typically hands, arms, feet, legs and the face. We used 55% of the total body area exposed to the product.

##### List of scenarios

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1. | Application phase | Primary exposure: Dermal exposure assessment for adults, children, toddlers and infants. | Non-professionals |
| 2. | Post-application phase | Secondary exposure (indirect exposure as a result of use): Hand-mouth transfer reverse reference scenario (oral exposure) | Non-professionals |
| 3. | Post-application phase | Inhalation of volatilised residues after application (inhalative exposure) | Non-professionals |
| 4. | Exposure during production | Mixing and Loading model – worst case for the production, formulation and disposal of the biocidal product | Professionals |

##### Industrial exposure

There is no concern about industrial exposure because of the intend of use apart for the production/formulation and disposal of the biocidal product. This exposure is address under a point below.

##### Professional exposure

Not relevant since the product is intended to be used by general public.

##### Non-professional exposure

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

| **Description of Scenario 1** | | |
| --- | --- | --- |
| NO PPE | | |
| For All categories | Dermal absorption | 6% |
| % of active substance in biocidal product | 20% |
| Number of application / day | 4 |
| Tier 1- Adult –  uncovered body parts treated | Body weight – body exposed | 60 kg – 9130 cm² |
| Amount of biocidal product/ application | 15.2 g |
| Tier 1- Child 6-11 –  uncovered body parts treated | Number of application / day | 4 |
| Body weight | 23.9 kg – 5060 cm² |
| Amount of biocidal product/ application | 8.4 g |
| Tier 1- Child 2-6 –  uncovered body parts treated | Number of application / day | 4 |
| Body weight | 15.6 kg – 3740 cm² |
| Amount of biocidal product/ application | 6.2 g |
| Tier 1- Toddler –  uncovered body parts treated  (2-6 jaar) | Number of application / day | 4 |
| Body weight | 10 kg – 2640 cm² |
| Amount of biocidal product/ application | 4.4 g |
| Tier 1- Infant –  uncovered body parts treated | Number of application / day | 4 |
| Body weight | 8 kg – 2255 cm² |
| Amount of biocidal product/ application | 3.8 g |

Tier 2:

**Number of applications:**

**1 for adults, children, toddlers and infants**

Calculations for scenario 1

**Dermal exposure:**

Number of application/day x amount b.p./application x percent of a.s. in b.p.

**Systemic exposure:**

Dermal exposure x percent of dermal absorption

**Dermal systemic exposure:**

Systemic exposure / body weight

| **Summary table: estimated exposure for non professional exposure** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** |
| Tier 1- Adult –  uncovered body parts treated | 1/ no PPE | n.a. | 12.2 mg/kg bw/day |
| Tier 1- Child 6-11 –  uncovered body parts treated | 1/ no PPE | n.a. | 16.9 mg/kg bw/day |
| Tier 1- Child 2-6 –  uncovered body parts treated | 1/ no PPE | n.a. | 19.2 mg/kg bw/day |
| Tier 1- Toddler –  uncovered body parts treated | 1/ no PPE | n.a. | 21.1 mg/kg bw/day |
| Tier 1- Infant –  uncovered body parts treated | 1/ no PPE | n.a. | 22.6 mg/kg bw/day |
| Tier 2- Adult –  uncovered body parts treated | 2/ no PPE | n.a. | 3.0 mg/kg bw/day |
| Tier 2- Child 6-11 –  uncovered body parts treated | 2/ no PPE | n.a. | 4.2 mg/kg bw/day |
| Tier 2- Child 2-6 –  uncovered body parts treated | 2/ no PPE | n.a. | 4.8 mg/kg bw/day |
| Tier 2- Toddler –  uncovered body parts treated | 2/ no PPE | n.a. | 5.3 mg/kg bw/day |
| Tier 2- Infant –  uncovered body parts treated | 2/ no PPE | n.a. | 5.6 mg/kg bw/day |

[Add and delete lines as needed. Output tables from exposure assessment tools can be included in Annex 3.2 to complement the table].

###### Scenario 2: Secondary exposure (indirect exposure as a result of use): Hand-mouth transfer reverse reference scenario (oral exposure)

| **Description of Scenario 2** | | |
| --- | --- | --- |
| This scenario is based on the one available in the CAR of IR3535®. It has been updated with the document : Biocide Human Health Exposure Methodology (Oct 2015). | | |
| For All categories | Oral absorption1 | 100% |
| % of active substance in biocidal product1 | 20% |
| Tier 1- Adult –  uncovered body parts treated | Body weight1 | 60 kg |
| Factor for oral intake by hand-mouth transfer2 | 4% |
| Amount of biocidal product/ application1 | 15.2 g |
| Tier 1- Child 6-11 –  uncovered body parts treated | Factor for oral intake by hand-mouth transfer2 | 8% |
| Body weight1 | 23.9 kg |
| Amount of biocidal product/ application1 | 8.4 g |
| Tier 1- Child 2-6 r –  uncovered body parts treated | Factor for oral intake by hand-mouth transfer2 | 8% |
| Body weight1 | 15.6 kg |
| Amount of biocidal product/ application1 | 6.2 g |
| Tier 1- Toddler 1-2 –  uncovered body parts treated | Factor for oral intake by hand-mouth transfer2 | 8% |
| Body weight1 | 10 kg |
| Amount of biocidal product/ application1 | 4.4 g |
| Tier 1- Infant –  uncovered body parts treated | Factor for oral intake by hand-mouth transfer2 | 8% |
| Body weight1 | 8 kg |
| Amount of biocidal product/ application1 | 3.8 g |

1 Efficacy dose 1g/600cm²

2 % is the factor of the total treated body surface (Head, hands, arms, legs and feet) reported to the surface area of the fingers. 8% is the factor of the total treated body surface (Head, hands, arms, legs and feet) reported to the surface area of the hands. They are default values currently discuss for a harmonisation of human exposure scenarios for PT19.

Calculations for scenario 2

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 applications of b.p. before exceeding the AEL via hand-mouth transfer:**

AEL / Oral systemic exposure via hand-mouth transfer

| **Summary table: estimated exposure for Hand-mouth transfer reverse reference scenario (oral exposure)** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Max applications before exceeding AEL** |
| Scenario 2 – ADULT | Tier 1 / no PPE | 2.5 applications |
| Scenario 2 – CHILD 6-11 | Tier 1 / no PPE | 0.9 applications |
| Scenario 2 – CHILD 2-6 | Tier 1 / no PPE | 0.8 applications |
| Scenario 2 – TODDLER | Tier 1 / no PPE | 0.7 applications |
| Scenario 2 – INFANT | Tier 1 / no PPE | 0.7 applications |

The label provided by the applicant says 4 applications per day. Children: do not apply on hands.

For the dermal exposure for children no application is save.

Together with the phrase: For children: do not apply on hands we can accept **1 applications per day for children and 2 applications per day for adults.**

###### Scenario 3: Inhalation of volatilised residues after application (inhalative exposure)

| **Description of Scenario 3** |
| --- |
| | 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 can’t be considered as negligible.  Exposure was assessed using ConsExpo – exposure to vapour – instantaneous release.  **General inputs to the model :**  Exposure duration: 24 hours (all day)  Product amount: calculated dependant of the amount applied per day and per age categories  Weight fraction compound: 20% (biocidal product information)  Room volume: 20m3 (default value of ConsExpo)  Ventilation rate: 2.5 /h (default value, ConsExpo, 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- Adult | Product amount1 | 15.2 g | | Body weight2 | 60 kg | | Respiration rate [m3/air/hour]2 | 1.25 m³/h | | Tier 1- Child 6 to < 12 years old | Product amount1 | 8.5 g | | Body weight2 | 23.9 kg | | Respiration rate [m3/air/hour]2 | 1.32 m³/h | | Tier 1- Child 2 to < 6 years old | Product amount1 | 6.2 g | | Body weight2 | 15.6 kg | | Respiration rate [m3/air/hour]2 | 1.26 m³/h | | Tier 1- Toddler | Product amount1 | 4.4 g | | Body weight2 | 10 kg | | Respiration rate [m3/air/hour]2 | 1.26 m³/h | | Tier 1- Infant | Product amount1 | 3.8 g | | Body weight2 | 8 kg | | Respiration rate [m3/air/hour]2 | 0.84 m³/h |   1 According the primary exposure, only one application per day can be authorized. Therefore, the product amount corresponds to 1 application/day. |
| 2 General information, see justification above |

Calculations for scenario 3

| **Summary table: estimated exposure for inhalation of volatilised residues after application (inhalative exposure)** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake of volatilised residues after application** |
| Scenario 3 – ADULT | Tier 1 /  no PPE | 1.3 mg/kg bw/day |
| Scenario 3 – CHILD (6-12) | Tier 1 /  no PPE | 1.9 mg/kg bw/day |
| Scenario 3 – CHILD (2-6) | Tier 1 /  no PPE | 2.0 mg/kg bw/day |
| Scenario 3 – TODDLER | Tier 1 /  no PPE | 2.2 mg/kg bw/day |
| Scenario 3 – INFANT | Tier 1 /  no PPE | 1.6 mg/kg bw/day |

##### Exposure of the general public

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

##### Monitoring data

N.a.

##### Dietary exposure

No exposure is foreseen. IR3535® is not used for and/or during food production, or in rooms where food is produced, processed or stored.

Following RMM should be sufficient to minimize the risk of a transfer of residues of IR3535 from hand to food

- 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.

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

In modern formulation plants typically automated equipment is used to add the formulation ingredients and to fill the formulated product into the respective vessels (closed systems). The workers (trained professionals) usually wear personal protective equipment (e.g. gloves). Thus the exposure can occur during the mixing and loading and have been calculated as a worst case.

###### Scenario 4 : Mixing and Loading model – worst case for the production, formulation and disposal of the biocidal product

| **Description of Scenario 4** | | |
| --- | --- | --- |
| For a worst case situation, it was estimated that the more sustainable model for industrial exposure production, formulation and disposal is : RISKOFDERM Dermal model (loading liquid, automated or semi-automated) from HEEG opinion 1 (2008). | | |
|  | **Parameters1** | **Value** |
| Tier 1 | Purity of the active substance1 | 99% |
| Dermal absorption1 | 50% |
| default potential exposure rates on clothing2 | 101 mg/min |
| default potential exposure rates on hand2 | 2.02 mg/ min |
| default potential exposure rates for inhalation2 | n.r. mg/m3 (and the substance has a low vapour pressure) |
| Bodyweight3 | 60 kg |
| Number of events per day | 1/day |
| Duration of task | 10 min |
| Tier 2 | Factor of protection for Uncoated cotton coverall3 | 75% |
| Factor of protection for gloves3 | 90% |

1 CAR (doc IIA)

General information, see justification above

2 RISKOFDERM Dermal model: loading liquid, automated or semi-automated (HEEG opinion 1, 2008)

3 Biocide Human Health Exposure Methodology (Oct 2015)

Calculations for Scenario 4

**Dermal exposure via clothing:**

default potential exposure rates on clothing x Purity of the active substance x Duration of task x Number of events per day (x (1-Factor of protection for clothing))

**Dermal exposure via hands:**

default potential exposure rates on hands x Purity of the active substance x Duration of task x Number of events per day (x (1-Factor of protection for gloves))

**Dermal systemic exposure:**

(Dermal exposure via clothing + Dermal exposure via hands) x percent of dermal absorption / body weight

**Inhalation exposure:**

Inhalation is no relevant for this model and is not taken into account

**Systemic exposure**:

Dermal systemic exposure + 0 (inhalation exposure n.r.)

| **Summary table: systemic exposure associated with production, formulation, and disposal** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario 4 | Tier 1/ no PPE | n.r. | 8.5 mg/kg bw/d | n.r. | 8.5 mg/kg bw/d |
| Scenario 4 | Tier 2/ Uncoated cotton coverall+gloves | n.r. | 2.1mg/kg bw/d | n.r. | 2.1 mg/kg bw/d |

##### Aggregated exposure

n.a.

##### 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 (uncovered body parts),4 applications/day | 12.2 mg/kg bw /day |
|  | Non-professionals, child 6-11 | Tier 1, no PPE, dermal (uncovered body parts), 4 applications/day | 16.9 mg/kg bw /day |
|  | Non-professionals, child 2-6 | Tier 1, no PPE, dermal (uncovered body parts), 4 applications/day | 19.2 mg/kg bw /day |
|  | Non-professionals, toddler | Tier 1, no PPE, dermal (uncovered body parts), 4 applications/day | 21.1 mg/kg bw /day |
|  | Non-professionals, infant | Tier 1, no PPE, dermal (uncovered body parts), 4 applications/day | 22.6 mg/kg bw /day |
|  | Non-professionals, adult | Tier 2, no PPE, dermal (uncovered body parts), 1 applications/day | 3.0 mg/kg bw/day |
|  | Non-professionals, child 6-11 | Tier 2, no PPE, dermal (uncovered body parts),1 applications/day | 4.2 mg/kg bw/day |
|  | Non-professionals, child 2-6 | Tier 2, no PPE, dermal (uncovered body parts),1 applications/day | 4.8 mg/kg bw/day |
|  | Non-professionals, toddler | Tier 2, no PPE, dermal (uncovered body parts),1 applications/day | 5.3 mg/kg bw/day |
|  | Non-professionals, infant | Tier 2, no PPE, dermal (uncovered body parts),1 applications/day | 5.6 mg/kg bw/day |
| 2. | Non-professionals, adult | Tier 1, no PPE, Hand-mouth transfer reverse reference scenario, oral | Max 2.5 applications |
|  | Non-professionals, child 6-12 | Tier 1, no PPE, Hand-mouth transfer reverse reference scenario, oral | Max 0.9 applications |
|  | Non-professionals, child 2-11 | Tier 1, no PPE, Hand-mouth transfer reverse reference scenario, oral | Max 0.8 applications |
|  | Non-professionals, toddler | Tier 1, no PPE, Hand-mouth transfer reverse reference scenario, oral | Max 0.7 applications |
|  | Non-professionals, infant | Tier 1, no PPE, Hand-mouth transfer reverse reference scenario, oral | Max 0.7 applications |
| 3. | Non-professionals, adult | Tier 1 / no PPE | 1.3 mg/kg bw/day |
|  | Non-professionals, child 6-11 | Tier 1 / no PPE | 1.9 mg/kg bw/day |
|  | Non-professionals, child 2-6 | Tier 1 / no PPE | 2.0 mg/kg bw/day |
|  | Non-professionals, toddler | Tier 1 / no PPE | 2.2 mg/kg bw/day |
|  | Non-professionals, infant | Tier 1 / no PPE | 1.6 mg/kg bw/day |
| 4. | Professionals | Tier 1/ no PPE | 8.5 mg/kg bw/d |
|  | Professionals | Tier 2/ Uncoated cotton coverall+gloves | 2.1 mg/kg bw/d |

#### Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **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  (not applicable here, maximum number of applications is 28 days per year) |
| 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 |

##### Risk for industrial users

###### Systemic effects

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario 4, mixing & loading, professional | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | 8.5 mg/kg bw/d | 170 | no |
| Scenario 4, mixing & loading, professional | 2 | 500 mg/kg bw/d | 5 mg/kg bw/d | 2.1 mg/kg bw/d | 42 | yes |

###### Local effects

The biocidal product is classified as eye damage/irritation cat 2, H319. However, appropriate risk mitigation measures are assumed to be taken by professionals during production, formulation and disposal. Consequently, there is no need to consider local effects separately.

###### Conclusion

There is no concern for professionals during production, formulation and disposal when using appropriate PPE (uncoated cotton coverall and gloves).

##### Risk for professional users

n.a.

##### Risk for non-professional users

###### Systemic effects

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario 1, dermal (uncovered body parts), adult | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | 12.2 mg/kg bw /day | 243 | NO |
| Scenario 1, dermal (uncovered body parts), child 6-11 | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | 16.9 mg/kg bw /day | 338 | NO |
| Scenario 1, dermal (uncovered body parts), child 2-6 | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | 19.2 mg/kg bw /day | 383 | NO |
| Scenario 1, dermal (uncovered body parts), toddler | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | 21.1 mg/kg bw /day | 422 | NO |
| Scenario 1, dermal (uncovered body parts), infant | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | 22.6 mg/kg bw /day | 452 | NO |
| Scenario 1, dermal (uncovered body parts), adult | 2 | 500 mg/kg bw/d | 5 mg/kg bw/d | 3.0 mg/kg bw/day | 61 | Yes |
| Scenario 1, dermal (uncovered body parts), child 6-11 | 2 | 500 mg/kg bw/d | 5 mg/kg bw/d | 4.2 mg/kg bw/day | 85 | Yes |
| Scenario 1, dermal (uncovered body parts), child 2-6 | 2 | 500 mg/kg bw/d | 5 mg/kg bw/d | 4.8 mg/kg bw/day | 96 | Yes |
| Scenario 1, dermal (uncovered body parts), toddler | 2 | 500 mg/kg bw/d | 5 mg/kg bw/d | 5.3 mg/kg bw/day | 106 | No |
| Scenario 1, dermal (uncovered body parts), infant | 2 | 500 mg/kg bw/d | 5 mg/kg bw/d | 5.6 mg/kg bw/day | 113 | No |
| Scenario 2, hand-mouth transfer, adult | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | Max 2.5 applications | n.a. | Reverse reference scenario |
| Scenario 2, hand-mouth transfer, child 6-11 | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | Max 0.9 applications | n.a. | Reverse reference scenario |
| Scenario 2, hand-mouth transfer, child 2-6 | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | Max 0.8 applications | n.a. | Reverse reference scenario |
| Scenario 3, hand-mouth transfer, toddler | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | Max 0.7 applications | n.a. | Reverse reference scenario |
| Scenario 2, hand-mouth transfer, infant | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | Max 0.7 applications | n.a. | Reverse reference scenario |
| Scenario 3, inhal, adult | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | 1.3 mg/kg bw/day | 26 | Yes |
| Scenario 3, inhal, child | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | 1.9 mg/kg bw/day | 38 | Yes |
| Scenario 3, inhal, child | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | 2.0 mg/kg bw/day | 40 | Yes |
| Scenario 3, inhal, toddler | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | 2.2 mg/kg bw/day | 44 | Yes |
| Scenario 3, inhal, infant | 1 | 500 mg/kg bw/d | 5 mg/kg bw/d | 1.6 mg/kg bw/day | 32 | Yes |

###### Local effects

The biocidal product is classified as eye damage/irritation cat 2, H319. However, appropriate risk mitigation measures will be imposed and taken up on the label: ’ For treatment of the face, the product should be applied to the hand and spread carefully on the face. Take care to protect the eyes. Do not apply to eye area. For children below 12 years of age: the repellent must be applied by adults. Do not use on children’s hands.’

Consequently, there is no need to consider local effects separately.

###### Conclusion

Application on face, arms, hands, legs and feet:

There is a concern for adults, children, toddlers and infants using Mouskito junior lotion as a Repellent Subtype PT19.01, when used four times per day on uncovered parts of the body.

For children it is important to put on the label to not apply the product on the hands to avoid hand to mouth transfer and ingestion.

There is no concern for indirect secondary exposure for adults and children > 2 years from the use of the biocidal product as a Repellent Subtype PT19.01 when used 1 time per day. Exposure via hand-to-mouth transfer is of minor concern when the product is used as intended (not to be applied to children’s hands), and inhalation of volatilized residues after application is limited.

The use of Mouskito junior lotion can be used from the age of 2.

For children below 2 years of age (toddlers and infants), no safe use could be established.

The following RMM are required:

* Use repellent safely. Always read the label and product information before use.
* Not suitable for children under 2 years of age.
* Keep out of reach of children. Use only outdoors or in a well-ventilated area.
* ONLY apply to uncovered parts of the arms, hands, legs, feet and face. For treatment of the face, the product should be applied to the hand and spread carefully on the face. Take care to protect the eyes. Do not apply to eye area.
* An adult should apply the product to children below 12 years of age. Do not use on children’s hands. Do not use under clothing.
* 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.
* Maximum number of applications per day: once a day for adults and children above 2 years of age.

##### Risk for the general public

See non-professional users

##### Risk for consumers via residues in food

n.a.

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

n.a.

### Risk assessment for animal health

n.a.

### Risk assessment for the environment

For the product Mouskito Junior Lotion no new studies or additional information for the environment have been provided. The active substance contained in this product is the same as evaluated in the CAR for IR3535 and therefore no new data/information on the active substance is required.

#### Effects assessment on the environment

All data used for the effect assessment of Mouskito Junior Lotion is based on the available information on the active substance IR3535, such as it is presented in its respective CAR.

No new data relevant for the environmental evaluation, nor on the product, nor on the active substance, have been submitted. Apart from the active substance, the product does not contain any formulants that are of ecotoxicological concern.

An overview of the environmental fate and behaviour for the active substance, taken from the EU CAR, is presented in the first two titles below.

##### Environmental fate and behavior of the active substance

IR3535® is used in insect repellents (PT19) that are applied on uncovered human skin. Products containing IR3535® will be used indoors and outdoors. However, the main emission pathway to the environment is assumed to be indirect due to bathing and showering of treated people. Based on the physico-chemical properties it is expected that the emissions primarily will affect the aquatic compartment.

IR3535® is not readily biodegradable according to two screening tests, but in a Sewage Treatment Plant (STP) simulation test 99 % elimination was measured. In an aerobic water/sediment degradation study, IR3535® was shown to remain mainly in the water phase. There it was first rapidly degraded to its free acid, after which this metabolite ultimately degraded after a lag phase.

No photolysis was observed in water and hydrolysis only occurred slowly under alkaline conditions (DT50 = 176.5 h at 25 °C and pH 9 or 866.13 h at 12 °C). Under acidic and neutral conditions IR3535® is hydrolytically stable.

The vapour pressure of IR3535® is low (0.15 Pa at 20 °C) which results in low exposure to the atmosphere. The half-life of IR3535® in air was calculated to be about 0.5482 days or 13.16 hours due to reaction with OH-radicals (24-hr day). Thus, accumulation of IR3535® in air and long range transport is unlikely.

IR3535® is a liquid at room temperature and the solubility in water is 70 g/L (at 20 °C). The log Pow is 1.7 (at 23-24 °C) indicating that IR3535® has a low potential for bioaccumulation.

Based on the adsorption/desorption test a mean (arithmetic) Koc form 475.25 L/kg was registered.

##### Effect assessment of the active substance

No toxic effects where observed during the acute toxicity studies on fish (*Brachydanio rerio*), *Daphnia magna* and algae (*Desmodesmus subspicatus*) (LC50 >100 mg/L). Therefore IR3535® is considered as not toxic for the aquatic environment.

The effect on aerobic biological sewage treatment processes was assessed by determining inhibition of respiration of the micro-organisms present in activated sludge following 3 hours contact. No inhibitory effect on aquatic microbial activity was registered for IR3535® (EC50 > 1000 mg/L).

Long term aquatic tests were not required because no acute toxicity was observed for the aquatic environment and the substance is primarily emitted to the STP before reaching the aquatic environment. Besides the Sewage Treatment Plant (STP) simulation test showed an elimination of 99 % in the STP.

No marine species were tested based on the presence of studies performed on freshwater species, all suggesting low toxicity, and because no major emissions to the marine environment are expected.

In the absence of any long-term toxicity endpoints and marine data, the TGD on Risk Assessment prescribes an assessment factor of 1000 for the freshwater environment and 10000 for the marine environment.

For the sediment compartment, there are also no toxicity data available. The PNECsediment was calculated based on equilibrium partitioning method and PNECwater.

No terrestrial toxicity tests were performed for IR3535®. Due to the method of application directly on the skin only limited and very local emissions to the soil are expected. IR3535® is not likely to become accumulated in the soil in large amounts. PNECsoil has been calculated based on the equilibrium partitioning method.

The physicochemical properties of IR3535® do not suggest that this substance will pose a risk to the atmospheric environment. Therefore no PNECs where calculated for this compartment.

The low BCF values suggest that IR3535® has a low bioaccumulation potential. Therefore the risk of secondary poisoning via ingestion of contaminated food (eg. earthworms or fish) by birds or mammals is also low and no avian dietary tests were required.

|  |  |
| --- | --- |
| **Summary of PNEC values for the active substance** | |
| **Compartment** | **PNEC value** |
| PNECaquatic | > 0.1 mg/l |
| PNECsediment | > 1.11 mg/kg wwt |
| PNECmicro-organisms (STP) | 100 mg/l |
| PNECsoil | > 0.85 mg/kg wwt |
| PNECsaltwater | > 0.01 mg/l |
| PNECmarine-sediment | > 0.111 mg/kg wwt |

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

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

|  |
| --- |
| **Conclusion on the environmental classification and labelling of the product** |
| Mouskito Junior Lotion does not require any environmental classification or labelling. |

##### Further Ecotoxicological studies

The assessment of the active substance in the CAR showed that there is no concern for the aquatic and terrestrial environment and thus no further ecotoxicological studies are required according to the CAR.

For this particular product, there is no direct exposure to the environment and the product does not contain formulants other than the active substance that could be of ecotoxicological concern, thus the data on the active substance are sufficient for the evaluation of the ecotoxicological effects of the biocidal product.

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

No further data are available.

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

The product is not in the form of bait or granules, so no such data are required.

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

The product is not in the form of bait or granules, so no such data are required.

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

Not relevant.

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

The foreseeable routes of entry into the environment have been described in the CAR for the active substance and are also valid for this product.

Direct release to soil is not considered relevant, whereas direct release to surface water (swimming lake scenario) is considered relevant, but was not yet assessed in the CAR due to the lack of an endorsed scenario.

Secondary release via wastewater and STP through showering and bathing is also a relevant route of emission.

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

No new data was submitted or is required. Information on the active substance suffices for the environmental risk assessment of the product. Moreover, the product does not contain any other substances relevant for the environment apart from the active substance.

##### Leaching behaviour (ADS)

Not relevant.

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

Since there is no direct release to soil and the soil compartment is not envisioned as a compartment of interest in the evaluation of this product, no such additional data are submitted or required.

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

No new data were submitted or are required.

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

No new data were submitted or are required.

##### 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 were submitted or are 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 were submitted or are required.

#### Exposure assessment

##### General information

|  |  |
| --- | --- |
| Assessed PT | PT 19 |
| Assessed scenarios | Scenario 1: Removal via showering and bathing of humans (ESD PT19, May 2015, §3.1.4.1)  Scenario 2: Release to surface water bodies via swimming (ESD PT19, May 2015, §3.1.4.2) |
| ESD(s) used | Emission Scenario Document for Product Type 19: Repellents and attractants, May 2015 (ECHA-15-B-10-EN) |
| Approach | Scenario 1: Average consumption Scenario 2: Average consumption |
| Distribution in the environment | Calculated based on Guidance on BPR Vol.IV B+C |
| Groundwater simulation | Not applicable |
| Confidential Annexes | None |
| Life cycle steps assessed | Scenario 1: Showering & bathing   * Production: No * Formulation: No * Use: Yes * Service life: No   Scenario 2: Swimming   * Production: No * Formulation: No * Use: Yes * Service life: No |
| Remarks | Evaluation done taking into account WGV2018 agreement on treated skin surface:  TAB ENV v2.0 entry **ENV 172** - Refinement of risk assessment PT19: reduction of treated skin surface area and taking into account dermal adsorption  The WG agreed to apply the new value of the HEAdoc recommendation of January 2018 for the treated skin area, i.e. 55% of 16600 cm2 (= 9130 cm²), since this could be considered as a mean value taking into account the different skin areas for women, men and children. |

##### Emission estimation

###### Scenario 1: Removal via showering and bathing

Consumption based scenario

For estimating the emission for products applied on human skin following showering or bathing, one could either use a tonnage based scenario or a consumption based scenario.

Tonnage based approaches are mostly only appropriate for assessing an active substance for approval and not so much for the authorisation of biocidal products. Therefore only the consumption based approach is assessed here.

However, the tonnage based approach was calculated in the IR3535 CAR and can be consulted in the confidential annex of said CAR. Anyway when considering the break-even tonnage, the consumption based scenario is deemed to be the most appropriate scenario.

Amount of product per application (Qformappl)

The most important input parameter for the consumption based scenario is the amount of product that will be used per application (Qformappl). As a default value in the ESD 0.6 mg product/cm² skin is proposed.

However, the ESD also mentions that the value for Qformappl must coincide with the efficacy of the product and must be adapted accordingly.

The validated efficacious dose for the product Mouskito Junior Lotion is 1g product/600cm² of skin. Consequently a dose of 1.67 mg/cm² will be considered for the environmental risk assessment instead of the default value from the ESD.

**Qformappl = 1.67 mg product/cm² skin**

Number of applications per day (Nappl)

Another important parameter is the number of applications per day (Nappl), which the ESD also links to the efficacy of the product.

The conclusion for efficacy of Mouskito Junior Lotion is that the product will remain efficacious between 7 and 8 hours, depending on the climate and the species to repel, when used at the application rate of 1.67 mg/cm². Following the ESD Table 3-2, 2 applications per day will thus be used in the risk assessment.

**Nappl = 2 d-1**

Treated area of human skin (AREAskin)

Following the agreement of the ENV WG-V-2018 to harmonise the value for the treated skin area with that of the Human Health assessment, a value of 55% of the total body surface area will be applied.

**AREAskin = 9130 cm²**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario: Release of repellents used on human skin based on the average consumption* | | | | |
| Number of inhabitants feeding one STP | Nlocal | 10 000 | cap | D |
| Active substance in product | (B) Cformweight | 200 | g/kg | (20 %) |
| Consumption per application | (D2) Qformappl | 1.67 | mg/cm² | (see above) |
| Number of applications per day | Nappl | 2 | d-1 | (see above) |
| Treated area of human skin | AREAskin | 9130 | cm² | (see above) |
| Fraction released to air | Fair | 0 | [-] | D |
| Fraction dermally absorbed | Fskin | 0 | [-] | D |
| Fraction released to wastewater | Fwater | 1 | [-] | D |
| Fraction of inhabitants using a repellent product | Finh | 0.2 | [-] | D |
| Market share of repellent | Fpenetr | 0.5 | [-] | D |
| Specific density of the product | RHOform | 1000 | kg/m³ | D |

Calculations for Scenario 1

**🡪 B and D2**

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Waste water | 6.09 | / |

###### Scenario 2: Release to surface water bodies via swimming

In the assessment report for IR3535, in the paragraph on the elements to be taken into account when authorising products, it is mentioned that direct emissions to surface water by swimmers should be kept in mind and assessed. With this new scenario for the ESD for PT19, this requisite is taken into account.

Amount of product per application (Qformappl)

Similarly as with scenario 1, the most important input parameter for this scenario is the amount of product that will be used per application (Qformappl).

The same notes and thoughts can be applied as with scenario 1. Therefore, also here it is decided that the efficacious dose will be applied.

**Qformappl = 1.67 mg product/cm² skin**

Treated area of human skin (AREAskin)

Following the agreement of the ENV WG-V-2018 to harmonise the value for the treated skin area with that of the Human Health assessment, a value of 55% of the total body surface area will be applied.

**AREAskin = 9130 cm²**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario: Release of repellents used on human skin due to swimming activities in surface water bodies* | | | | |
| Daily number of swimmers | Nswimmer | 1500 | [-] | D |
| Fraction of swimmers using the repellent | Fswim | 0.02\* | [-] | P |
| Number of applications per day | Nappl | 1 | d-1 | D |
| Fraction released to surface water body | Fwaterbody | 1 | [-] | D |
| Active substance in the product | (B) Cformweight | 200 | g/kg | (20%) |
| Consumption per application | (D2) Qformappl | 1.67 | mg/cm² | (see above) |
| Treated area of human skin | AREAskin | 9130 | cm² | (see above) |
| Specific density of product | RHOform | 1000 | kg/m³ | D |

\*For this scenario, only the value Fswim=0.02 was used (the default value).

We do not consider that a higher value of Fswim (0.1) can be appropriate for this product because this product will be used mainly by children and not adults and therefore this higher value does not reflect the reality of use.

Intermediate calculation for Scenario 2

**🡪 B and D2**

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Surface water | 0.091 | / |

Final calculation for scenario 2

In the intermediate 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 water body, the actual concentration in active substance in this water body should be calculated.

As a first TIER evaluation, concentrations are calculated for emission periods of 1 day and 91 days, without taking into account possible degradation progresses, which represents the worst-case.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating surface water concentration** | | | | |
| **Input** | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario: Release of repellents used on human skin due to swimming activities in surface water bodies* | | | | |
| Local emission to surface water body | Elocalwater | 0.091 | kg/d | O (Intermediate calculation) |
| Volume of water body | Vwaterbody | 435 000 | m³ | D |
| Number of emission days TIER 1 | Temission, 1d | 1 | d | D |
| Number of emission days TIER 2 | Temission, 91d | 91 | d | D |
| Number of emission events | Nemission, 91d | 91 | [-] | D |

| **Resulting local concentrations in the waterbody** | | |
| --- | --- | --- |
| **Compartment** | **Local concentration**  **(Clocalcompartment) [kg/m³]** | **Remarks** |
| Surface water – after 1 day | 2.10x10-7 | / |
| Surface water – after 91 days | 1.91x10-5 | (without considering possible degradation) |

##### Fate and distribution in exposed environmental compartments

###### Scenario 1:

Applied product is removed from the body through showering or bathing. The wastewater from washing is then removed to the municipal waste water treatment plant, after which the effluent is emitted to the surface water where it can expose both fresh water and fresh water sediments.

Exposure to other compartments is not considered relevant.

###### Scenario 2:

Applied product is removed from the body directly to the surface water through swimming, where it can expose both fresh water and fresh water sediments.

Exposure to other compartments is not considered relevant.

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Molecular weight | 215.29 |  |  |
| Melting point | -90 | °C |  |
| Boiling point | 300 | °C |  |
| Vapour pressure (at 20 °C) | 0.15 | Pa |  |
| Water solubility (at 20 °C) | 70 000 | mg/l |  |
| Log Octanol/water partition coefficient | 1.7 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 475.25 | l/kg |  |
| Henry’s Law Constant (at 20 °C) | 4.613x10-4 | Pa/m3/mol |  |
| Biodegradability | Inherently biodegradable |  |  |

In the CAR for IR3535, calculations according to EUSES are available for the distribution in the STP, which in this case is only relevant for scenario 1. As a worst-case assessment the distribution presented in the CAR is taken over for the assumption that there is no degradation. As a TIER 2 evaluation, 99% degradation in STP is taken into consideration.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Calculated fate and distribution in the STP** | | | | |
| **Compartment** | **Percentage [%]** | | | **Remarks** |
| **Scenario 1**  **TIER 1** | **Scenario 1**  **TIER 2** | **Scenario 2** |
| Air | 0.000547 | 0 | Not relevant |  |
| Water | 99 | 1 |  |
| Sludge | 1 | 0 |  |
| Degraded in STP | 1.000547 | 99 |  |

##### Calculated PEC values

Neither for scenario 1, nor for scenario 2, calculations were made for the sediment, since the PNECsediment was determined through the EPM-method. This means that the risk assessment for water is applicable for the sediment as well.

As mentioned before, for the scenario 2, possible degradation in surface water is not taken into account as a worst-case evaluation.

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | |
|  |  | **PECSTP** | **PECwater** |
| [mg/m3] | [mg/l] |
| **Scenario 1** | TIER 1 | 3.01 | 3.01x10-1 |
| TIER 2 | 3.04x10-2 | 3.04x10-3 |
| **Scenario 2** | Day 1 | n/a | 2.10 x 10-4 |
| Day 91 | n/a | 1.91 x 10-2 |

##### Primary and secondary poisoning

###### Primary poisoning

Not applicable, since this product is a repellent and has no intention of killing.

###### Secondary poisoning

Not relevant, since no bioaccumulation is expected.

#### Risk characterisation

##### Atmosphere

Conclusion:

Only negligible exposure to the atmosphere is expected and no threat to the atmosphere is expected.

##### Sewage treatment plant (STP)

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
|  |  | **PEC/PNECSTP** |
| Scenario 1 | TIER 1 | (3.01/100) = **3.01x10-2** |
| TIER 2 | (3.04x10-2/100) = **3.04 x 10-4** |
| Scenario 2 | Day 1 | **Not relevant** |
| Day 91 | **Not relevant** |

Conclusion:

No adverse effect for the STP is expected

##### Aquatic compartment

Neither for scenario 1, nor for scenario 2, calculations were made for the sediment, since the PNECsediment was determined through the EPM-method. This means that the risk assessment for water is applicable for the sediment as well.

For the scenario 2, possible degradation in surface water is not taken into account as a worst-case evaluation.

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
|  |  | **PEC/PNECwater** |
| Scenario 1 | TIER 1 | (3.01x10-1/0.1) = **3.01** |
| TIER 2 | (3.04x10-3/0.1) = **3.04 x 10-2** |
| Scenario 2 | Day 1 | (3.81x10-4/0.1) = **2.10 x 10-3** |
| Day 91 | (3.47x10-2/0.1) = **1.91 x 10-1** |

For the scenario 1, when considering the worst-case assessment where no elimination from the STP is taken into account, an adverse effect for the surface water is calculated. However, when considering the TIER 2, where 99 % elimination from the STP is considered, no adverse effects are calculated.

For the scenario 2, no adverse effects are expected, neither at day 1 nor at day 91, without considering degradation in the surface water.

Even if the PEC/PNEC values for scenario 2 are calculated taking into account 10% of swimmers using the repellent (as a large worst case for areas with higher insect infestation) the RCR results would be 5 times higher but still less than 1 and therefore without any inacceptable risk for the aquatic compartment.

Conclusion:

No adverse effect for the aquatic compartment is expected

##### Terrestrial compartment

Not relevant.

##### Groundwater

Not relevant.

##### Primary and secondary poisoning

Since the product is a repellant and has no intention to kill, primary poisoning is not applicable.  
Secondary poisoning is not relevant, since no bioaccumulation is expected.

##### Mixture toxicity

Not relevant.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| No adverse effect for the environment is expected. |

### Assessment of ED properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in Mouskito Junior Lotion:

1. Assessment of the ED properties of the active substances in Mouskito Junior Lotion:

* According to section 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures. As IR3535 is not part of the list[[8]](#footnote-8) of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.
* Therefore, BE eCA considers that there are no concerns regarding ED properties of IR3535.

1. Assessment of the ED properties of non-active substances (co-formulants) in Mouskito Junior Lotion:

* After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex - ED assessment), one of the co-formulants is subject to an on-going evaluation regarding its ED properties. Pending the final decision regarding the ED properties of this substance, BE eCA will not request further data or perform further assessment of the ED properties of this co-formulant.
* None of the other co-formulants has been identified as having ED properties or are subject to an on-going evaluation or a decision regarding their ED properties. Therefore, based on the available information, BE eCA considers that there is no concern regarding the ED properties of these co-formulants.

Overall conclusion on the biocidal product/family regarding ED properties:

Based on the existing knowledge and the data provided by the applicant, there may be a potential concern regarding the ED properties of one of the substances used in the biocidal product Mouskito Junior Lotion.

Pending the final decision regarding the ED properties of this substance, it was not possible to conclude whether the non-active substance should be considered to have ED properties before the expiration of the legal deadline in the BPR and therefore the process will be concluded at the post-authorisation stage (Please refer to section 2.1.2 (34) of CA-March18.Doc.7.b-final).

However if one or several components are identified as having ED properties, the conditions for granting the biocidal product/family authorisation will be revised according to CA-March18.Doc.7.b-final, section 2.3 (47).

### 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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title** | **Report No.** | **Owner Company** | **Report date** |
| M. Van Diest | 2015 | Mouskito Junior Lotion: Appearance – Test report | - | Laboratoria QUALIPHAR NV/SA | 2015-09-22 |
| B. de Ryckel | 2015 | Physico-chemical properties of Mouskito Roller | 24050 | Laboratoria QUALIPHAR NV/SA | 2015-10-26 |
| M. Van Diest | 2015 | Mouskito Junior Lotion: Storage Stability Report | - | Laboratoria QUALIPHAR NV/SA | 2015-09-22 |
| M. Van Diest | 2016 | Mouskito Junior Lotion: Storage Stability Report | - | Laboratoria QUALIPHAR NV/SA | 2016-03-03 |
| L. Clincke | 2017 | Mouskito Junior Lotion: Storage Stability Report – 24 months | - | Laboratoria QUALIPHAR NV/SA | 2017-04-01 |
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| B. Serrano | 2015 | Laboratory assessment of a personal skin repellent against Stomoxys biting flies | 1832n-  MSRD2837B2/0914 | Laboratoria QUALIPHAR NV/SA | 2015-07-27 |
| B. Serrano | 2017 | Mouskito junior lotion\_efficacy report\_ticks | *Mouskito junior lotion\_efficy report\_ticks*  2017-05-12 *I2LResearch Ltd* | Laboratoria QUALIPHAR NV/SA | 2017-05-12 |
| B. Serrano | 2015 | Assessment of the repellency of a personal skin repellent against wasps and bees | 1832r-  MTRRD2834F2/0914 | Laboratoria QUALIPHAR NV/SA | 2015-08-27 |
| P. Gomond | 2007 | Acute dermal irritation/corrosion test in the rabbit | Tn 077/07-0352 | Laboratoria QUALIPHAR NV/SA | 2007-02-20 |
| P. Gomond | 2007 | Acute eye irritation/corrosion test in the rabbit | Tn 078/07-0352 | Laboratoria QUALIPHAR NV/SA | 2007-02-26 |
| P. Gomond | 2007 | Skin sensitisation in the guinea-pig - Maximisation test - GPMT | Tn 079/07-0352 | Laboratoria QUALIPHAR NV/SA | 2007-03-26 |
| P. Gomond | 2007 | Acute oral toxicity test in the rat - Acute toxic class method | Tn 080/07-0352 | Laboratoria QUALIPHAR NV/SA | 2007-03-05 |
| P. Gomond | 2007 | Acute dermal toxicity test in the rat - Limit test | Tn 081/07-0352 | Laboratoria QUALIPHAR NV/SA | 2007-03-05 |
| J.C.W. Rijk | 2015 | Determination of the dermal absorption of ethyl butylacetylaminopropionate (IR3535) in different formulations through human skin *in vitro* | 508299 | Laboratoria QUALIPHAR NV/SA | 2015-06-11 |

## Output tables from exposure assessment tools

   

## New information on the active substance

None

The manufacturer is the same as included in the Union list of approved active substances.

## Residue behaviour

Not relevant

## Summaries of the efficacy studies

IUCLID available.

## Confidential annex

See separate document.

## Other

Not relevant

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)
2. Please delete as appropriate. [↑](#footnote-ref-2)
3. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-3)
4. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-4)
5. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-5)
6. Copy this section as many times as necessary (one table per use). [↑](#footnote-ref-6)
7. Data derived from in vitro tests; calculated by addition of the standard deviation to the mean value (EFSA Guidance on Dermal Absorption, EFSA Journal 2012; 10(4):2665 section 5.4) [↑](#footnote-ref-7)
8. Please refer to CA-September18.Doc.7.5.a-final . [↑](#footnote-ref-8)